

ABSTRACT: For more than 40 years, electrical stimulation procedures for unilateral recurrent laryngeal nerve palsy (URLNP) therapy have been proposed. However, it is unclear whether electrical stimulation therapy is effective for URLNP patients. In this study we compare the outcome of traditional voice exercise treatment (VE) with electrical stimulation–supported voice exercise (ES). A total of 90 URLNP patients were recruited to participate in a prospective, randomized trial. The decrease in vocal fold irregularity (CFx) and increase in maximum phonation time (MPT) after a 3-month therapy period were the dependent variables. In the ES group, CFx improved to a significantly greater extent than in the VE group. MPT increased similarly in both groups. Our data indicate that ES is superior to VE for patients with URLNP. Because no further data exist, it can be assumed that improvement following VE only reflects spontaneous recovery. However ES appears to be an effective non-surgical therapeutic procedure.

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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

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Vocal fold palsy may occur as a result of recurrent nerve injury following thyroid gland surgery or ablation of tumors in the neck region, trauma, or viral infection, or it may be spontaneous without evident etiology. Among others, symptoms include voice impairment ranging from hoarseness to aphonia and limited pitch range, diplophonia, dysphagia, and breathing problems. As many as 30% of all patients are asymptomatic.³⁹

A variety of surgical methods for treating unilateral vocal fold palsy/unilateral recurrent laryngeal

nerve palsy (URLNP) have been proposed. These include injection thyroplasty, such as injection of viscous materials like Teflon paste, fat suspension, collagen, and hyaluronic acid; laryngeal framework surgery (external thyroplasty); and nerve and nerve muscle pedicle transfer (for reviews, see Benninger et al.² and Hartl et al.¹²). Injection thyroplasty and laryngeal framework surgery have proven to be very beneficial for those URLNP patients who do not recover spontaneously and who suffer from severe aspiration. The degree of spontaneous recovery has been reported in up to 40% of URLNP patients following thyroid gland surgery.^{12,30}

Considering that at least some patients may have relief from symptoms, non-surgical procedures should be tried prior to surgery. These non-surgical procedures include drugs like steroids, voice exercise therapy, electrical stimulation, and gene therapy.^{11,13,18,22,23,35,41} The efficiency and effectiveness of these approaches have not been investigated thoroughly.

Abbreviations: CFx, vocal fold vibration irregularity index; EMG, electromyography; ES, electrical stimulation–supported voice exercise therapy; MPT, maximum phonation time; Qx, closed quotient; URLNP, unilateral recurrent laryngeal nerve palsy; VE, voice exercise therapy

Key words: electrical stimulation; prospective, randomized trial; unilateral recurrent laryngeal nerve paralysis; voice treatment

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Despite a lack of robust data,⁵ voice exercise therapy (VE) is the standard therapy for URLNP patients prior to surgery in Germany.³⁸ VE is of a compensatory nature. Ideally, lateral movement of the non-impaired vocal fold should cross the midline and approximate the paretic vocal fold, thus minimizing glottic incompetence.³⁸ Usually, patients are guided and supervised for VE by voice therapists once or twice a week. Although VE is effective for other conditions,^{29,37} it is not known whether it is effective for URLNP patients.

Electrical stimulation–supported therapy (ES) is a well-known modality in the field of orthopedics and physical medicine.²¹ The aim of ES is threefold:

- To prevent atrophy of the paretic muscle.
- To speed up the regeneration process.
- To prevent fibrillation.

Recently, it was shown that ES can induce recovery even in long-term–denervated human muscles.¹⁶

The use of ES for patients with voice disorders has been discussed for many decades.^{3,17,31} Schleier et al. compared the effects of ES plus VEs vs. VEs alone in patients with muscle tension dysphonia. They found that the combination ES plus VE is better than VE alone.³³ Kruse recommended that ES should be carried out together with a special voice exercise treatment called functional voice training, but did not present data to support this view.¹⁸ Pahn introduced the concept of the “neuro-muscular electro-phonatory stimulation (NMEPS),”²³ where the patient performs voice exercises together with single stimulation pulses.

