ORIGINAL ARTICLE

IN VITRO EVALUATION OF A DOUBLE-MEMBRANE–BASED VOICE-PRODUCING ELEMENT FOR LARYNGECTOMIZED PATIENTS

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Abstract: *Background.* A sound generator based on a double-membrane design that fits into a regular tracheoesophageal shunt valve may improve voice quality after total laryngectomy in patients rehabilitated with surgical voice prostheses.

Methods. Voice-producing element (VPE) prototypes were manufactured using medical grade biocompatible materials and tested in vitro under physiological conditions.

Results. Basic sound, containing multiple harmonics, was successfully produced under physiologic air pressure and airflow conditions. The fundamental frequency and sound pressure level (SPL) is controlled by changing the driving pressure, thus enabling sufficient intonation for day-to-day speech. The obtained frequency range (190–350 Hz) is appropriate for producing a female voice. The low noise-to-harmonics ratio (mean 0.15) and also the efficiency of sound production (5.5×10^{-5} at 80 dB(A) and 0.15 m microphone distance) is comparable to that of normal vocal folds.

Conclusions. Functional restoration of the voice after laryngectomy with a double-membrane VPE appears to be a feasible concept for female laryngectomized patients with a hypotonic, or atonic pharyngoesophageal segment. ©2007 Wiley Periodicals, Inc. *Head Neck* **29:** 665–674, 2007

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Laryngeal carcinoma sometimes can only be treated with a total laryngectomy. Because of the removal of the laryngeal vocal folds, the patient loses the ability to produce voice in a natural way, which is one of the most radical changes experienced by the patient after the surgical operation. For voice rehabilitation, an appropriate and convenient method must be found to replace the vocal fold function of setting the vocal tract air column into vibration. Vibrations with proper aero-acoustic characteristics can be converted to speech by the patient. The shunt valve assisted tracheoesophageal (TE) voice[1–3] is widely used nowadays. The mean fundamental frequency of the esophageal voice is usually 60 to 90 Hz.[4–7] This low frequency causes problems especially for women, since in normal female laryngeal voice production this frequency has a mean value of approximately 210 Hz. But also for males, with normally a mean fundamental frequency of about 120 Hz,[8,9] the

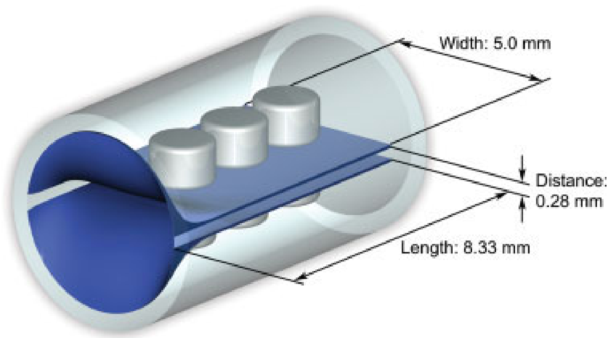

FIGURE 1. Drawing of the double-membrane-based VPE, with the membrane geometry. [Color figure can be viewed in the online issue, which is available at www.interscience.wiley.com.]

esophageal voice is rather low-pitched. Furthermore, in some laryngectomized patients, the tonicity of the pharyngoesophageal (PE) segment is too low or even absent, which leads to a breathy TE voice of a poor quality.[10,11]

The voice quality of laryngectomized patients might be improved by the application of a voice-producing element (VPE). A VPE is a small device that converts a constant flow of air into a complex sound, thereby serving as a substitute voice source. The VPEs are meant to be placed inside a TE shunt valve, and when the tracheostoma is closed off they can vibrate the air in the vocal tract through a flow of air emanating from the lungs. Because sounds unintentionally produced by a vibrating PE segment can interfere with the prosthetic voice sound, the VPE is currently best suited for patients suggestive of a hypotonic, or atonic TE voice.[12]

In the last decade, several types of a VPE have been developed. Hagen et al[13] and Herrmann et al[14] presented results of clinical tests with a reed-based VPE. A metal reed vibrated, influenced by air coming from the lungs. Using this device, patients were able to produce clear voiced sounds, with a fundamental frequency higher than that normally found in TE speech. However, the disadvantage of the reed-based elements is that they produced a sound with a fixed frequency, leading to an unnaturally monotonous voice. Furthermore, the element appeared to be sensitive to blockage by tracheal secretions. De Vries et al[15] developed a different kind of VPE, consisting of a single silicone rubber lip that could periodically interrupt the flow of air from the lungs, thereby creating a voice source. In clinical tests, however, Van der Torn et al[16] observed that the functioning of the silicone rubber lip was also sensitive to the mucus that entered the element. The lip sometimes stuck to the interior of its housing.

