ORIGINAL ARTICLE

CLINICAL EVALUATION OF A MEMBRANE-BASED VOICE-PRODUCING ELEMENT FOR LARYNGECTOMIZED WOMEN

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Abstract: *Background.* A newly developed artificial voice source was clinically evaluated in laryngectomized women for voice quality improvements. The prosthesis was placed in a commercially available, tracheoesophageal shunt valve.

Methods. In 17 subjects, voice-producing element (VPE) prototypes were compared with the subject's regular tracheoesophageal shunt voice in a randomized cross-over trial. The evaluation was based on aeroacoustic measurements and perceptual analysis.

Results. Considerably higher fundamental frequencies were attained with the use of the VPE. The sound pressure level also increased for most subjects. The required driving pressures of the lung and air flow rates were altered, allowing significantly longer phonation times in 1 breath. Accumulation of mucus did not interfere with the proper functioning of the device during these tests.

Conclusion. A VPE with sound-generating membranes is suitable for providing a substitute voice source for laryngectomized patients, especially patients suggestive of a severely hypo-

tonic or atonic pharyngoesophageal segment who can benefit from a more melodious and louder voice. © 2008 Wiley Periodicals, Inc. *Head Neck* **30:** 1156–1166, 2008

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An established technique for voice rehabilitation after total laryngectomy is the insertion of a 1-way valve in a surgically created tracheoesophageal (TE) shunt, enabling the production of a TE voice.[1–3] The TE voice is produced by vibrations of the pharyngoesophageal segment, initiated by a flow of air diverted from the lungs to the esophagus. Problems arise, especially for female patients, because of the usually low pitch of the substitute voice.[4–6] Furthermore, for some laryngectomized patients, the tonicity of the pharyngoesophageal segment is too low or even absent, which leads to a breathy TE voice of poor quality.[7,8]

Recent studies focused on the development of an artificial voice source that can be placed in com-
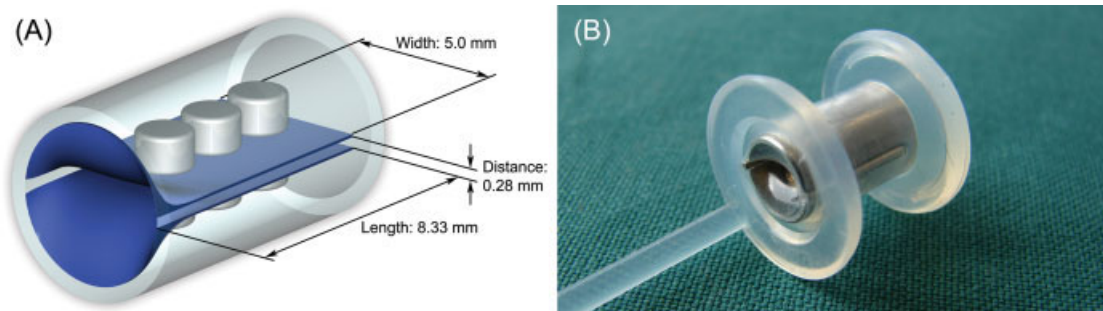
FIGURE 1. The membrane-based voice-producing element. (**A**) Drawing showing the membrane geometry and the masses placed on top of the membranes. (**B**) Photograph of the voice-producing element inside a shunt valve (Groningen ultralow resistance button), as viewed from the upstream side. [Color figure can be viewed in the online issue, which is available at www.interscience.wiley.com.]

mercially available shunt valves to improve the voice quality after laryngectomy. Such a sound-generating prosthetic device, called a voice-producing element (VPE) in this study, produces a substitute voice source under the influence of airflow from the lungs when the patient occludes the tracheostoma during expiration. The first attempts (Herrmann et al[9] and Hagen et al[10]) resulted in monotonous voices. An increase in lung pressure was suggested to lead to an increase in pitch, thus preventing a monotonous voice. Pitch and sound intensity levels—we measured the sound pressure level (SPL)—should be appropriate for producing audible speech at physiologically acceptable driving pressures and airflow rates. During laryngeal phonation, the driving pressure normally ranges from 0.2 to 3.0 kPa, with an airflow range of 45 to 350 mL/s.[11] The fundamental frequency f_0 of the voice has a mean value of about 120 Hz for men and 210 Hz for women. A normal intonation pattern contains a frequency variation of about 7 semitones,[12,13] while the SPL range is 60 to 80 dB measured 0.3 m from the mouth.[11]

De Vries et al[14] designed and tested a VPE in which the sound generation was based on the vibrations of a silicone rubber lip inside a square housing. In vitro test results indicated satisfying sound characteristics, including sufficient intonation. However, in vivo tests performed by Van der Torn et al[15–17] showed that the functioning of the silicone rubber lip was sensitive to the mucus that entered the element. During the short test period (about 1 hour) the lip was found to stick to the interior of its housing due to the mucus in 60% of the test subjects. Furthermore, in contrast with the expectations from in vitro experiments, male prototype versions of this VPE were found to produce a voice in male patients at fundamental frequencies (f_0 = 125–160 Hz) considered too high for male speech.