Based on the different ideas about ES for voice disorders an ES therapy program and a corresponding ES system were developed.²⁶ Key features of this concept include²⁸:

- The electrical stimulation pulse is individually programmed for each patient.
- The stimulation pulse is an adjustable exponential current, thus enabling selective stimulation of the paretic vocal fold.
- Each pulse should have a minimal intensity to just elicit a minimal twitch of the paretic vocal fold as seen by laryngoscopy.
- The patient delivers the stimulation pulse himself using a handheld control unit while simultaneously carrying out phonation exercises.
- The patient is instructed in use of the system, and then performs ES voice training at home three to five times per day.
- Every 2 weeks the stimulation parameters are

controlled and eventually readjusted during a laryngoscopic examination.

- Therapy sessions carried out at home are recorded on the same chip card. This enables the physician to monitor how often the patient actually used the system.

The ES, as just outlined, and the conventional VE therapy both employ some form of voice exercise. Apart from the fact that ES includes electrical stimulation, they differ considerably. VE involves supervision by a voice therapist, whereas ES sessions are done at home in a non-supervised environment. The frequency of therapeutic sessions is also quite different. Usually, VE patients visit the voice therapist’s office once or twice a week for a 45-minute therapy session, whereas ES patients are advised to exercise three to five times per day in 5–10-minute sessions.

In Germany, VE is the standard therapy for URLNP patients. Health insurance companies cover costs for VE, but not for ES. Unfortunately, no reliable data regarding efficiency and effectiveness are available for either VE or ES. Furthermore, it is not known to what extent symptoms of URLNP resolve spontaneously, at least within the first months of paresis.

We designed a prospective clinical trial to test the hypothesis that ES is as effective as VE in URLNP patients (non-inferiority hypothesis). Effectiveness was defined as a decrease in vocal fold vibration irregularity and increased maximum phonation time.

To assess vibration irregularity we measured the irregularity index, Cfx, according to Fourcin.^{8,9} Cfx has been shown to correlate with the commonly used subjective voice grading system, “RBH” (i.e., roughness, breathiness, and hoarseness).²⁷ Measuring maximum phonation time is a routine procedure in voice clinics.

METHODS

Design. We conducted a prospective, randomized clinical trial in which the URLNP patients referred to our department were randomly assigned to either VE or ES. T0 was defined as “prior to therapy” and T1 was “end of therapy.” Therapy was performed for 3 months from T0 to T1, except for those patients who had remission of paresis and its symptoms during the time of the study. In such cases, data from the last examination were taken as T1 values.

The study was approved by the ethics committee of the Medical School Hannover. The study was registered at Current Controlled Trials, Ltd., Inter-

national (ISRCTN17141238; <http://www.controlled-trials.com/isrctn/trial/|/0/17141238.html>).

Therapeutic Procedures. *Electrical stimulation–supported voice therapy (ES).* For ES, commercially available VocaStim systems (Physiomed, Germany) were used. Stimulation parameters were programmed at T0 and every 14 days thereafter. All stimuli were exponential currents with a 240-ms duration. The amplitude was adjusted to a just-visible twitch of the paretic vocal fold as confirmed by laryngoscopy.

At T0, patients were instructed on how to use the system. They were asked to do the stimulation procedures with voice exercises three to five times per day.

Voice exercise therapy (VE). Patients assigned to VE treatment were offered an in-house therapy or were referred to a local voice therapist. All patients received their therapy from an officially certified therapist. All therapists were asked to follow the guidelines outlined by Schwarz, Stengel, and Strauch (based on the “Aachener Rahmenplan”³⁴). All therapists were asked to submit a report about the treatment administered.

Patients. URLNP patients referred to our department were recruited for the study. They were informed about the study by a physician. Participation was voluntary and there were no disadvantages for patients who chose not to be involved. Participants received no reimbursement and were required to sign a letter of consent. Exclusion criteria were as follows:

- Voice therapy or any other therapy prior to T0.
- Paresis onset <2 weeks or >6 months prior to therapy.
- Age <18 years.
- Paresis following resection of the recurrent nerve.
- Pareses due to muscle or joint injuries.
- Hearing loss >40 dB in the 500–3000-Hz range.
- Presence of other conditions possibly interfering with the therapy, such as cognitive deficits or other serious diseases.