We have developed a new VPE concept, based on a double-membrane principle as the sound source. The double membrane as a sound-generating principle was developed in a previous study using up-scaled models.[17] The VPE based on this concept consists of 2 elastic membranes placed parallel to each other inside a circular housing (see Figure 1). A constant flow of air from the lungs can be led between the membranes, which then start to vibrate via aerodynamic forces, and thereby generate a complex sound. The underlying working principle is comparable to the oscillating lips of a musician playing a brass instrument,[18–20] but also to the avian vocal system, the syrinx, in which the membranous sections at the junction of the 2 avian bronchi interact with the airflow from the lungs, producing a frequency-modulated sound.[21,22] An advantage of the double-membrane VPE over the reed- and lip-based VPEs is that the double-membrane concept is expected to be less sensitive to blockage by 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.

In this in vitro study, we evaluated clinic-ready prototypes of the double-membrane–based VPE to examine how they function under physiological conditions. The evaluation was based on the requirements that follow from the physiological working environment. First of all, the air pressures and flow rates necessary for sound production must not exceed the patients' physical capabilities. Lung pressure varies significantly with vocal intensity; during laryngeal phonation, the pressure ranges from 0.2 to 3.0 kPa. The airflow range is 45 to 350 mL/s under normal speaking conditions.[8] Furthermore, the sound produced by the prototypes should contain a fundamental frequency suitable for producing a male (mean 120 Hz) or female voice (mean 210 Hz). The laryngectomized patient should be able to produce understandable speech, which means that harmonics up to 4 kHz should be present in the sound signal. To include the possibility for intonation, our intention is that the patient can control the vocal pitch with lung pressure; by increasing the driving pressure, the fundamental frequency of the sound produced should also increase. The intonation pattern during normal phonation contains a frequency variation of about 7 semitones,[9,23] with a sound pressure level (SPL) range of 60 to 80 dB, measured 0.3 m from the mouth.[8]

MATERIALS AND METHODS

Double-Membrane Voice-Producing Element. The VPE prototypes consist of 2 elastic membranes fixed inside a circular metal housing (Figure 1). Each membrane is loaded with 3 identical metal weights to decrease the vibration frequency.

The geometry of the housing is adapted to be inserted in the lumen of TE shunt valves, like the Groningen Button[3] or the Provox valve,[24] with lumen lengths of 5 to 11 mm, depending on the thickness of the tissue wall between the trachea and esophagus. The length of the prototype housing is 10.0 mm. To investigate the optimal properties of the other geometrical parameters, an up-scaled model was build and tested.[17] On the basis of these findings, an outer housing diameter of 6.0 mm was chosen, in contrast with the more obvious size of 5 mm that would allow direct placement in standard shunt valves. The larger diameter is necessary to realize a sufficiently low fundamental frequency and low driving air pressure. As a consequence of the larger prototype housing, during the tests an adapted shunt valve had to be used. This Groningen Ultra-Low Resistance Button with a larger internal shaft diameter was manufactured and supplied by Medin (Groningen, The Netherlands). The outer shaft diameter of the valve remained identical to the commercially available Groningen Button, so that the TE tract does not have to widen. The geometry of the membranes is shown in Figure 1, with the relations between the different measures based on the best membrane configuration found during the tests with the up-scaled models. The membrane thickness is between 0.07 and 0.08 mm. On top of each membrane, 3 cylinder-shaped weights are placed, each of which has a height of 1.2 mm and a diameter of 1.8 mm. The mutual distance is 0.3 mm, so that they are equally distributed lengthwise along the membrane.

