Treatment Effectiveness of Novafon Local Vibration Voice Therapy for Dysphonia Treatment

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Summary: Background. The objective of this study was to explore the effectiveness of the five-week Novafon local vibration voice therapy (NLVVT) program with and without Novafon local vibration for dysphonia treatment.

Methods. Twenty-two voice-disordered subjects were divided into two groups. The intervention group (IG) performed the NLVVT program and the control group (CG) had the same voice exercises of this program without local vibration.

Results. After NLVVT, the IG showed significantly high results in all parameters of acoustics, multiparametric indices, and self-evaluation (all *P* values < 0.01). The CG revealed mostly much significantly lower results (*P* values < 0.05) or nonsignificant results for these parameters after the treatment. The intergroup comparison under consideration before and after NLVVT showed a large and significant treatment effect in voice quality (ie, narrowband spectrograms, and Acoustic Voice Quality Index), in which the IG had better treatment results. The aerodynamic measurement showed no significant changes for both groups after NLVVT (*P* value > 0.05).

Conclusion. After the NLVVT program both groups showed significant improvements of various voice measurements, in which the IG revealed better treatment results than the CG. However, next to voice exercises an extra benefit for local vibration with the Novafon appliance was assessed in voice quality.

Key Words: Voice assessment-Voice therapy-Novafon-Local vibration therapy-Dysphonia-Treatment.

INTRODUCTION

The treatment-seeking population with voice disorders is estimated up to 15%, in which voice problems affect one in thirteen adults annualy.¹ The values significantly increase for special groups as for example, females (ie, about twice as much males), $^{1-4}$ people who live in urban areas (85%), 2 and professional voice users (71.9%).³ The most frequent voice disorders are laryngitis,^{1,2} functional dysphonia,^{3,4} vocal fold edema,³ vocal nodules,⁴ and vocal fold paralysis.^{3,4} Voice therapy is a successful treatment, which has shown significant improvements of different types of dysphonia.^{5–9} The evidence of some voice therapy programs confirms the improvement and enhancement of vocal function, voice quality, and self-evaluation in voice-disordered subjects, for example, Accent Method,^{10–12} Vocal Function Exercises,¹³ Manual Laryngeal Therapy,^{14,15} Stemple's Resonance Therapy,¹⁶ and Lessac-Madsen Resonant Voice Therapy.¹⁶ Local vibration is a new concept in voice therapy and was successfully evaluated in a preliminary study.¹⁷ The Novafon local vibration voice therapy (NLVVT) program combines local vibration with the Novafon sound wave appliance and voice exercises in a five-week treatment. Local vibration with the Novafon sound wave appliance is a noninvasive solution to treat successfully, for example

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pain,^{18–20} effects after a stroke,^{21,22} and the muscle tension reduces in cases of neurological spastics.^{23,24} The mechanic vibrations of the Novafon sound wave appliance penetrate six centimeters deep into the tissue.²⁵ The local vibration stimulates two physiological effects, which might have also an extra benefit in dysphonia treatment. First, the vibration on the skin stimulates superficial and lower layer mechanor-eceptors,²⁶ which enables a high selective nature of the involved sensors under the "gate-control" hypothesis²⁷ to treat, for example symptoms of odynophonia.

Second, the local vibration evokes muscle contraction via stretch reflexes,²⁸ which should principally increase the physical fitness by type two fibers of muscles.²⁹ Particularly, the percentages of type two fibers have a higher concentration in the thyroarytenoid muscle and cricothyroid muscle,³⁰ which regulate the glottal closure of the vocal folds. To summarize, the treatment with Novafon sound wave appliance might be both relaxing and activating. However, the benefit of the Novafon sound wave appliance has not yet been tested in the treatment of dysphonia. The aim of the present study was to investigate the NLVVT program¹⁷ with and without the Novafon sound wave appliance in the treatment of dysphonia (ie, benign vocal fold lesions, vocal fold paralysis, and nonorganic voice disorders). Thus, some voice-disordered subjects did only the voice exercises of the NLVVT program and other subjects with dysphonia received the combination of local vibration and voice exercises. Because voice is a multidimensional phenomenon, various voice characteristics had to be analyzed by using mostly objective voice measurements. To describe the treatment effects between before and after the NLVVT program the following voice assessment categories are used: acoustics, aerodynamics, multiparametric indices, and self-evaluation measurements.

