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Functional Electrical Stimulation for Presbyphonia: A Prospective Randomized Trial

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Objectives: The aim of this prospective study was to examine the effects of transcutaneous functional electrical stimulation (FES) in a group of elderly women with presbyphonia.

Study Design: Prospective randomized study.

Methods: Fourteen participants were enrolled prospectively and attributed randomly to two different treatment groups, where one group (n = 7) received 8 weeks of training (5 days a week), whereas the other group (n = 7) received 4 weeks of ineffective stimulation, followed by 4 weeks of effective training. Stimulation protocols were established during baseline examination and confirmed with endoscopy to ensure a glottal reaction. Numerous acoustical, vocal, patient-centered, and respiratory parameters were obtained at several time points.

Results: Neither 4 weeks nor 8 weeks of functional electrical transcutaneous stimulation led to changes of vocal, acoustical, or respiratory parameters, apart from patient-centered items (Voice Handicap Index 12, Voice-Related Quality of Life), which improved over time. However, there were no differences between the two arms for both items.

Conclusions: Transcutaneous FES over 4 weeks and 8 weeks did not lead to significantly improved objective voice and acoustical parameters, which could be caused by the fact that the muscles of interest cannot be targeted specifically enough. However, we found a significant improvement of subjective voice perception and voice-related quality of life in both groups. We explain this finding with an observer-expectancy effect secondary to the very time-consuming and elaborate study procedures.

Key Words: Presbyphonia, aged voice, functional electrical stimulation, presbylarynx, transcutaneous stimulation.

Level of Evidence: 1b

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INTRODUCTION

Epidemiologic studies of the prevalence of voice disorders in the elderly general population showed that almost 30% reported a current voice problem, with a lifetime prevalence of 47%.[1] However the number of treatment-seeking patients is considerably lower at just about 15% to 20%, as vocal problems are often seen as a natural part of ageing by many people.[2] Nevertheless, voice problems in the elderly will receive a wider public awareness in the near future, as this generation is the fastest growing in most Western countries and many parts of Asia, and their workforce will be required longer than ever before.

The term presbyphonia summarizes symptoms of the aged voice, whereas the term presbylarynx delineates age-related morphological changes of the larynx. However, to date there is no generally accepted definition of presbyphonia, and age-related changes of the larynx are often unspecific, which is why usually a set of different parameters is used. These comprise vocal symptoms (decreased loudness, hoarseness, breathiness, increased vocal effort, vocal range),[3] laryngoscopic (bowed vocal folds [VFs] of various degrees secondary to atrophy of laryngeal mucosa and the vocalis muscle),[4] and stroboscopic findings (abnormal vibratory amplitudes, reduced periodicity).[4] Furthermore, acoustical characteristics comprise changes of the harmonic and vocal range, tremor, and a number of perturbation parameters such as jitter or shimmer.[5,6]

Glottal incompetence is commonly seen as the hallmark of laryngoscopy in presbyphonic patients. The underlying anatomical reason is sarcopenia, the loss of muscle mass, quality, and strength.[3,7] Furthermore, changes in the extracellular matrix (ECM) composition of the lamina propria contribute, namely a decrease of hyaluronic acid.[3] Interestingly, age-related ECM turnover is gender specific, with a degeneration of elastic fibers in males and unaltered in age-matched females,[8] and increased amounts of collagen fibers.

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However, it is the subject of an ongoing debate whether changes associated with the aging larynx should be considered pathological. The borders between physiological aging and voice impairment as a result of pathological process related to vocal misuse are blurred. In addition, VF bowing is not limited to older populations, as Reulbach et al. could identify previously undiagnosed glottal incompetence from bowed VFs in 72% of a cohort of healthy adults aged 40 years and older.[9] Interestingly, a study investigating laryngostroboscopic findings in a group of individuals aged over 74 years could not distinguish dysphonic from control subjects without complaints. However, signs of presbylarynges were visible in 87% and 85%, respectively.[10]

The aim of this study was to evaluate the effects of transcutaneous functional electrical stimulation (FES) in a cohort of elderly women with presbyphonia as defined by vocal complaints and glottal incompetence in a prospective trial.