Tack et al[18] developed a VPE based on a different concept: 2 vibrating membranes placed parallel to each other inside a circular housing (Figure 1). The functioning of this membrane-based VPE is expected to be less sensitive to the mucus, since the exhaled air has to pass the lumen between the membranes, thus removing the mucus. Moreover, the membranes can be pushed away from each other to create a larger through-flow opening for passing mucus, while afterward the membranes will always return to their initial position because of their attachment to the housing. Prior to this study, the authors published results from an in vitro study using prototypes of this VPE, showing promising sound characteristics for the restoration of female speech, as the fundamental frequency f_0 typically ranged from 190 to 350 Hz.[19]

In this study, we evaluated the membrane-based VPE prototypes in vivo, with a group of 17 laryngectomized women. The evaluation was based on measurements of quantitative data, as well as perceptual evaluation of voice quality parameters. The study set-up was quite similar to previous clinical trials involving the lip-based VPE[17] to increase interstudy comparability. The aim of the study presented here was 2-fold: (1) to examine whether the voice quality improved with the use of a VPE as compared to the patients' regular TE voice and (2) to observe whether the VPE functions properly under environmental influences such as the presence of tracheal mucus.

MATERIALS AND METHODS

Subjects. Clinical data for this study are presented in Table 1 in the order of pharyngoesophageal segment tonicity. The estimation of the phar-

Table 1. Clinical data for the 17 women in the study group.

Subject	Age, y	Postoperative, mo	Myotomy	Radiotherapy	PE segment tonus
F01	67	108	Yes	Preoperative	Atonic
F02	64	192	Yes	Postoperative	Atonic
F03	60	127	Yes	Postoperative	Atonic
F04	59	178	No	Postoperative	Severely hypotonic
F05	75	141	No	Preoperative	Severely hypotonic
F06	75	4	No	Preoperative	Severely hypotonic
F07	56	63	No	Preoperative	Severely hypotonic
F08	70	183	Yes	Postoperative	Severely hypotonic
F09	54	96	Yes	Preoperative	Severely hypotonic
F10	70	46	Yes	Preoperative	Severely hypotonic
F11	67	123	Yes	Postoperative	Slightly hypotonic
F12	65	84	Yes	Preoperative	Slightly hypotonic
F13	53	120	Yes	Preoperative	Slightly hypotonic
F14	67	135	No	Preoperative	Slightly hypotonic
F15	58	96	Yes	Preoperative	Normotonic
F16	76	182	No	Preoperative	Normotonic
F17	70	108	Yes	Preoperative	Normotonic

Abbreviation: PE, pharyngoesophageal.

yngoesophageal segment tonicity, using visual and acoustic cues, was based on a 4-point scale: atonic, severely hypotonic, slightly hypotonic, or normotonic. The classification was performed by a medical doctor and a voice and speech pathologist experienced with laryngectomized speakers in general. We tried to include subjects especially suggestive of an atonic or hypotonic pharyngoesophageal segment, thus excluding laryngectomized patients with a hypertonous TE voice. As shown in previous studies by Van der Torn et al,[17] sounds unintentionally produced by a vibrating pharyngoesophageal segment can interfere with the prosthetic voice sound, which could complicate the comparison between these voices. All 17 subjects were women who underwent total laryngectomy. They were familiar with TE voice production and received a TE puncture 4 to 192 months (mean, 117 months) prior to this study. Every subject received radiotherapy pre- or post-laryngectomy, and 11 subjects underwent a primary pharyngeal myotomy.

All subjects received a new Groningen ultra-low resistance[20,21] TE shunt valve (Groningen ULR, Medin, Groningen, The Netherlands) before the start of the measurements. The study was performed at 2 different locations: the University Medical Centre St. Radboud, Nijmegen (9 subjects), and the Erasmus Medical Centre, Rotterdam (8 subjects). The medical ethics committee of each center approved the research protocol. Spoken and written informed consent was obtained from all subjects.

Voice-Producing Element Prototypes. The membrane-based VPE prototypes (see Figure 1) were based on the prototype design tested in vitro prior to this study (Tack et al[19]). The geometry of the membranes (Figure 1A) was based on an optimization study using upscaled VPE models (Tack et al[18]). On top of each membrane, 3 cylinder-shaped weights were placed to decrease the vibration frequency.

Materials with biocompatible properties were used in the prototype manufacturing. The membranes comprised a medical grade polyurethane (Tecothane TT-1085A, Noveon, Cleveland, OH) manufactured via dip molding. Gold-coated metal discs were dipped in the polyurethane as well. The resulting membrane thickness measured 0.07 mm on average. The membranes were stretched and placed inside a circular stainless steel housing via 2 stainless steel pins (Figure 1B) and fixed to this housing with a medical grade cyanoacrylate glue (MediCure 222, Dymax, Torrington, CT). A new VPE prototype was assembled for each subject, a procedure for which only sterilized metal parts were reused. Typical in vitro ranges for operation and sound characteristics for the VPE prototypes were: driving pressure, 0.5 to 3.0 kPa; airflow rate, 20 to 110 mL/s; fundamental frequency, 185 to 340 Hz; and SPL, 55 to 80 dB(A) at a microphone distance of 0.15 m.