Accepted for publication May 24, 2018.

Conflict of interest: None.

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Journal of Voice, Vol. ■■, No. ■■, pp. 1–8

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METHODS

Subjects

Voice-disordered subjects who had an otolaryngology letter of referral were recruited from German speech-language therapy practices. The inclusion criteria were older than 18 years old and presented a nonorganic or organic laryngeal pathology. Subjects were excluded who underwent earlier voice therapy or phonosurgery, and had a laryngeal trauma or head and neck cancer. From 32 voice-disordered subjects that were initially asked to participate, only 22 subjects underwent and finished the NLVVT program. Ten subjects had to quit the program for various reasons (eg, illness). The 22 subjects were divided equally into two groups (i.e., 11 subjects in each group). The first group was the intervention group (IG), which followed the initial NLVVT program.¹⁷ The second group was the control group (CG), which used only the voice exercises from the NLVVT program.¹⁷ Table 1 summarizes further details of the twentytwo subjects separated into the two groups. The IG and the CG are comparable with each other regarding sex, age, and type of voice disorder because no significant differences were found between both groups.

This investigation consisted of a prospective study with an interventional analysis of recordings and measurements. The requirements of the Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects were used. Additionally, every subject signed a statement of agreement and data privacy policy.

NLVVT program

The NLVVT program lasts five weeks. The voice exercises of this program included evidenced-based exercises as humming, ^{16,31–34} chewing, ^{35,36} tongue-trill, ^{34,37} lip-trill, ^{34,37} combination of tongue-trill and hand over mouth approach, ³⁴ and resonant voice. ¹⁶ The voice exercises varied every week. The Novafon classic sound wave appliance

(Novafon GmbH, Weinstadt, Germany) with 100 Hz vibration was used during all voice exercises of the NLVVT program. A local vibration part without voice exercises was also included at the beginning of the program. The intensity of the vibration was adjusted individually to the highest intensity level, which was still comfortable in vibration pressure for the user. The placement of the Novafon sound wave appliance was applied on the thyroid lamina. The user had to hear an extra buzzing sound during phonation resulting from the local vibration of the Novafon sound wave appliance. The buzzing sound during phonation is the control for the user to ensure that the vocal folds are extra stimulated through local vibration. In cases of organic larvngeal pathologies, the placement and side of local vibration on the thyroid lamina can vary (eg, unilateral polyp on the left anterior side, and unilateral vocal fold paralysis of the right side).

The NLVVT program contains five individual 45-minute sessions with a speech-language pathologist for each subject and daily practice for at home. One individual session a week for five weeks was planned to control the handling with the Novafon sound wave appliance and present the new voice exercises. Every week, the next step in the hierarchy of the NLVVT program was completed. The daily practice was obligatory for each subject. The content of the exercises for the daily practice was dependent on the number of conducted sessions with their related hierarchy level. All subjects did daily home exercises with their own Novafon sound wave appliance, which was borrowed for the purpose of this study, for 10 minutes practice sessions, twice per day.

Voice diagnostic measures

The voice measurements were conducted before and after the NLVVT program. Mostly objective voice measurements were used under consideration of gender independent voice measures for acoustic measurements, multiparametric

TABLE 1.

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Variable	IG (n = 11)	CG (n = 11)	<i>P</i> value	
Sex			0.618*	
Male	3	5		
Female	8	6		
Age in years (mean \pm standard deviation;	55.91 \pm 17.60; 29 to 80 years	59.36 \pm 21.27; 22 to 91 years	0.594 [†]	
range from minimum to maximum age)				
Voice disorder			0.771*	
Paralysis or paresis	7	3		
Functional Dysphonia	1	3		
Nodules	1	2		
Polypoid mucosa (edema)	_	1		
Parkinson desease	_	1		
Cordectomy	_	1		
Polyp	1	-		
Adductor spasmodic dysphonia	1	_		

* Chi-square test based on likelihood ratio results.

[†] Wilcoxon signed-rank test.