MATERIALS AND METHODS

Cohort

We enrolled German-speaking women aged between 55 and 75 years who reported persistent voice problems for longer than 3 months, which was reflected by elevated levels of the Voice Handicap Index (VHI)-12. All of them demonstrated glottal configurations of laryngeal myasthenia and/or presbylarynx (vocal fold bowing, anterior glottal gap) during videostroboscopy (Olympus ENT Imaging Platform CV-170; Olympus, Tokyo, Japan). Each examination video was reviewed by a board-certified otolaryngologist to verify the absence of VF pathology and rate the glottal configuration (scale: 1 = complete, 2 = posterior gap, 3 = incomplete, 4 = irregular, 5 = anterior gap, 6 = spindle gap). Participants proved to be anatomically, physiologically and mentally compatible with the criteria for participation in the clinical trial and demonstrated the ability and motivation to use an electrostimulation device on their own. Participants with VF disorders (e.g., unilateral and bilateral paralyses, joint arthrosis, benign lesions), history of VF or thyroid surgery, respiratory and cardiac conditions, smokers, age-related hearing loss, generalized muscle diseases, carriers of active implants, known allergies or intolerance to the material used for the investigation were excluded.

Interventions

Suitable stimulation pattern procedures were established in a pretrial.[11] In short, we used biphasic sawtooth or rectangular pulses with different amplitudes, impulse durations, and frequencies (see Supporting Table 1). Stimuli were delivered using a pair of conductive rubber electrodes, 40×28 mm in size (Schwa-Medico, Giessen, Germany), placed bilaterally alongside the upper posterior margin of the thyroid cartilage, with moistened sponge pads providing a low-resistance electrode skin junction. Reactions to the stimuli were considered positive when a clear, visually observable VF twitch was seen by the examining otolaryngologist via transnasal endoscopy. Responses of the ventricular folds, swallowing and laryngeal descent by an activation of the prelaryngeal muscles were not considered as a positive reaction.

Individual stimulation parameters were stored on a stimulation device (Stimulette r2x; Dr. Schuhfried Medical, Vienna, Austria) and handed over to the participants for home training. They were instructed and trained by the investigators in placing the surface electrodes and applying the stimuli.[11] They were also taught how to remove the surface electrode and switch the stimulation off in case of an adverse event.

Subjects were attributed randomly in two arms (A and B). Accordingly, subjects enrolled in arm A applied stimulation patterns that induced an observable glottal response at baseline

TABLE I.
Time Schedule With Corresponding Procedures.

Timeline	Screening ≤−1 mo	Baseline 0	First Home Visit 2 wk ± 1 wk	First Control 4 wk ± 1 wk	Second Home Visit 6 wk ± 2 wk	Second Control 8 wk ± 2 wk	First Follow-up 10 wk ± 1 wk	Second Follow-up 14 wk ± 2 wk
Stimulation	None	Yes	Yes	Yes	Yes	Yes	None	None
Arm A	None	Effective	Effective	Effective	Effective	Effective	None	None
Arm B	None	Subthreshold	Subthreshold	Effective	Effective	Effective	None	None
Videolaryngoscopy	Yes	Yes	No	Yes	No	Yes	Yes	Yes
RP	No	Yes	No	Yes	No	Yes	Yes	Yes
Jitter	No	Yes	No	Yes	No	Yes	Yes	Yes
Shimmer	No	Yes	No	Yes	No	Yes	Yes	Yes
DSI	No	Yes	No	Yes	No	Yes	Yes	Yes
RBH	No	Yes	No	Yes	No	Yes	Yes	Yes
VRP	No	Yes	No	Yes	No	Yes	Yes	Yes
MPT	No	Yes	No	Yes	No	Yes	Yes	Yes
PQ	No	Yes	No	Yes	No	Yes	Yes	Yes
VST	No	Yes	No	Yes	No	Yes	No	No
VHI-12	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
V-RQOL	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes

DSI = Dysphonia Severity Index; MPT = maximum phonation time; PQ = phonation quotient; RBH = roughness–breathiness–hoarseness scheme; RP = respiratory parameters (vital capacity and forced vital capacity); V-RQOL = Voice-Related Quality of Life; VHI-12 = Voice Handicap Index 12; VRP = voice range profile; VST = voice strain test.

examination for 8 weeks. Subjects enrolled in arm B received 4 weeks of ineffective stimulation (superficial stimulation of platysma, no glottal response visible), followed by 4 weeks of effective stimulation (as in arm A). Home-based training was carried out accompanied by simple phonations (sustained vowels [e.g., /aaaa/] and alternating vowels [e.g., /a-o-a-o/]). A stimulation session consisted of three sets, each lasting 3 minutes with a 2-minute break in between to relax. Stimulation exercises were performed 5 days a week. The participants were asked to keep a diary where current intensity, start and end time of the stimulation, rating of stimulation comfort, and specific events such as swallowing or coughing triggered by the stimulation were recorded. To explore effects of time, we chose two different stimulation periods of 4 weeks and 8 weeks, respectively. This was chosen according to Ziegler et al., who demonstrated effects with a muscle-fatiguing approach after 4 weeks.[12] Our study procedures comprised four clinical and two home visits; an overview of time points and examinations is given in Table I.