For testing purposes, the VPE could be placed in the lumen of an adapted Groningen ULR shunt valve via the subject's tracheostoma with a pair of tweezers. The inner diameter of this Groningen ULR valve was increased to 6.0 mm, whereas the
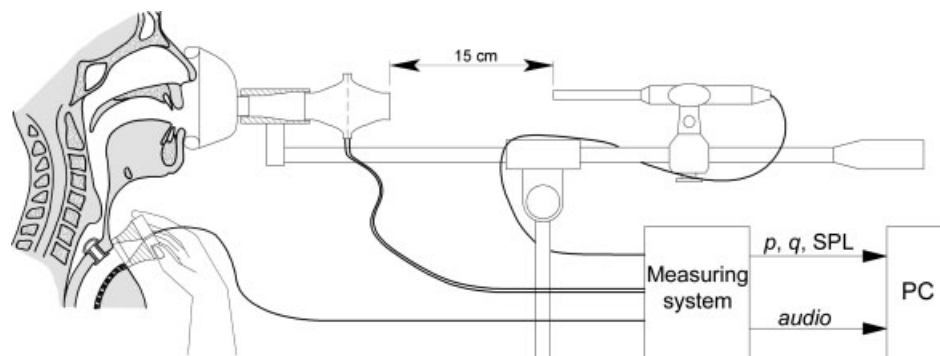
FIGURE 2. Schematic representation of the in vivo measuring set-up. *p*, driving air pressure; *q*, airflow rate; SPL, sound pressure level.

outer diameter (7.0 mm) was unchanged. The tube part of the valve, ie, the distance between the flanges, ranged from 7 to 11 mm, depending on the thickness of the TE wall. The typical airflow resistance of this shunt valve was about 0.1 kPa at 20 mL/s and 0.4 kPa at 120 mL/s. A thread was attached to the VPE prototype housing and guided outside the subject's stoma for security reasons. This thread could also be used to pull the VPE out of the shunt valve, thus preventing the need to replace the entire shunt valve during the measurements.

Measuring Equipment. Figure 2 shows the experimental setup that allowed us to measure various aerodynamic and acoustic parameters in vivo during a sustained phonation of a vowel.[22] Identical, but separate, measuring systems were used at the 2 test locations.

Intratracheal air pressure (p) was measured with a pressure transducer (Honeywell 40PC006 G2A, Freeport, IL) connected via a polyethylene catheter (length 1.4 m) to a custom-made silicone rubber tracheostoma adapter. Using this adapter, the subject's tracheostoma could be closed off in a similar way as the subjects were accustomed to produce their TE voice. Calibration of the sensor was performed using a U-shaped water manometer. The typical accuracy of the air pressure measurements was ±0.01 kPa.

Airflow rate (q) was measured using a Lilly-type[23] wire gauze flowhead (AD Instruments MLT300L, Oxfordshire, UK) connected to a differential pressure transducer (Honeywell DC001NDC4, Freeport, IL) by 2 flexible tubes. The measurements were taken using a face mask (Vygon anesthesia mask 5557.55, Ecouen, France), which covered the subject's mouth and nose. The flow measurements system was calibrated using a

flowmeter (Brooks Instrument GT1357, tube type R-6-25-B, Veenendaal, The Netherlands) and compressed air from a cylinder. The accuracy of the flow measurements was ±10 mL/s.

Sound was measured in a sound-treated room with an omnidirectional condenser microphone (Behringer ECM8000, Willich, Germany) at a fixed distance of 0.15 m from the flow outlet of the flowmeter. The distance from mouth to microphone was therefore approximately 0.33 m. The SPL was determined from the A-weighted sound signal using a custom-built integrator, which was set at exponential averaging and an integration time of 25 ms. The calibration of the SPL measuring system was accomplished with a calibration loudspeaker (B&K Acoustical Calibrator 4231, Copenhagen, Denmark). The accuracy of the SPL measurements was ±2 dB.

The sensors, connected to custom-built amplifiers and data acquisition boards, were all situated inside a measuring box. The *p, q,* and SPL signals were sampled with a rate of 2 kHz and digitally registered using a PC with custom-built software. During the measurements, the microphone's audio signal from the measuring system was fed to a PC for digital recording of the voice, using a sampling rate of 44.1 kHz.

Intratracheal pressure, airflow rate, and SPL were read offline from the raw data, whereas the fundamental frequency (f_0) of the voice was determined from the recorded sound signal using an autocorrelation pitch-detection method.[24] To examine the various frequency components in the sound signal, a spectrogram was computed for frequencies up to 4 kHz by means of a voice analysis program (PRAAT, version 4.5.02, http://www.praat.org).

Measuring Procedure. All measurements were made with both the subject's regular TE voice and

the VPE-assisted voice. Two block-randomized subject groups (block size 2) were formed for this cross-over trial for different test sequences. One group started the measurements with their own TE voice using a Groningen ULR shunt valve, whereas the other group first performed all measurements with the VPE placed in the same button. The subjects were allowed to experience and practice this new mechanism of alaryngeal voice for approximately 30 minutes before the actual sound recordings.