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indices, aerodynamic measurement, and self-evaluation. All measures of the present study are explained in detail in the following sections. To verify the level of environmental noise of the voice recordings post-hoc, the signal-to-noise ratio by Deliyski et al^{38,39} was used. All voice samples were consistent with the recommended signal-to-noise ratio norm for acceptable circumstances of acoustic recordings and analysis. Furthermore, the voice recordings were obtained in a quiet office. All acoustic recordings for the acoustics and multiparametric indices were conducted using the Voice Profiler 5.0 system (Alphatron Medical Systems, Rotterdam, The Netherlands). This system consists of a dual cardioid type microphone headset (ie. relatively close and far microphones to assure continuously calibrated sound recordings), and an individually designed USB-audio card by Alphatron Medical Systems. The voice samples were digitized at 44,100 samples per second, saved as WAV file, and analyzed with the following computer programs: Voice Profiler,⁴⁰ and Praat.⁴¹

Acoustic measurements

First, the narrowband spectrography was used to evaluate the voice quality on a three-second mid-vowel [a:]. The classification scheme for signal typing in voice was used by Sprecher et al.⁴² Recent results have confirmed that this classification scheme for signal typing in voice on sustained vowels is meaningful as a valid complement in the objective evaluation of the voice quality aspects of hoarseness and breathiness.⁴³ The interpretation of the scheme for narrowband spectrograms scores was based on the guidelines by Sprecher et al.⁴² Level A is normal and adapted to a score of 0 and all other levels (ie, B to D) received the score 1 to 3.

Second, the voice range profile (VRP) was conducted with the Voice Profiler.⁴⁰ The examiner guided the subjects in how to reach the maximum boundaries of their voice. The subjects were instructed to phonate the vowel [a:] for at least two seconds to measure the lowest pitch, the lowest intensity, the highest frequency, and the highest intensity. For further quantitative analyses only intensity and frequency range were used based on the guidelines by the European Laryngological Society^{44,45} which concluded that the frequency range > 24 semitones, and the intensity range > 40 dB are normal for females and males.

Multivariate indices

First, a multivariate index of overall voice quality severity was administered. The Acoustic Voice Quality Index (AVQI) version 02.02 is a six-factor acoustic model to quantify hoarseness in concatenated continuous speech and sustained vowel segments.^{46,47} The AVQI analysis was applied on the first 22 syllables of the German phonetically-balanced text "Der Nordwind und die Sonne" [The Northwind and the Sun] and three-second mid-vowel [a:]. Both speech types were recorded at comfortable pitch and loudness. Before calculating the AVQI score, the continuous speech part was automatically processed to contain only voiced segments using the extraction Praat-script by Maryn et al.⁴⁶ Although AVQI was originally developed for Dutch speakers, the AVQI has also been approved for German speakers.⁴⁸ The interpretation of the AVQI scores for the version 02.02 was based on the guidelines by Barsties and Maryn⁴⁸ which concluded that an AVQI score ≤ 2.70 is normal. The test-retest variability was measured about a difference of 0.54 in AVQI values.⁴⁹ This AVQI value implies the clinically significant change between two AVQI scores (eg, after a treatment intervention).

Second, the Dysphonia Severity Index (DSI) was used as an another multivariate index to measure the status of vocal function.^{50,51} The DSI is based on a weighted combination of the parameters of maximum phonation time (MPT), jitter percent on a three-second mid-vowel [a:], the highest frequency of the VRP outcome, and the lowest intensity of the VRP outcome. The results of the VRP outcomes were used from the Voice Profiler,⁴⁰ which was described earlier. The jitter percent was measured with Praat.⁴¹ The outcome of the MPT is based on habitual pitch and loudness on the vowel [a:], which had to be sustained as long as possible after taking a deep breath. The longest MPT trial of two trials was used related to the interpretation of the displayed oscillogram and narrowband spectrogram in the program Praat.⁴¹ The duration in seconds can be measured as precisely as possible detecting the beginning and end of phonation. The interpretation of DSI scores was based on the guidelines by Hakkesteegt et al⁵² which concluded that an DSI score > 3.00 is normal. The test-retest variability of a DSI change of 1.5 is recommended for clinical practice to interpret the clinically significance between two DSI scores (eg, after a treatment intervention).⁵³