Outcome Parameters

Numerous outcome parameters before, during, and after the study (wash-out phase) were obtained (see Table I and Supporting Table 2). These were in detail (normal/cutoff values in brackets): jitter (<1%), shimmer (<4%), maximum phonation time (MPT) (>15 seconds), voice range profile comprising lowest physiological tone (165 Hz), highest physiological tone (659 Hz), mean speaking fundamental frequency, and the sound pressure level (SPL) variables SPL for the softest tone (<50 dB), SPL for the loudest tone (>90 dB), and SPL mean speaking intensity. Furthermore, Dysphonia Severity Index (<3.72)[13] and the phonation quotient (ratio between the vital capacity [VC] and the MPT, <0.2 L/sec). Norm values correspond to the European Laryngological Society protocol[14] and Goy et al.[6]

Acoustical parameters were acquired by recording a sustained /a/ in a soundproof room using a head-mounted microphone (XION Medical, Berlin, Germany) providing a defined microphone distance (30 cm) and recorded by multi dimensional voice profile (MDVP) (KayPENTAX Corp, Montvale, NJ). Voice range profile was carried out using RPszene (Rehder/Partner GmbH, Hamburg, Germany). The roughness–breathiness–hoarseness (RBH) evaluation scheme was performed by a speech–language pathologist (M.F.). A computer-assisted voice strain test was performed using DiVAS software (XION Medical). The strain task consists of reading a German text for 15 minutes, aiming to reach an SPL of 70 dB for the first 5 minutes, 75 dB for the second 5 minutes, and 70 dB for the third 5-minute interval. The percentage of the 15-minute time interval in which the participants could not reach the targeted SPL was measured. The German version of the VHI-12[15] and VR-QOL[16] as subjective voice-quality parameters were included. Respiratory parameters included VC and forced VC and were obtained by a spirometer (Vitalograph Model 6800, Vitalograph, Lenexa, KS). All video and audio files were recorded and evaluated after randomization.

Statistical Analysis

Generalized estimating equations modeling for incomplete longitudinal data were used to compare changes over time between groups (arm A and arm B). The main effects of time and group (randomization) and interaction effects between time and group were analyzed. All statistical tests were performed using SPSS version 25.0 (IBM, Armonk, NY). Continuous data were presented as total number, ordinal data as mean ± standard deviation and median and interquartile range (25th percentile and 75th percentile), and categorical data were shown as frequencies in percent. A two-tailed P value of <.05 was considered as statistically significant.

RESULTS

An overview of the results of common voice and patient-centered parameters is given in Table II. All participants tolerated the procedures well, proving that FES is a safe method. Neither 4 weeks nor 8 weeks of stimulation led to changes of important vocal or acoustical parameters. Patient-centered items (VHI-12, VR-QOL) improved significantly over time in both groups, when comparing single time points to baseline (P always <.05). However, there was no

TABLE II.
Results in Mean Values and Standard Deviation.