For aerodynamic and acoustic analysis, using the setup shown in Figure 2, the subjects were asked to phonate sustained /a/, /i/, and /u/ vowels at a comfortable loudness and pitch. Subsequently, the phonation of the vowel /a/ was repeated 3 times: as soft as possible, at a comfortable loudness level, and as loud as possible. In this way, the dynamic and the melodic ranges were determined. The mean values of the aerodynamic and acoustic parameters for a stable period of vowel phonation were calculated afterward from the raw data registrations. The maximum phonation time was also measured by asking the subject to phonate for as long as possible the vowel /a/ at comfortable loudness and pitch after a maximum inhalation. The phonations were repeated 3 times, and the median of the measurements was used for analysis, except that the maximum phonation time with the best attempt was used.

To establish speech rate, determined as the number of words per minute (wpm), each subject was asked to read the first paragraphs of the Dutch prose "De Vijvervrouw" in a normal conversational manner. The mean speech rate of 52 laryngeal reference speakers from the medical institute in Amsterdam (VU Medical Centre, Amsterdam, The Netherlands) was 181 wpm, with an SD of 24 wpm.[15] Van der Torn et al[15] also presented results from 6 laryngectomized patients (1 man, 5 women) with the following mean speech rate values: TE voice, 115.8 (SD = 27.1) wpm; and lip-based VPE voice, 118.5 (SD = 37.5) wpm. Sound recordings of approximately 90-second read-aloud prose were used to evaluate the intonation capability of the voice by measuring the median f_0 and the 10% to 90% interquartile f_0 range. Furthermore, approximately 90 seconds of spontaneous conversation with the investigator was recorded for each subject.

For perceptual evaluation of the voice, directly after finishing the measurements, each subject was asked to provide a primary judgment of their voice using a short questionnaire. Likewise, the recorded voices were rated later on by a professional listener, who was blinded to the clinical data. The questionnaires used for the perceptual voice assessments were in accordance with the questionnaire designs used by Van der Torn et al[17] in a similar study.

The subjects' primary judgment of voice quality attained with a VPE, as well as their regular TE shunt valve, was assessed on 4-point scales. The 7 items of the self-assessment questionnaire were pitch of voice, vocal intensity, effort required for speaking, availability of the voice, fluency of the speech, pitch control for intonation, and a general impression of voice quality. The questionnaire for the perceptual voice evaluation by a professional listener contained a subset of the 7-point bipolar semantic scales, which was developed by Nieboer et al[25] and later modified by Van As et al[26] as well as Festen and Verdonck-de Leeuw.[27] This subset included the following 5 scales: low pitch–high pitch, weak–powerful, tense–nontense, gurgling–nongurgling, and monotonous–melodious. Recordings of approximately 30-second read-aloud speech and 90-second spontaneous speech were presented twice in random order to a voice-and-speech pathologist experienced with laryngectomized speakers. Intrarater reliability was calculated from the difference between test and retest. The reliability was defined as the percentage of test minus retest differences smaller than, or equal to 1 scale value.

Results obtained for both types of voices were compared and statistically analyzed (SPSS 15.0, SPSS, Chicago, IL) using paired Student's t test for parametric data or Wilcoxon-matched pairs signed-rank test and Mann-Whitney U-test for ordinal data.

RESULTS

Observations. The VPE prototypes could be placed inside the subject's shunt valve without difficulties. Directly after placement, all subjects were able to produce voice with this new prosthesis. Although the subjects were allowed to practice and experience their new voice for a short period of time prior to the measurements, some subjects still felt uncomfortable using the VPE during the measurements because of the large difference in tonality between the VPE and the subject's regular TE voice.

Because of the replacement of the shunt valve prior to the experiments, most subjects exhibited

Table 2. Averaged parameter values as measured for 17 laryngectomized women using their tracheoesophageal shunt voice without and with voice-producing element.

Subject	Regular TE shunt voice				Voice-producing element in shunt			
	p, kPa	q, ml/s	f_0, Hz	SPL, dB[A]	p, kPa	q, ml/s	f_0, Hz	SPL, dB[A]
F01	1.5–3.1	218–478	NA	59–65	2.1–3.9	23–59	230–311	70–84
F02	1.9–4.6	77–316	NA	61–74	1.9–5.7	46–140	209–347	57–71
F03	0.9–2.4	103–323	NA	56–60	1.7–4.1	43–111	227–313	65–71
F04	6.0–10.7	86–125	111–125	68–72	4.0–6.7	24–65	195–311	57–73
F05	3.5–4.7	525–787	68–100	63–69	4.1–5.4	85–111	259–330	68–83
F06	2.9–5.9	290–401	52–67	69–79	3.1–5.4	22–48	278–324	73–80
F07	2.3–4.7	253–675	41–65	64–73	3.0–5.9	106–160	230–297	66–73
F08	3.1–10.0	35–158	86–95	52–61	1.8–6.6	22–64	221–320	58–84
F09	3.0–5.0	177–430	32–45	61–67	3.2–4.9	42–71	287–349	64–71
F10	2.2–4.3	112–141	NA	58–68	1.6–3.3	19–34	231–308	61–75
F11	5.0–9.4	48–90	87–116	58–76	6.8–10.9	37–57	219–240	53–73
F12	1.3–3.5	15–85	53–72	54–67	2.1–4.4	21–47	227–317	61–73
F13	1.9–5.2	193–398	30–67	57–65	1.6–4.5	17–53	239–329	72–84
F14	5.8–6.4	117–147	112–137	71–77	5.9–7.7	67–74	249–292	64–72
F15	4.0–10.0	47–178	124–161	64–76	5.8–8.9	69–110	242–310	71–78
F16	1.0–3.1	172–350	44–58	60–75	1.6–5.4	32–58	179–320	60–87
F17	1.4–3.0	150–252	21–28	57–69	3.1–3.9	50–63	261–309	62–67
Mean range	2.8–5.6	154–314	66–87	61–70	3.1–5.7	43–78	234–313	64–76