In manufacturing of the prototypes, we anticipated the possibility of in vivo studies by selecting materials with optimal biocompatible properties. The membranes were composed of a medical grade polyurethane (Tecothane TT-1085A, Noveon, Cleveland, OH) and were manufactured via dip molding. The metal discs were composed of steel

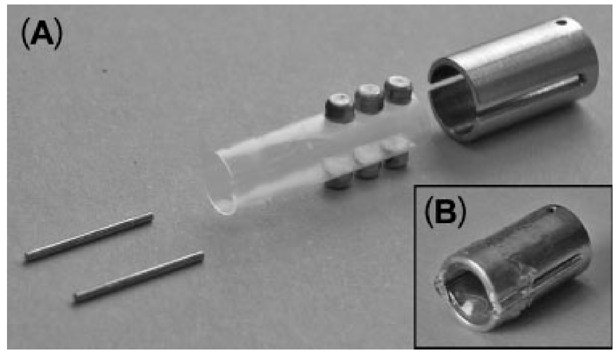

FIGURE 2. Photograph of a clinic-ready, double-membrane prototype before assembling (**A**), and after assembling (**B**).

(AISI 02; density = 7.85 g/cm^3), and dipped in the polyurethane as well. The result of the dipping process was a polyurethane tube, with the 6 weights incorporated in the polyurethane, as shown in Figure 2A. The elastic tube was stretched by 2 stainless steel pins that fit into the slits on both sides of the stainless steel housing to obtain 2 prestressed, parallel membranes. The strain of the membranes was 1.8%. The protruding portion of the tube was folded over the outside of the housing (Figure 2B) and glued with a medical grade cyanoacrylate glue (MediCure 222, Dymax, Torrington, CT).

Experimental Set-up. The experimental set-up shown in Figure 3 is a model of the physiological situation in a patient; it allowed us to measure various acoustical and aerodynamic parameters in vitro. The vocal tract, lungs, and trachea present an acoustical load such that the required resonance frequencies (formants) can influence the fundamental frequency produced by the sound source. Therefore, physical models of the vocal tract, lungs, and trachea were integrated, which closely resembled the acoustic properties of the altered airway geometry after laryngectomy. These models consist of interconnected hard-walled tubes with specific lengths and diameters designed to obtain the proper resonance frequencies[25,26] and are described by Van der Plaats et al.[27] The model representing the acoustical load of the lungs and trachea was fixed inside a large pressure reservoir, which was coated inside with a sound absorbing material. Via an air cylinder, a flow of dry air at room temperature was supplied that was able to build up a pressure inside this reservoir. On top of the outflow opening of the lung model a VPE prototype was placed inside a Groningen Button shunt valve. Additionally, 3 different acoustical loads could be placed downstream to the prototype, which

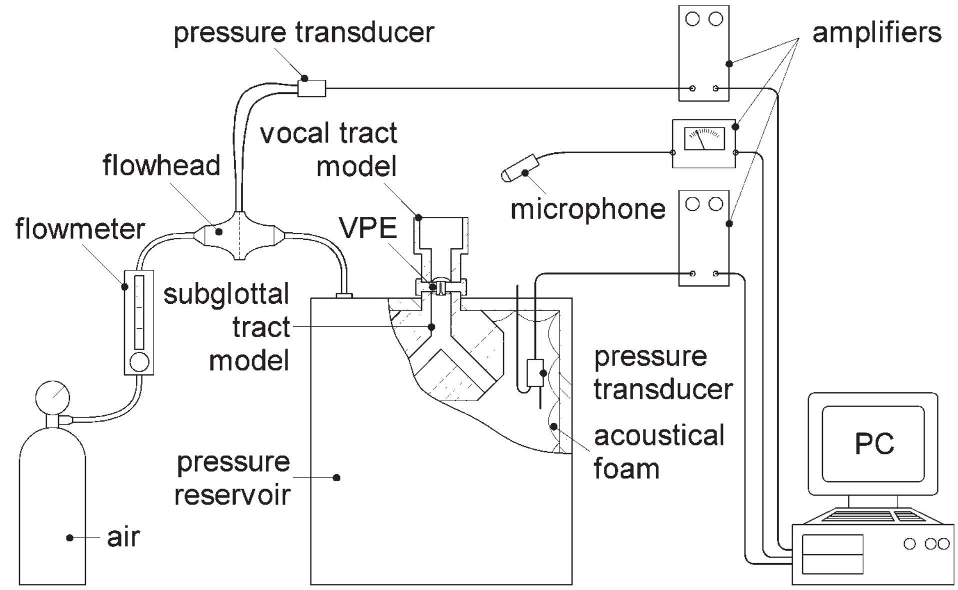

FIGURE 3. Schematic representation of the in vitro experimental set-up. Components are not to scale. VPE, voice-producing element prototype.