Both indices are useful in the evaluation of voice disorders. Several studies confirmed the assumption that AVQI is a more valid measurement than DSI in relation to the evaluation of objective overall voice quality.^{54,55} Because DSI relies on more than only voice quality-associated markers, increases its potential to differentiate better than AVQI between more general states of normophonia and dysphonia.⁵⁶

Aerodynamic measurement

The aerodynamic measurement was the phonation quotient (PQ in mL/s). The PQ was calculated as the ratio between vital capacity and MPT. To analyze the vital capacity in mL, the subject was asked to exhale air as long as possible after a maximum inhalation in a spirometer of Riester (Jungingen, Germany). This measurement was repeated twice. The interpretation of the PQ scores was based on the guidelines by the European Laryngological Society^{44,45} which concluded that a PQ score < 200 ml/s is normal.

Self-evaluation measurement

The Voice Handicap Index (VHI) was used as a questionnaire to quantify the impacts of voice problems. The original version of the VHI was introduced by Jacobson et al,⁵⁷ and it consists of 30 questions divided into three subscales (ie, functional (VHI-F), physical (VHI-P), and emotional (VHI-E)). The subjects answer on a five-point Likert scale (from 0 = never to 4 = always). The total VHI score (VHI-T) is the sum of all questions and ranges from 0 to 120 points. The highest value represents the maximum level of self-experienced voice handicap. The VHI has also been approved and found reliable in German speakers.⁵⁸ For the present study, the digital version of the VHI was conducted.⁵⁹ The interpretation of the three subscales and total scores was addressed to the guidelines by Vanneste and Verbrugghe⁶⁰ which concluded that a VHI-T < 24, a VHI-F < 6, a VHI-P < 17, and a VHI-E < 6 are normal.

STATISTICS

All statistical analyses were completed using SPSS for Windows version 23.0 (IBM Corp., Armonk, NY, USA). First, a one-way MANOVA was conducted to evaluate significant differences of all voice measures before NLVVT between both groups estimating the start condition. The MANOVA test allows assessing the comparability of dysphonia severity between both groups. To determine significant differences of the voice measures before the NLVVT treatment between both groups the MANOVA F value of Pillai's Trace approach was used. Second, the t test for paired samples was used to evaluate significant differences between the various voice measures before and after NLVVT for both groups separately. The results of MANOVA F value of Pillai's Trace test and t test were considered statistically significant at $P \leq 0.05$. Third, a one-way repeated measure analysis of variance (ANOVA) was conducted to evaluate the changes of the various voice measures before and after the NLVVT regarding the intergroup comparison. Effect sizes were estimated by means of the partial eta-squared statistic, which describes the proportion of total variability attributable to a factor. A partial eta-squared value between 0.01 and 0.06 indicates a small effect, a value between 0.06 and 0.14 a medium effect, and a value higher than 0.14 a large effect.⁶¹

RESULTS

The starting condition was tested with a one-way MAN-OVA and no significant differences were revealed (Pillai's Trace: F = 1.145, P = 0.412). Thus, before the treatment of NLVVT no significant differences in the voice measures between both groups were found. Table 2 lists the outcomes of the gender independent voice measures before and after NLVVT for both groups. Figures 1 and 2 show the clinically significant changes after the NLVVT treatment of AVQI⁴⁹ and DSI⁵³ between the IG and the CG. The IG revealed for both indices more often clinically significant improvements than the CG. Furthermore, the results of significant differences and effect size measures of all voice measures are presented in Table 2 as well. The following sections summarized the outcomes in time of measurement for each group and the outcomes between intergroup and time of measurement comparisons.

Outcomes in the time of measurement: intervention group

Before voice treatment in nearly all voice measures abnormal values were found for the IG by following the guidelines of abnormal values as described above. The two parameters for the VRP (ie, frequency range and intensity range) were excluded. In the voice categories of acoustics: voice quality, multiparametric indices, and self-evaluation high significant improvements were revealed after NLVVT (all *P* values < 0.01). Based on their guidelines, most measures reached normal values after voice treatment excluding narrowband spectrograms, and AVQI.