Abbreviations: NA, not applicable; TE, tracheoesophageal.
Note: The parameters measured during soft and loud phonation of a sustained vowel /a/ are tracheal air pressure (p), airflow rate (q), fundamental frequency (f$_0$), and the sound pressure level (SPL) at a 0.15-m microphone distance.

an increased phlegm production. The coughed-up phlegm and mucus from the lungs and trachea did not terminate the functioning of the VPE. For both the VPE and the TE voice, all measurements could successfully be performed with the 17 subjects.

Aerodynamic and Acoustic Evaluation. Table 2 shows the mean tracheal air pressure (p), airflow rate (q), fundamental frequency (f_0), and the SPL values as measured during a soft and loud phonation of a sustained vowel /a/. The mean range for all 17 subjects is also presented. For subjects F01 and F03, the f_0 of the TE voice could not be measured, because the latter was a mere whisper. Furthermore, subjects F02 and F10 had a highly gurgling TE voice missing a periodic signal, making the determination of f_0 impossible.

The pressures as measured for the TE shunt voice were comparable to those required for the production of voice using the VPE. For some subjects (F04, F08, and F15), for which high pressures were required to produce a TE voice, less effort was required for producing a voice with the VPE at similar, or even higher, SPLs. The flow rates for the TE voice were approximately 4 times higher on average, but these values varied widely between subjects. The voice of most subjects increased in SPL by the application of the VPE; overall the maximum SPL increased by 6.2 dB

(SD = 8.6), and this difference was significant (t_{16} = 2.94; p = .010). Using the VPE, all subjects attained considerably higher fundamental frequencies, which was consistent with the frequencies (f_0 = 185–340 Hz) measured inside an experimental in vitro setup. Increased driving pressure caused increased pitch, with a mean frequency range of 5.1 (SD = 2.3) semitones. This range was smaller than the ranges measured in vitro (about 10.5 semitones) for the VPE prototypes. In some subjects (F04, F05, F11, F14, F15, and F17), sounds unintentionally produced by the PE segment vibrations interfered with the voice sounds as produced by the VPE placed inside the shunt valve. The interference sometimes occurred suddenly for a short period of time, whereas for some subjects the interference was constantly present, resulting in the unnatural perception of a voice containing 2 different pitches.

Figure 3 shows the spectograms of a sustained vowel /a/, as produced by subject F03 for 2 types of voice. For comparison reasons, the spectrogram of a healthy laryngeal voice is also shown, as measured from a female speech therapist. These graphs illustrate the added harmonic strength of the VPE, which enabled a better distinction of vowels.

Voice and Speech Parameters. Fundamental frequency values as measured for read-aloud prose
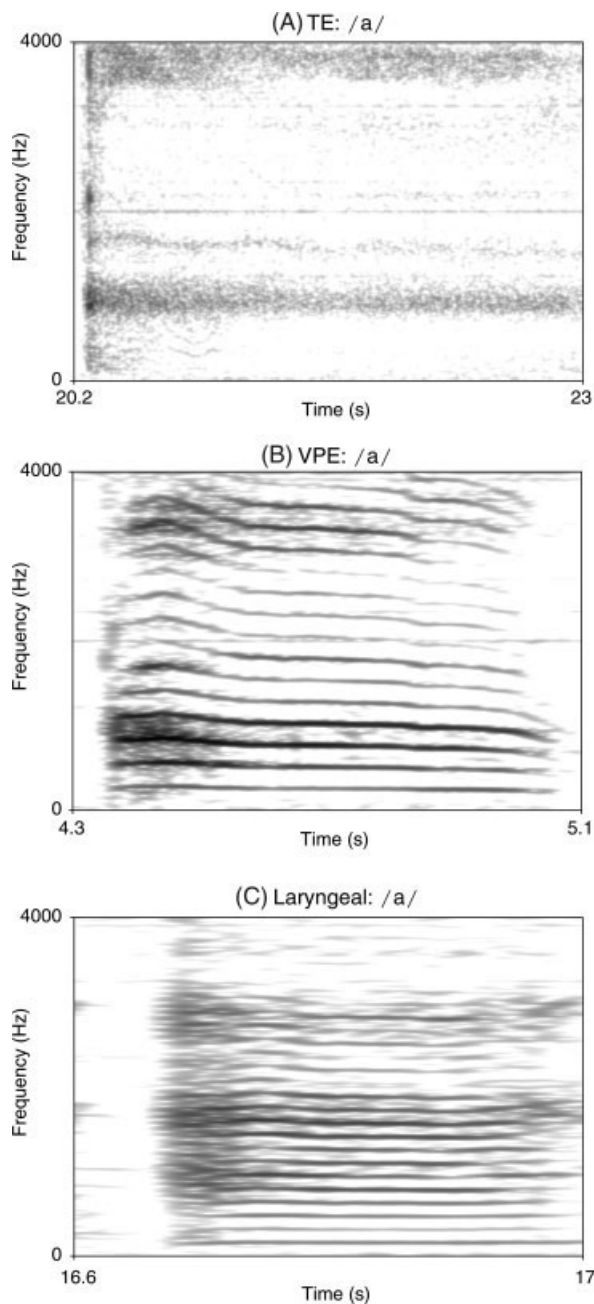
FIGURE 3. Distribution of the spectral energy in the sound produced during a sustained phonation of a vowel /a/, as measured for subject F03 (**A**) for the tracheoesophageal shunt voice and (**B**) the voice-producing element–assisted voice, and (**C**) as measured for a healthy, female speech therapist.