A total of 90 URLNP patients were initially recruited. There were several drop-outs: 9 patients (5 in VE, 4 in ES) did not show up for control studies after the initial examination for unknown reasons, and two ES patients did not return after initial programming of the stimulus parameters. Data from two patients (1 in VE, 1 in ES) could not be used because of technical errors. One VE patient reported after T0

Table 1. Overview of patients' data.

	VE group	ES group
No. of patients	36	33
Age	57 ± 12.6 (min 27, max 83)	54.1 ± 16.1 (min 20, max 84)
No. of VE sessions	15.29 (min 6, max 28)	NA
No. of ES sessions	NA	191.0 (min 92, max 268)
Paresis right/left	11/25	17/18
Etiology		
Postoperative	24	25
Idiopathic	7	6
Postinfectious	1	2
Other	3	0

VE, voice exercise; ES, electrical stimulation; min, minimum; max, maximum; NA, not applicable.

that he had voice therapy previously, but forgot to mention so initially. Three VE patients refused to continue therapy for unknown reasons, and 1 ES patient refused to continue because his preexisting tinnitus worsened. For 2 VE patients there were radiologic signs of arytenoid luxation after T0.

One ES patient experienced a complete remission almost immediately after programming the stimulus parameters. We did not use her data. In summary, a total of 21 patients were excluded for calculation of CFX/T0 – CFX/T1 and MPT/T0 – MPT/T1, respectively.

Four VE patients and four ES patients had remission during the therapy, so prolonged therapy was no longer necessary. One ES patient had complete symptom relief, although residual paresis was still seen during laryngoscopy. She declined to continue therapy. Data from the last examination (i.e., the examination after which we discontinued therapy) from each of these 9 patients were taken as T1 values.

A total of 69 data sets were obtained (36 VE, 33 ES). Table 1 lists further details (age, side of paresis, etiology). A grading of the paresis was purposefully omitted, although it is widely used in the clinical routine. It is a purely subjective grading, and its theoretical foundation appears questionable.^{39,40}

Variables. Assignment to either VE or ES was the independent variable. For assessing irregularities of the vocal fold cycle, patients read a phonetically balanced, standardized text (“Nordwind und Sonne”). During reading, glottographic signals were recorded, and the index CFX was calculated offline.^{8,9}

For estimating maximum phonation time (MPT), patients were asked to phonate a neutral vowel (“schwa-vowel”) for as long as possible. The time of the sustained phonation was recorded.

The percentage of CFx decrease ($CFx/T0 - CFx/T1$) and the percentage of MPT increase ($MPT/T1 - MPT/T0$) were dependent variables.

Statistics. We analyzed data according to the intention-to-treat principle. $CFx/T0 - CFx/T1$ and $MPT/T1 - MPT/T0$ differences were compared using Student’s t-test for unpaired samples (SSPS v15.0G). Data from drop-out patients as defined earlier could not be used to calculate a difference.

RESULTS

$CFx/T0$ and $MPT/T0$ did not differ significantly between groups for all patients (Table 2), or for only those with data sets from T0 and T1 (Table 3) (*t*-test for unpaired samples). This confirmed that no group had an initial advantage and that drop-outs did not generate bias.

At the end of the 3-month therapy the final $CFx/T1$ had dropped in both groups to 24.6 ± 23.8 (VE) and 13.0 ± 8.8 (ES), respectively (Table 3; $P = 0.009$). Correspondingly, the actual decrease of $CFx/T0 - CFx/T1$ differed significantly between VE (13.9 ± 26.6) and ES (27.42 ± 27.2). Thus, CFx was reduced by 18.6% in the VE group and 53.3% in the ES group ($P < 0.012$).

The MPT increased for both groups: to 14.9 seconds in the VE group, and to 13.7 seconds in the ES group (not statistically significant). Neither the MPT increase in absolute terms (VE: 4.6 ± 8.3 seconds; ES: 3.6 ± 5.4 seconds) or in percentage change differed significantly between the groups (Table 3).

Table 2. Initial T0 values for vocal fold vibration irregularity index and maximum phonation time for all patients including drop-outs.

	<i>n</i>	Minimum	Maximum	Mean	SD
CFx/T0					
VE	46	6.3	90.1	41.5	27.0
ES	42	5.8	100.0	38.9	29.7
MPT/T0					
VE	45	2.2	29.7	10.4	6.7
ES	42	1.6	28.7	10.8	6.5

Between-group differences were not statistically significant. CFx, vocal fold vibration irregularity index; MPT, maximum phonation time (in seconds); VE, voice exercise; ES, electrical stimulation-supported voice exercises; *n*, number of patients in each group; NA, not applicable.