There was no significant difference for the aerodynamic voice assessment category after treatment (P > 0.05), but the PQ values reached a normal value according to the European Laryngological Society^{44,45} guideline.

Outcomes in the time of measurement: control group

Before voice treatment abnormal values in nearly all voice measures were found for the CG by following the guidelines of abnormal values as described above. Again, the two parameters for the VRP (ie, frequency range and intensity range) were excluded. Only the VHI-T, VHI-F, and VHI-P of the self-evaluation category showed high significant results after NLVVT (P < 0.01). Further significant results were revealed in the intensity range, frequency range, narrowband spectrograms, DSI, and VHI-F (P values ≤ 0.05). There were no significant differences for the AVQI, VHI-E, and PQ after treatment (P > 0.05). Normal values after treatment were only found in VHI-P according on their guidelines.

Outcomes between intergroup and time of measurement comparisons between IG and CG

Although significant differences in voice measures were found before and after NLVVT for both groups, the ANOVA test showed significant differences for only two parameters in which intergroup and time of measurement comparisons between IG and CG were considered. High significant differences with a large effect size for narrowband spectrograms were revealed ($P \le 0.01$, partial eta squared = 0.495). For the AVQI results significant differences with a large effect size were found as well (P < 0.05, partial eta squared = 0.421).

Further large effect sizes were revealed in frequency range, intensity range, VHI-T, and VHI-E but all these parameters showed no significant differences in the ANOVA test (P > 0.05). The results for VHI-F showed a medium effect size without significant differences of the ANVOVA test as well (P > 0.05).

Voice Assessment Category	Parameters	Pretherapy			Posttherapy			Paired-samples <i>t</i> test (Time of Measurement)				ANOVA (Intergroup* Time of Measurement				
		IG		CG		IG		CG		IG		CG		Comparison)		
		Mean	SD	Mean	SD	Mean	SD	Mean	SD	t	<i>P</i> value	т	<i>P</i> value	F	<i>P</i> value	Partial Eta Squared
Acoustic: voice range profile	Frequency range (in semitones)	29.00	7.47	26.09	11.90	35.64	6.00	30.00	9.37	-4.312	0.002 [†]	-2.340	0.041*	2.272	0.16	0.185 [§]
	Intensity range (in dB)	42.92	8.42	40.32	12.47	54.49	6.37	46.01	14.67	-3.904	0.003 [†]	-2.485	0.032*	3.479	0.09	0.258 [§]
Acoustic	Narrowband spectrograms	1.82	0.60	2.09	0.70	0.82	0.60	1.73	0.90	7.416	0.000 [†]	2.390	0.038*	9.800	0.01 [†]	0.495 [§]
Multiparametric indices	Dysphonia severity index	1.36	2.02	-0.55	3.60	4.85	2.69	2.19	3.77	-2.848	0.004 [†]	-2.045	0.041*	0.268	0.62	0.026
	Acoustic voice quality index	4.46	1.18	5.01	1.84	2.83	0.97	4.61	2.04	-5.802	0.000 [†]	-2.137	0.058	7.268	0.02*	0.421 [§]
Self-evaluation	Voice handicap index – Total	41.18	18.38	45.64	25.06	18.36	15.38	30.27	28.21	4.422	0.001 [†]	7.525	0.000 [†]	1.993	0.19	0.166++
	voice handicap index — Functional	10.45	7.23	12.36	11.72	3.82	4.62	8.00	11.95	3.912	0.003 [†]	3.612	0.005 [†]	1.040	0.33	0.094 [‡]
	voice handicap index — Physical	20.55	5.48	22.09	8.22	11.82	6.60	13.91	8.48	3.867	0.003 [†]	4.189	0.002 [†]	0.044	0.84	0.004
	Voice handicap index – Emotional	9.36	6.09	11.64	9.38	2.73	5.76	8.36	9.35	4,098	0.002 [†]	1.943	0.081	3.046	0.11	0.233 [§]
Aerodynamic	Phonation quotient (ml/sec)	228.08	86.20	287.51	152.25	185.75	85.14	213.28	95.43	1.218	0.251	1.688	0.122	0.217	0.65	0.021

* Significant at the 0.05 level.

TABLE 2.

[†] Significant at the 0.01 level.