are presented in Table 3 for both the TE shunt voice and the VPE voice. As compared with the sustained phonation of the vowel /a/, the melodic ranges during speech were larger, with the ranges determined by the 10% to 90% spreading of f_0. The average number of semitones was 12.1 (SD = 4.9) for the TE voice, and 7.1 (SD = 4.1) semitones for the VPE

voice. A paired Student's t test showed that the difference in semitones between the TE and VPE voice was not significant ($t_{12} = 1.985$; $p = .070$). The pitch increase due to the VPE was evident from the median f_0 values ($t_{12} = 10.2$; $p < .001$).

Table 4 shows the results obtained for both voices of the maximum phonation time of a sustained vowel /a/ and also the speech rate at read-aloud prose. With a VPE, subjects were able to sustain the vowel /a/ much longer ($t_{16} = 5.264$; $p < .001$). However, most subjects were not able to attain the same speech rate as compared with their regular TE voice. Nevertheless, for some women, the VPE greatly improved the speech rate, eg, subject F08 (+28% wpm) and F12 (+31% wpm). On average, the amount of words per minute decreased, but this difference was not significant ($t_{16} = 0.677$; $p = .508$).

Perceptual Voice Evaluation. The subject's primary judgment of the VPE voice when compared with their regular TE voice is shown in Table 5 for the 7 questionnaire items. Subjects F03 and F08 were not able to compare the pitch of the VPE voice to their regular TE voice, because the latter was merely a breathy, whisper voice. According to separate Wilcoxon matched-pairs signed-rank tests, only the low pitch–high pitch scale signifi-

Table 3. Median and the 10% to 90% interquantile spreading of the fundamental frequency during read-aloud prose for approximately 90 seconds, comparing the tracheoesophageal shunt voice with the voice-producing element–assisted voice.

	f_0 (Hz) regular TE voice		f_0 (Hz) VPE voice	
Subject	Median	10–90% range	Median	10–90% range
F01	NA	NA	284	232–305
F02	NA	NA	244	211–270
F03	70	48–152	249	223–342
F04	110	91–171	242	134–278
F05	86	69–154	245	191–279
F06	70	44–90	286	198–314
F07	69	32–79	235	205–259
F08	NA	NA	264	226–284
F09	36	36–45	310	260–357
F10	NA	NA	279	246–299
F11	86	72–115	246	217–333
F12	73	51–95	234	189–265
F13	61	43–95	251	220–282
F14	133	105–158	179	111–305
F15	137	92–182	272	150–375
F16	66	48–78	222	199–254
F17	46	22–74	332	275–378
Mean (SD)	80.2 (30.3)	58–115	257.2 (35.2)	205–305

Abbreviations: NA, not applicable; f_0, fundamental frequency; TE, tracheoesophageal.

Table 4. Maximum phonation time of sustained vowel /a/, and speech rate at read-aloud prose for 17 laryngectomized women using their regular tracheoesophageal shunt voice without and with voice-producing element.

	Regular TE shunt voice		Voice-producing element in shunt	
Subject	Max. phonation time, s	Speech rate, wpm	Max. phonation time, s	Speech rate, wpm
F01	6	165	10	151
F02	13	135	16	148
F03	7	149	5	121
F04	6	157	9	155
F05	2	104	4	111
F06	1	115	3	119
F07	3	128	8	114
F08	7	82	11	113
F09	2	76	5	63
F10	5	140	16	150
F11	8	141	19	114
F12	4	89	10	128
F13	3	177	9	166
F14	2	151	3	141
F15	9	121	13	111
F16	9	119	14	107
F17	6	125	12	110
Mean (SD)	5.5 (3.2)	127.8 (28.7)	9.7 (4.8)	124.8 (24.9)

Abbreviation: TE, tracheoesophageal.

cantly differentiated between regular TE shunt voices and VPE voices; 7 subjects (F02, F04, F07, F10, F12, F16, F17) preferred the higher vocal pitch attained with the VPE, whereas only 1 woman (F11) rejected it because of a constant interference with her pharyngoesophageal segment.