represented the 3 basic vowels /a/, /i/, and /u/. The specific formant frequencies of the vowel /a/ were 600 and 1000 Hz, of vowel /i/ 250 and 2100 Hz, and of vowel /u/ 190 and 560 Hz.

The following aero-acoustic parameters were measured and digitally processed, using a PC with a data acquisition card (National Instruments PC-LPM-16, Austin, TX) and custom-build software (National Instruments LabVIEW 6.1, with Sound and Vibration Toolset 2.0, Austin, TX). All signals were sampled real-time with a sampling rate of 8 kHz.

Airflow Rate and Air Pressure. The flow from the air cylinder was manually adjusted via a Brooks flowmeter (Brooks Instrument GT1357, tube type R-6-25-B, Veenendaal, the Netherlands). The mean airflow rate (q) was measured by a Lilly flowhead (Mercury Electronics, Glasgow, Scotland), connected to a differential pressure transducer (Honeywell 164DC01D76, Freeport, IL) and custom-built amplifier. The calibration of the flowhead was accomplished with the Brooks flowmeter mentioned. The error of the flow measurements was $\pm$5 mL/s.

The air pressure (p) inside the pressure reservoir, which represents the driving lung pressure, was measured in relation to the atmospheric pressure with a differential pressure transducer (Honeywell 163PC01D48, Freeport, IL), connected to a custom-build amplifier and calibrated against a water manometer. The typical accuracy of the air pressure measurements was $\pm$0.01 kPa.

Fundamental Frequency and Sound Pressure Level. The sound was measured with a condenser microphone (B&K 4134, Copenhagen, Denmark), connected to an amplifier (B&K 2609, Copenhagen, Denmark). The calibration of the microphone's SPL was accomplished with an Acoustical Calibrator (B&K 4231, 94 dB SPL – 1000 Hz, Copenhagen, Denmark). In LabVIEW, the sound level was exponentially averaged with a pressure reference of 20 μPa, using a time constant of 125 milliseconds. Furthermore, an A-weighting filter was applied to the sound signal. The microphone was placed outside the stream of air, and close to the sound source since the sound measurements were performed in an acoustically nondefined room of relatively small size. We used a 0.15-m distance from the microphone to the prototype or vowel model, if applied. By approximation, the SPL measurements in our set-up were 6 dB higher as compared with measurements in a sound-treated room at a microphone distance of 0.30 m.

The level of the fundamental frequency and the presence of harmonics are important factors in the production of the different vowels during speech. To examine the various frequency components in the sound signal and the effect of the physical vowel models, an averaged power spectrum was computed for frequencies up to 4 kHz using LabVIEW. For the composition of these spectra RMS averaging was applied, with a linear weighting of 20 averages over 10 seconds. This averaging method reduced the signal fluctuations, but not the noise floor. Moreover, an A-weighting filter was applied to the signal in the time domain.

The fundamental frequency (f_0) of the sound produced was derived from the power spectrum by means of a peak search algorithm in the Sound and Vibration Toolset of LabVIEW.

Efficiency of Sound Production and Noise-to-Harmonics Ratio. The sound quality of the prototype was further quantified by calculating the efficiency of sound production and the noise-to-harmonics ratio (NHR). An acoustic efficiency was calculated as the ratio of acoustic power to the power provided to produce the sound. To calculate the acoustic sound power, it is assumed that the sound intensity is constant on the surface of a hemisphere in front of the prototype's flow outlet and that the sound intensity on the other half of the sphere can be neglected. Following the efficiency calculations performed by Van den Berg,[28,29] and Schutte and Nieboer,[8,30] the efficiency of sound production was calculated as

$$\text{Efficiency} = \frac{\text{Acoustic power}}{\text{Provided power}} = \frac{2\pi r^2 \times 10^{(\text{SPL}/10)} \times 10^{-9}}{pq}$$

with r [m] the distance from the microphone to the sound source, SPL [dB(A)] the SPL, p [Pa] the mean driving pressure, and q [L/s] the mean airflow rate.