		Baseline, Mean ± SD	First Control, Mean ± SD	Second Control, Mean ± SD	First Follow-up, Mean ± SD	Second Follow-up, Mean ± SD
MPT (sec)	A	19 ± 5	16 ± 6	17 ± 3	18 ± 4	19 ± 7
	B	19 ± 7	20 ± 4	20 ± 4	21 ± 3	20 ± 3
Jitter (%)	A	1.13 ± 0.68	1.06 ± 0.62	1.58 ± 1.87	0.91 ± 0.44	1.11 ± 0.54
	B	1.19 ± 1.27	1.17 ± 0.30	1.25 ± 0.60	0.93 ± 0.37	1.00 ± 0.46
Shimmer (%)	A	3.87 ± 2.01	3.79 ± 1.55	5.23 ± 4.90	3.44 ± 0.99	3.67 ± 1.10
	B	4.57 ± 3.46	4.34 ± 2.32	4.99 ± 2.87	4.10 ± 2.06	4.88 ± 4.22
DSI	A	5.3 ± 2.0	5.5 ± 1.9	4.8 ± 3.4	5.7 ± 1.8	6.0 ± 1.7
	B	5.0 ± 2.0	4.7 ± 0.9	4.9 ± 1.2	5.0 ± 0.8	4.9 ± 0.9
PQ (L/s)	A	0.2 ± 0.0	0.2 ± 0.1	0.2 ± 0.0	0.2 ± 0.0	0.2 ± 0.0
	B	0.2 ± 0.1	0.2 ± 0.0	0.2 ± 0.0	0.1 ± 0.0	0.2 ± 0.0
VHI-12	A	10.8 ± 5.9	7.7 ± 4.7	6.9 ± 5.8	6.2 ± 4.3	5.3 ± 3.1
	B	10.0 ± 6.2	7.1 ± 6.7	5.1 ± 5.1	5.0 ± 7.0	6.4 ± 6.9
V-RQOL	A	82.2 ± 12.5	87.1 ± 11.2	88.9 ± 11.4	88.8 ± 10.1	90.7 ± 8.1
	B	90.0 ± 6.9	87.9 ± 13.5	92.1 ± 10.4	92.5 ± 13.5	91.8 ± 11.3
	B	85.9 ± 10.4	85.7 ± 13.8	91.7 ± 11.8	92.3 ± 13.9	91.7 ± 12.0

DSI = Dysphonia Severity Index; MPT = maximum phonation time; PQ = phonation quotient; SD = standard deviation; V-RQOL = Voice-Related Quality of Life; VHI-12 = Voice Handicap Index 12.

TABLE III.
Standard Classification of Glottal Closure (GC) and RBH Scheme at Baseline and Second Control.

		Baseline				Second Control			
ID	Arm	GC	R	B	H	GC	R	B	H
1	A	**5**	1	1	1	**5**	2	1	2
2	A	**5**	0	1	1	**5**	0	0	0
3	A	**5**	1	1	1	**5**	1	0	1
4	A	**5**	0	1	1	**2**	0	1	1
5	A	**5**	1	1	1	**5**	1	0	1
6	A	**5**	0	1	1	**3**	0	0	0
7	A	**5**	1	1	1	**1**	0	1	1
8	B	**5**	1	0	1	**2**	0	0	0
9	B	**3**	1	1	1	**5**	1	1	1
10	B	**3**	2	1	2	**6**	2	1	2
11	B	**3**	1	0	1	**5**	0	1	1
12	B	**5**	0	1	1	**5**	1	0	1
13	B	**5**	1	1	1	**2**	0	0	0
14	B	**5**	1	1	1	**5**	1	0	1

Glottal closure (GC) = 1: complete, 2: posterior gap, 3: incomplete, 4: irregular, 5: anterior gap, 6: spindle gap); roughness–breathiness–hoarseness (RBH) scheme = 0: no deviance, 1: slight deviance, 2: moderate deviance, 3: severe deviance or aphonic.

Bold values are all categorial variables. P-values are were always > 0.05.

effect of FES, meaning that the two arms did not differ (P = .84). Likewise, interaction effects between time and randomization were not statistically significant (P always >.05). Glottal configuration and values of the RBH scheme did not change either (Table III). Supporting Table 2 summarizes all remaining parameters. Here again, no significant differences could be described between the groups and over the course of time.

DISCUSSION

Numerous quality-of-life studies demonstrate the impact of vocal complaints on quality of life in the elderly.[17] Elderly subjects who are aware of their vocal deterioration report a tendency to avoid social situations. Vocal impairment is furthermore associated with negative impacts on activity, participation, psychosocial well-being, and overall quality of life.[18,19]

To date, there are several concepts to treat these patients, with voice therapy being the most frequent. Common practices to improve voice efficacy are multidimensionally based and include different vocal function exercises and resonant voice training.[20] Improvements were reported in subjective (voice handicap index, voice-related quality of life), as well in objective (MPT, airflow measures) and audio-perceptual parameters, even though the set of measures varied widely between the studies. Furthermore, many studies were pursued in small cohorts without control groups or only retrospectively, which is why the level of evidence is generally weak.[20–22] Voice therapy per se has some inherent limitations though. With increasing age, patients become more easily frustrated with repetitive and tiresome exercises. Furthermore, their pulmonary/respiratory system often might not be capable of the required capacities that are needed to compensate the glottal air loss.