Table 5. Self-assessment by the patients of the voice-producing element–assisted voice as compared with their assessment of regular tracheoesophageal shunt voice.

	Questionnaire items (number of scale values based on a 4-point scale*)						
Subject	Pitch of voice	Vocal intensity	Effort required	Availability of the voice	Fluency	Intonation	General impression
F01		+1	−3		−3		
F02	+1		−1	+3	+1	+1	+1
F03	NA		−3	−1	−2		−1
F04	+1	+2	−1	+1	−1		
F05			+1		+1	−1	
F06		−3		−1	−1	−1	
F07	+1					−1	−1
F08	NA	+3	+3	+3	+2	+1	+3
F09		−2	−2				−1
F10	+1	+3	+1			+1	
F11	−1	−2		−2	−1		−1
F12	+2	+1	+3			+2	−1
F13		+2		+1	−2	−2	
F14			+1	+1	+1		+1
F15		+1	+1	+2	+1	+2	
F16	+1	−2	−2		−2	−3	−2
F17	+3	+1			+3		
Mean	0.60	0.18	0.00	0.41	−0.18	−0.06	−0.12
Significance†	0.034	0.753	0.972	0.227	0.593	0.917	0.493

Abbreviation: NA, not applicable.
*A positive number of scale values indicates improvement by the voice-producing element (VPE) compared with the regular tracheoesophageal shunt voice: improved pitch, better vocal intensity, less effort required for speaking, better availability of the voice, better fluency, better pitch control for intonation, and a better general impression of the voice. A negative number of scale values indicates the opposite. Items unaltered by the VPE were left out.
†Significance of differences resulting from prosthesis is based on Wilcoxon matched-pairs signed-rank tests

Table 6. Perceptual evaluation of voice quality on a bipolar 7-point scale by an expert listener for 17 laryngectomized women, using the voice-producing element, as compared with their regular tracheoesophageal shunt voice.

Subject	Bipolar semantic scales (number of scale values based on a 7-point scale*)				
	Low pitch–high pitch	Weak–powerful	Tense–nontense	Gurgling–nongurgling	Monotonous–melodious
F01	+1	+4	+0.5	−4	
F02	+4	−1	−2	+3	+2
F03	+3	+4.5	−0.5		+1
F04	+2	−1	−3	+5.5	+1.5
F05	+5	−1.5	−2.5	−2	
F06	+3	+0.5	+1	+1.5	+3.5
F07	+3.5	+1	−0.5	−0.5	+2
F08	+2.5	+4.5		−4	
F09	+5	−3.5	−3.5	+1.5	+2.5
F10	+2	+4.5			+0.5
F11	+5	−2.5	−3	+0.5	−4
F12	+3.5	+2.5	+1.5	+3	+3.5
F13	+2.5	+2.5	−3	−3	+1.5
F14	+3.5	−2	−4	−1	−4
F15	−1	−1.5	+0.5	+2	
F16	+5	−4	−3	+0.5	−0.5
F17	+5	−3.5	−4	−0.5	−2.5
Mean (SD)	3.2 (1.6)	0.2 (3.0)	−1.5 (1.9)	0.1 (2.5)	0.4 (2.2)
Significance†	<0.001	0.740	0.012	0.842	0.462

*A positive number of scale values indicates improvement by the voice-producing element (VPE) compared with the regular tracheoesophageal shunt voice: higher pitch, better vocal intensity, less tense, less gurgling, and more melodious. A negative number of scale values indicates the opposite. Items unaltered by the VPE were left out.
†Significance of differences resulting from prosthesis is based on Wilcoxon matched-pairs signed-rank tests.

The effects of the VPE on the other 6 scales varied widely between subjects.

Table 6 presents the difference in voice quality rating between the VPE and the subject's regular TE shunt voice for each subject and scale, as assessed by a professional speech therapist. The total number of judgments by the professional listener was 170 (17 subjects × 2 different voices × 5 scales). For 125 judgments, the first rating was within 1 scale value of the second rating, rendering an intrarater reliability of 74%. Test and retest was identical in 45% of the patients. According to separate Wilcoxon-matched pairs signed-rank tests, 2 scales significantly differentiated between regular TE shunt voices and VPE voices: the VPE-assisted voices were rated higher pitched but also more tensed. Subjects with an atonic or severely hypertonic pharyngoesophageal segment (F1–F10) gained on average 1.3 scale values (SD = 1.2) on voice melodiousness by using the VPE, whereas the other 7 subjects lost 0.9 scale values (SD = 2.8). This difference was not significant ($U = 16.5; p = .069$).