The NHR was determined with the Multidimensional Voice Program (MDVP) via the Computerized Speech Lab (Kay Elemetrics, Pine Brook, USA). The NHR is an average ratio of the inharmonic spectral energy in the frequency range 1500 to 4500 Hz to the harmonic spectral energy in the frequency range 70 to 4500 Hz.

Measuring Procedure. Four identical prototypes were tested inside the in vitro experimental setup. Initially, the prototypes were tested without an acoustical load placed downstream. Subsequently, 1 prototype was also tested with the physical models for the /a/, /i/, and /u/ vowels to illustrate the influence of the acoustical loads on the sound produced.

After the equipment was calibrated, the airflow rate was increased until the membranes of a prototype started to vibrate and a sound was produced. All aero-acoustic parameters mentioned were recorded digitally at stable values of the mean air pressure and airflow rate. Next, the airflow rate was increased by approximately 10 mL/s, and all parameters were recorded again at a stable air pressure and flow rate. This process—increasing the airflow rate and measuring the accompanying parameter values—was repeated until the driving pressure exceeded 3 kPa.

In addition to these measurements, videostroboscopic recordings were made during the tests in order to observe the membrane vibrations from the downstream side.

RESULTS

In Figure 4, characteristic data are presented as measured for the 4 identical double-membrane prototypes, numbered DM1 to DM4. The charts show the relation of the driving air pressure to, respectively, the airflow rate, the fundamental frequency, the SPL, and the NHR. Ideally, the 4 hand-made prototypes would show an identical pattern in these charts, but some deviations, especially regarding the airflow rate, were observed.

As shown in Figure 4A, the airflow rate increase was approximately linear with increased driving pressure. The pressure at which the prototypes began to produce sound, the threshold pressure, averaged to 0.70 kPa. Pressures up to 3 kPa were reached without difficulties. Within this pressure range, the prototypes functioned normally, and the corresponding average airflow range was 27 to 100 mL/s. The relationship between the pressure and fundamental frequency (Figure 4B) was also approximately linear. The measured f_0 range was about 190 to 350 Hz, which involved almost 11 semitones. Figure 4C demonstrates the SPL curves, which are nearly logarithmic in appearance. The average SPL range was about 57 to 81 dB(A), as measured for the prototypes without the vowel models attached. Figure 4D shows the data for the NHR, together with the threshold value of 0.19 that was used as the threshold for a normal healthy voice in human voice analysis with MDVP (Kay Elemetrics, Pine Brook, USA). Generally, the NHR data of the prototypes lay below this threshold, yet the NHR values tended to rise in the vicinity of the pressure range extremities. Considering all data points, the mean NHR was 0.15, meaning that the voiced sound could be classified as "normal."

Figure 5 shows how the prototypes' SPL relates to the power that was supplied for the sound production. The straight line in this double logarithmic figure shows that the SPL and the total acoustic power were nearly proportional to $(pq)^2$. This quadratic increase was also expressed