DISCUSSION

Data from this clinical, randomized trial indicate that ES was more effective than VE in terms of voicing. However, we noted a discrepancy between the CFx and MPT results: CFx dropped significantly more in ES than in VE patients, whereas MPT increased similarly in both groups of patients. Nevertheless, a significant overall difference in favor of SE remained, even after Bonferroni correction.

Our data indicate but do not prove beyond doubt that ES is superior to VE in terms of true neuromuscular recovery. Compared with electromyographic (EMG) assessment in skeletal muscles, laryngeal EMG has several limitations (e.g., difficulty in measuring spontaneous activities,^{4,6,7} only qualitative testing is possible,³⁶ and low sensitivity and specificity³²), and therefore cannot provide reliable data for monitoring neuromuscular recovery.

Unfortunately, only very limited data about spontaneous regeneration in URLNP are available. The similar increase in MPT in both groups may reflect that both ES and VE are effective in reducing glottal incompetence. However, it may be possible that both are ineffective, and the MPT increase merely reflects spontaneous recovery that would have occurred without therapy.

A different picture evolves from the CFx data, as we observed a significant difference between groups. It may still be the case that CFx data from VE patients simply mirrors spontaneous recovery. CFx in ES patients decreased significantly more than in VE patients. This indicates a “true” therapeutic effect above spontaneous recovery.

CFx and MPT are both indicators of quite different laryngeal actions. MPT indicates how well the vocal folds are approximating at the end of each closing phase during a vibration cycle. MPT also depends on lung function. The latter can be neglected for the present purposes, because a change in lung function is unlikely. Thus, it may be fair to assume that any change in MPT reflects changes in the glottal gap. Setting aside structural deficits, such as tumors or resection deficits, closing the glottis depends on the action of the intrinsic laryngeal muscle. Muscles mainly involved in closing the vocal folds are the m. cricoarytaenoideus lateralis, m. interarytaenoideus, and m. thyroarytaenoideus lateralis.

The vibration cycle during phonation is a complex and not fully understood phenomenon. To assess cycle stability and to have access to the intrinsic quality of a voice without the influences of either consonantal structures or language, many voice clin-

Table 3. Data from patients who finished therapy.

	Group	Minimum	Maximum	Mean	SD	P	95% confidence interval of the difference	
							Lower level	Upper level
CFx/T0	VE	6.3	88.4	38.5	27.1	NS	-15.37836	11.57281
	ES	9.0	100.0	40.4	29.0			
CFx/T1	VE	2.6	92.9	24.6	23.8	0.009	3.05872	20.18633
	ES	3.4	51.8	13.0	8.8			
CFx/T0-CFx/T1	VE	-55.0	72.2	13.9	26.6	0.041	-26.47577	-0.57484
	ES	-0.8	83.6	27.4	27.2			
% CFx difference	VE	-257.1	92.2	18.6	72.8	0.012	-61.4586	-7.8604
	ES	-9.2	91.7	53.3	31.7			
MPT/T0	VE	2.2	29.7	10.6	7.2	NS	-2.734135	3.637357
	ES	1.6	28.7	10.1	5.9			
MPT/T1	VE	2.1	39.3	14.9	9.5	NS	-2.710474	5.077287
	ES	3.0	31.0	13.7	6.2			
MPT/T1-MPT/T0	VE	-14.6	32.6	4.6	8.3	NS	-2.383980	4.434733
	ES	-7.4	15.7	3.6	5.4			
% MPT difference	VE	-71.7	488.9	81.7	130.0	NS	-46.2696	69.4086
	ES	-51.2	411.3	70.1	107.0			

Voice exercise (VE) group: 36 patients; electrical stimulation-supported voice exercise (ES) group: 33 patients. CFx, vocal fold vibration irregularity index; MPT, maximum phonation time; NS, not significant.

ics employ some form of jitter measurement during sustained phonation of vowels.¹ The most common definition of jitter is²⁵:

$$\text{Jitter}\% = \frac{\text{average temporal perturbation/}}{\text{average vocal fold cycle duration}} \times 100$$

For routine measurements phonatory onset and offset are excluded. The stable mid-portion of a vowel sustained at comfortable pitch gives the best approximation to a steady state that can be obtained for voiced speech sounds.