DISCUSSION

The most recent attempt to improve voice quality after laryngectomy revealed that a VPE-based on a lip principle was very sensitive to the mucus that entered the device during use.[17] In 60% of the test subjects, the lip stuck to the interior of its housing. Such clogging problems were not an issue for the membrane-based VPE evaluated in this study, because they were not observed and, moreover, none of the 17 subjects experienced significantly deteriorating effects in voice availability or fluency (Table 5) during these tests. We would like to emphasize that the current study was for short-term analysis only, as a consequence of which conclusions about proper functioning after a long period of rest (eg, sleep) were not possible. Furthermore, contrary to their regular TE voice, the subjects had only a short training period and no previous experience with this novel method of alaryngeal voice production. Hypothetically, training for a longer period could have improved some voice quality parameters (Table 6), and the subjects' judgments of their own voice (Table 5) in some instances. For example, some subjects who were accustomed to giving short strong bursts of air for producing their TE shunt voice tended to give the same all-out treatment when the VPE was placed inside the shunt valve, while this device was designed for a more subtle handling.

Similar to the lip-based VPE from previous clinical evaluations, the membrane-based VPE proved to be a feasible concept for voice restoration after total laryngectomy for female patients. The application of a VPE increased the relatively low fundamental frequencies to levels (Tables 2 and 3) that are considered more suitable for female voice (mean laryngeal f_0 = 210 Hz). Especially, subjects lacking a voice pitch, atonic of severely hypotonic in general, can benefit from a louder and clear voice. Nevertheless, the aerodynamic, acoustic, and perceptual evaluation also showed that the current VPE prototypes cannot be considered as an improvement over the TE shunt voice on all voice quality items.

Quantitative Parameters. The parameter values (Table 2) as measured for a VPE-assisted voice were according to expectations from experimental in vitro measurements.[19] In line with these in vitro measurements, on average, lower flow rates were required (ie, allowed) for producing a voice with the VPE as compared with the subject's regular TE shunt voice. This could implicate that subjects, normally requiring large flow rates, could produce voice at equal sound intensities with less effort and more fluently. This was observed, for example with subjects F05, F08, and F13, who assessed their VPE voice positively (Table 5) at these items. Some subjects, however, experienced the restricted flow rates as an increased effort for producing voice, leading to higher driving pressures. The individual differences may be attributed to differences in pharyngeal-esophageal anatomy, personal skills, and training.

The hypothetical benefit of the low-flow characteristic of the membrane-based VPE could be that it does not evoke pharyngoesophageal segment vibrations. However, interference from pharyngoesophageal segment vibrations was still observed in some subjects, even in subjects classified as severely hypotonic (F04 and F05). A correlation between any of the quantitative parameters, such as airflow rate, and the subjects' susceptibility toward diplophonia was not found from these measurements.

Perceptual Parameters. To appreciate the patient's self-assessment properly, one should take into account the psychological effect of a TE shunt voice, which the subject is familiar with, in contrast to the novel experience of a VPE voice, which has a different timbre and sound source location and requires a slightly different han-

dling. Naturally, a subject tends to give a higher rank to the voice the subject is acquainted with than to a completely new and higher-pitched voice. For example, subject F06 judged her VPE voice inferior on vocal intensity by a maximum score of −3 scale values (Table 5), while similar SPL values were measured for both voices (Table 2). Furthermore, subject F13 gained a considerable 19 dB in SPL using the VPE (Table 2) but still did not assess the new voice as an improvement on her vocal intensity, hereby assuming the perceived loudness to be related directly to the SPL measured.

Although higher pitched, the VPE-assisted voice was also perceived as more tense, following from the professional perceptual voice evaluation (Table 6). This was possibly due to the audible artificial timbre of the VPE voice. Consequently, the VPE voice was sometimes described as a whining voice. A small number of subjects described the new experience as having a robot-like, electro-larynx inside their throat, whereas the VPE did provide sufficient intonation (Table 3) for day-to-day speech. The voice was also perceived more melodious than regular TE shunt voice by the speech therapist (Table 6) for most subjects.

CONCLUSIONS

The new voice of 17 laryngectomized women, obtained with a membrane-based VPE placed inside their TE shunt valve, was evaluated on voice quality improvements. Quantitative voice measurements clearly showed the increase in fundamental frequency (f_0 was 3.5× higher on average; f_0 = 205–305 Hz), whereas the SPL also increased significantly (SPL increased by 4 dB on average; SPL = 64 to 76 dB[A] measured at a 0.33-m distance from the mouth). The application of the VPE did not lead to unacceptable increases in driving lung pressure. As compared with the subject's regular TE shunt voice, the flow rates were lower for most subjects (about 4 times lower), leading to significantly longer phonation times in 1 breath (about 2 times longer).

A perceptual evaluation not only confirmed the elevated voice pitch but also showed that the substitute voice was perceived as more tensed. Nevertheless, subjects especially suggestive of a severely hypertonic or atonic pharyngoesophageal segment, having a weak and whispering TE shunt voice, can benefit from a more melodious and louder voice using the VPE.

The double-membrane concept for sound production appears to be a feasible concept for appli-

cation in a VPE, because mucus from the lungs and trachea did not interfere with its functioning. However, further research is necessary on the VPE performance on a long-term basis, including a voice quality assessment after a training period of a few days. Future research should also be directed at the development of a lower pitched VPE suitable for male voices, the integration of a shunt valve function, and a VPE cleaning procedure for the user.

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