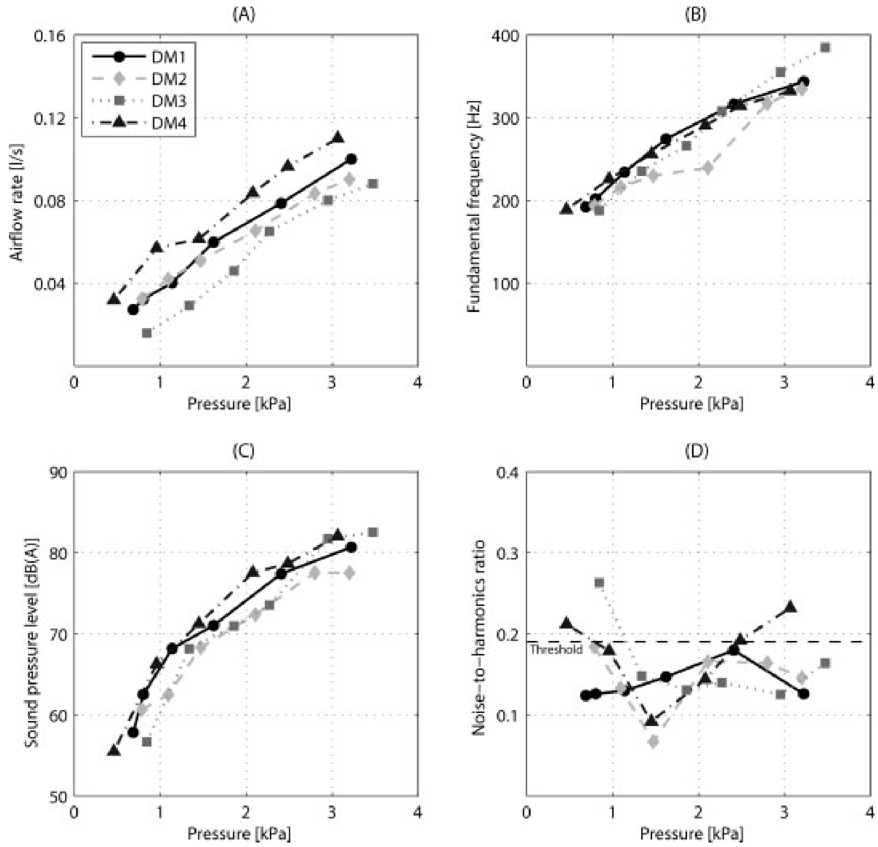

FIGURE 4. The relation between the driving air pressure and the airflow rate (**A**), the fundamental frequency (**B**), the sound pressure level (**C**), and the noise-to-harmonics ratio (**D**), as measured for the 4 prototypes (DM1 to DM4).

in the efficiency values calculated. Overall, the efficiency varied from approximately 0.6×10^{-5} at 60 dB to 5.5×10^{-5} at 80 dB, measured at a distance of 0.15 m from the sound source.

The influence of introducing an acoustical load on top of the prototype's flow outlet was measured with prototype DM1. The loads are associated with 3 different physiological vocal tract shapes, when producing the vowel /a/, /i/, or /u/, respectively. The vowel models acted like a resonator filter, amplifying specific frequencies present in the sound signal. In Figure 6 the power spectra of the sound signal show the fundamental frequency and the multiples of this frequency, the harmonics, up to a frequency of 4 kHz. The power spectra of the "unfiltered" sound produced by prototype DM1 are shown in Figures 6A–6C, for different driving pressures. Figures 6D–6F show the spectra at the driving pressure of 1.6 kPa, under influence of the 3 different vowel models. In comparison with the situation in which there was no vowel model applied, no significant differences could be observed in the driving pressures and airflow rates necessary for sound production. The influence of the vocal tract models on the f_0 and SPL parameters is illustrated in Figure 7.

Furthermore, the vowels had a positive effect on the NHR. With a vowel model, all NHR had a value below the threshold, and their average value was 0.11. The vowels also had an effect on the efficiency of sound production, depending on

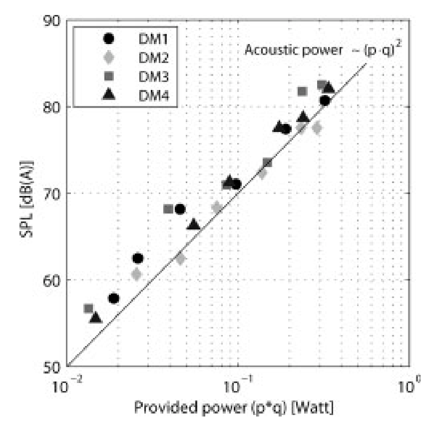

FIGURE 5. The pressure level of the sound produced by the prototypes (DM1 to DM4) in relation to the power supplied to vibrate the membranes.