Surgery is another treatment option to compensate glottal insufficiency, namely type I thyroplasties and VF augmentation with various fillers.[2,23] Again, good results were reported; however, no studies were carried out in a homogeneous setting of presbylarynges.[24,25]

FES was widely used in laryngology,[26,27] mainly in the therapy of VF paralysis, but the interest and applications dropped in the last years. The lack of controlled, randomized trials with inconsistent results might be the reason why FES found no general acceptance in the community and was only seen as a supplementary treatment option.[26,28,29] More recently, FES was expanded to treat other laryngeal pathologies, such as bilateral paralysis and spasmodic dysphonia.[30,31]

Our group did extensive research on aged larynges[32] and FES during the last years. We could show in an aged ovine model that FES was able to reverse muscular VF atrophy by increasing muscle fiber diameter, as well as the volume of the thyroarytenoid muscle.[33,34] In these trials, an electrode was implanted adjacent to different sections of the recurrent laryngeal nerve and stimulation ran automatically once an implant was activated over time periods reaching from 8[34] to 11[33] weeks. Based on these experiences we pursued a pretrial in humans, where stimulation was applied transcutaneously by surface electrodes and effects were confirmed via endoscopy.[11]

The present study is the first prospective, randomized trial in humans exploring the effects of transcutaneous stimulation in a cohort of elderly women. Our stimulation paradigm is based on the concept that FES during vocal exercises fatigues the laryngeal muscles involved, leading to a muscular hypertrophy, which subsequently diminishes the glottal gap.[34] A similar approach, but without electrical stimulation, was pursued by Ziegler et al.[12] Their well-designed study included a control group and comprised phonation resistance training over 4 weeks, leading to improved VR-QOL scores and reduced vocal fatigue; however, no data on VF configuration were provided. Data on FES and presbylarynges are scarce, and to date there is only one prospective study (n = 6) where VF bowing was treated with behavioral therapy in combination with FES (five secondary to presbylarynges, one postintubational).[35] Behavioral therapy with adjunctive FES improved the VHI (five out of six, not significant) and MPT (only significant for /i/); loudness data were not reported. In addition, a control group was not included.

In our study, the VHI-12 initially reflected a moderate vocal impairment in both groups that improved significantly in arm A and B to no impairment at the last time point. Interestingly, VHI-12 scores dropped significantly as soon as the first home-based visit, even in arm B, where no effective stimulation was applied. Likewise, VR-QOL values increased significantly in both groups over the course of time (higher values reflecting a higher voice-related quality of life). This is in contrast to the observed acoustical and vocal parameters that did not improve. Based on our data on subjective voice perception (VHI-12 and VR-QOL), we infer a possible observer-expectancy effect in our cohort, meaning that participants modified their awareness in response of

participating in a laborious and time-consuming study. The results are furthermore in contrast to our previous data in animal trials where stimulation led to an increase of numerous muscle parameters (muscle fiber diameter and volume of the thyroarytenoid muscle), though we could not examine the same parameters in humans of course. However, an increase of the volume of the thyroarytenoid muscle would have resulted in altered vocal parameters related to the muscular bulk, such as MPT, which was not the case.

There are several possible reasons why superficial FES failed to improve voice outcome in our cohort. Transcutaneous stimulation can never be that specific when compared to a setting where efferent nerves are targeted directly by an implanted device as in our animal studies. We took considerable effort in positioning the electrodes established during our previous trial; a glottal twitch under stimulation was observed in all participants at the beginning and during the study. However, transcutaneous FES always unintendedly stimulates several overlying muscles, and a costimulation of other neural structures (efferent and afferent nerves) cannot be ruled out. Lastly, stimulation was always carried out at the highest amplitude/intensity still tolerated by the participants, so even if higher amplitudes would have been more beneficial, they could not have been applied.

CONCLUSION

Transcutaneous FES over 8 weeks did not improve vocal or acoustical parameters in a cohort of elderly women. In contrast, patient-centered variables (as reflected by the VHI-12 and VR-QOL) improved significantly, also in a group who received ineffective stimulation. We explain this by an observer effect, where participants altered their self-perception by the fact of being included in a study. Our data from this prospective study indicate that transcutaneous FES has no objectively measurable effects on the aged voice, as this type of stimulation is too unspecific and cannot target particular laryngeal muscles.

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