However, in day-to-day conversational use of the voice, the speaker's vocal folds are under almost constant adjustment to meet changing speech targets. Both intonation and the vowel- and consonant-dependent interactions between the speaker's larynx and supraglottal vocal tract lead to continuously changing vocal fold settings and conditions of voice onset and offset that do not occur in sustained vowel production. Voice in connected speech is not only heard differently from sustained vowels, but it is also produced differently.¹⁰

Taken together, these observations question the value of jitter measurements as defined earlier. Therefore, we used connected speech samples from reading a standardized text and calculated the CFx. First, we compared the duration of each cycle progressively against the other. Then we used half tone, 6%, just noticeable difference (JND)-related analysis intervals and calculated the total number of pairs of

vocal fold cycles in a 6% frequency bin divided by the total number of vocal fold cycles in the whole voice recording. This resulted in an auditory physiology-related probability index of vocal fold irregularity.

Vocal fold vibration regularity during connected speech is maintained by several interdependent mechanisms such as muscle tension and air flow from the lungs. One intrinsic laryngeal muscle mainly responsible for a stable tension within the vocal fold is the m. cricoarytaenoideus medialis.

Related to these theoretical considerations our results indicate that intrinsic laryngeal nerve/muscle units responsible for adjusting and maintaining vocal fold tension may be a better target for electrical stimulation therapy than nerve/muscle units responsible for closing the glottal gap.

Despite the apparent advantage in favor of ES, our results should be interpreted with some caveats. Our aim was to compare routine procedures recommended for URLNP patients. Taking a closer look at both procedures one can easily recognize more differences than just the exercise part. As mentioned earlier, generally VE patients visit their therapists and undergo the treatment session. Our VE patients had an average of 15.3 sessions (minimum of 6 and maximum of 28 sessions), each lasting 45–60 minutes, equaling approximately one session per week.

ES patients performed an average of 191 sessions (minimal of 92 and maximum of 268 sessions). This corresponds to a frequency of approximately two per day. Obviously, ES patients had many more thera-

peutic sessions than VE patients. This imbalance still holds when time is taken into consideration: ES sessions usually take 5–10 minutes, whereas VE sessions last an average of 45–60 minutes. Typically, a voice therapist asks patients to do some exercises at home. Unfortunately, we did not record the time of voice exercises at home in VE patients, so it is difficult to compare actual therapy times. In summary, ES patients had a therapy advantage, both in frequency and probably in time.

The high number of therapeutic ES sessions also serves as an indicator of good compliance for this kind of therapy.

To compare ES and VE it would have been more appropriate to include only patients with a left or right URLNP and patients with a similar etiology of paresis instead of the variety mentioned earlier. Unfortunately, this was too difficult in terms of patient recruitment. The randomization should have eliminated any such bias anyway. For example, an ex post analysis showed that there was a significant difference in favor of ES ($P < 0.021$) in CFX data taken only from patients suffering from a postoperative paresis (49 patients).

Further studies should also examine patients' voice control associated with closed phase duration. The glottal closed quotient (Qx), which varies between 10% and 40% for sustained phonation in healthy volunteers,¹⁵ is the fraction of time the glottis is considered closed. It has been regarded as a good indicator of voice quality²⁴ and appears to differentiate between trained and untrained adult singers.¹⁴ Qx has already been used as an outcome variable in clinical studies.^{19,20} Based on findings in the literature and our own clinical experience, examinations of Qx index and Qx irregularity index appear to be valuable and reliable parameters for monitoring voice control progress, especially for cases in which voice control improves but CFX remains unchanged.

In conclusion, URLNP can have a significantly negative impact on affected patients. If there is no spontaneous regeneration, or if therapy fails, operative procedures like thyroplasty should be considered. Prior to any operation, however, it seems advisable to offer a conservative treatment. Voice exercises alone may work, but it remains questionable as to whether there is a therapeutic effect beyond spontaneous regeneration. Based on the data presented herein, electrical stimulation–supported voice exercises are the method of choice for URLNP patients, at least within the first 6 months after onset. A “wait-and-see” tactic is not justified.

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