⁺ Medium effect size (partial eta squared between 0.06 and 0.14).

 $^{\$}$ Large effect size (partial eta squared > 0.14).

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FIGURE 1. Bar chart of the clinically significant improvement of the Acoustic Voice Quality Index in percentage between the IG and the CG.



FIGURE 2. Bar chart of the clinically significant improvement of the Dysphonia Severity Index in percentage between the IG and the CG.

DISCUSSION

In the present study, the NLVVT program was evaluated on various voice characteristics on subjects with different degrees and types of dysphonia. To assess the benefit of local vibration in voice therapy two groups with voicedisordered subjects were included. The IG followed the NLVVT program as initial proposed by Barsties v. Latoszek¹⁷ and the CG did only the voice exercises of this program without the Novafon sound wave appliance. The start condition for both groups was comparable regarding sex, age, variation of voice disorders, and severity level of all voice measures. No significant differences were found between both groups. The treatment results after five weeks of the NLVVT program showed more significant improvements in the voice characteristics for the IG (90%) than the CG (70%). Furthermore, the significant results of IG were in 67% higher than the CG. According to the guidelines above, normal results were revealed after treatment in 80% and 30% of the voice measures for IG and CG, respectively. The PQ was the only voice parameter, which did not significantly differ in both groups before and after NLVVT, although normal results were found in the IG after voice treatment. This aerodynamic voice aspect also showed no significant resuts¹⁷ in the preliminary study of the NLVVT program and might be less effective in this program. To Summarize, the results of the present study and the preliminary study¹⁷ showed that the NLVVT program might be a useful and effective voice therapy program in the treatment of dysphonia, in which local vibration has a meaningful benefit for the effectiveness of voice improvement. However, the benefit of local vibration of the NLVVT program was confirmed for voice quality. The results revealed significant improvements for the IG after treatment for narrowband spectrograms, and AVQI in comparison with the CG. A potential rationale regarding the benefits of local vibration for voice quality might depend on the stimulation of the regulation of muscle tension. The vibration of the Novafon sound wave appliance penetrates six centimeters deep into the tissue,²⁵ and the local vibration directly stimulates the muscles. Particularly the type two fibers of muscles react to the local vibration.²⁸ Other studies showed that the regulation of the muscle tension through laryngeal manual techniques/methods (with and without voice exercises) improves the voice quality.62

To evaluate further the NLVVT program next to the present and preliminary¹⁷ study results future research should focus on several other aspects to assess the effectiveness of this voice treatment program. First, a follow up procedure after the last treatment is useful to assess the longterm treatment effects of the NLVVT program. Second, the present study showed large effect sizes in the VRP, and some aspects of self-evaluation (partial eta squared > 0.14) but the results were not significant. According to the large effect sizes, it might be useful to investigate further these parameters of vocal function, and self-evaluation, in which local vibration might have a benefit of voice improvements as well. Third, other voice measures might be included to evaluate the effect on the voice through the NLLVT as for example, laryngeal imaging, further aerodynamic measures (eg, phonation threshold pressure and collision threshold pressure), and gender dependent voice parameters (eg, MPT and extreme markers of the VRP). The laryngeal imaging

prevents knowing the true status/health of the vocal folds and surrounding structures. Thus, the findings would have been strengthened by additional information regarding laryngeal/vocal structure and physiology. Further aerodynamic measures, which showed sensitive results in vocal function (eg, phonation threshold pressure,^{63,64} and collision threshold pressure^{65,66}), should be included to increase the knowledge of potential improvements in voice. Fourth, future studies should also investigate treatment effects in homogeneous groups of voice disorders and selected groups of age. By controlling these two factors, a better estimation of treatment effects might be possible.

CONCLUSION

The results of the present study showed that the NLVVT program might be an effective voice treatment for subjects with dysphonia. Most voice measures improved significantly after the treatment with and without local vibration. The effectiveness of local vibration plus voice exercises in the treatment of dysphonia in comparison with only voice exercises might be more prominent. However, an extra benefit of local vibration in voice therapy in comparison with only voice exercises was confirmed only for voice quality aspects (ie, narrowband spectrograms and AVQI).

FUNDING

This work was supported by Novafon GmbH.

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