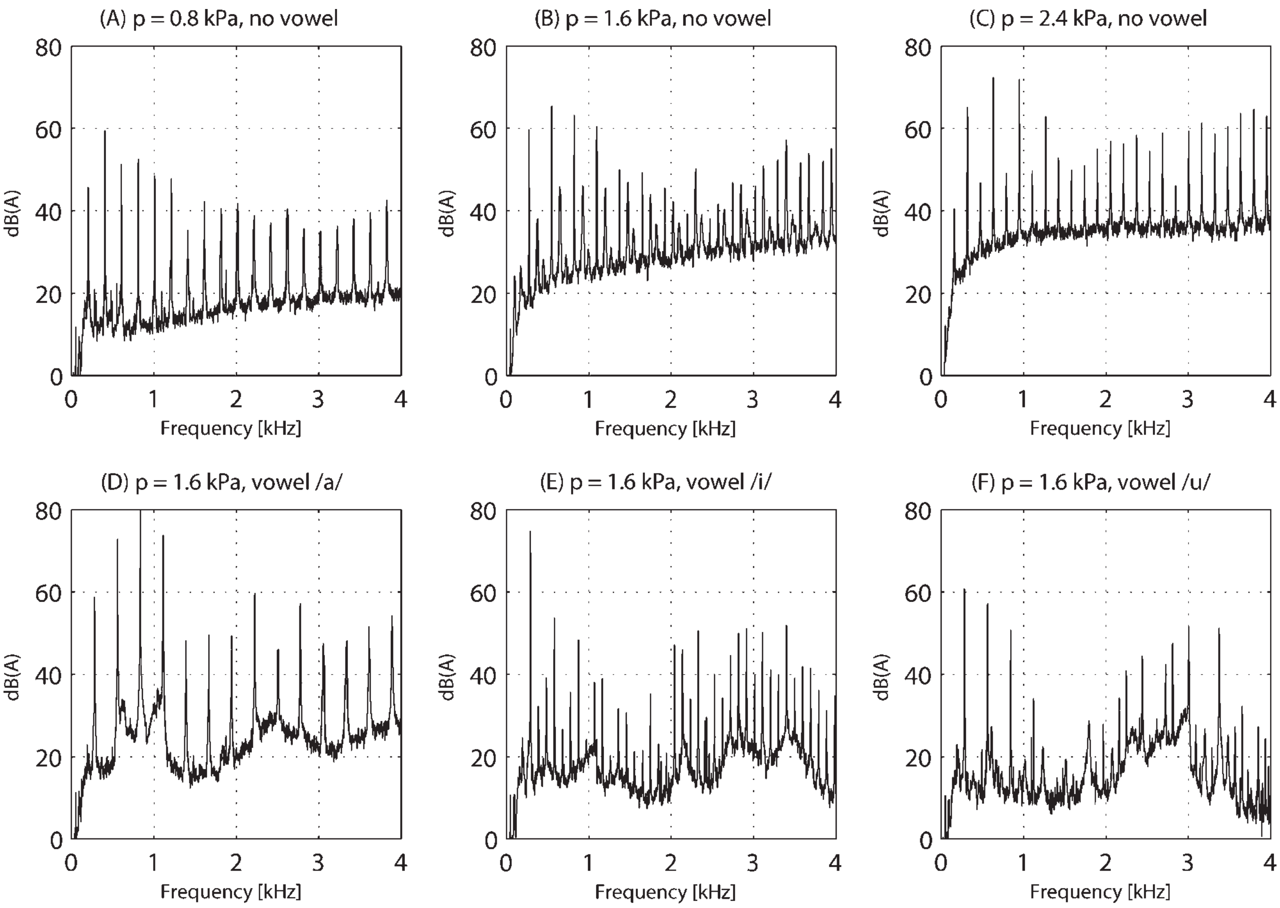

FIGURE 6. The sound spectra as measured for prototype DM1 at the driving pressures of 0.8 kPa (**A**), 1.6 kPa (**B**), and 2.4 kPa (**C**) without a physical vowel model, and, at a driving pressures of 1.6 kPa, also with filtering by the model for the vowel /a/ (**D**), the vowel /i/ (**E**), and the vowel /u/ (**F**).

which vowel model was applied. This influence on the efficiency was most pronounced when the vowel /a/ was applied, as can be seen from Figure 7B, as the SPL increased with approximately 10 to 20 dB while the power provided for sound production was nearly constant. As a result, the efficiency increased to approximately 7.4×10^{-4} at 82 dB, and the maximal efficiency value measured at a distance of 0.15 m from the sound source was 1.2×10^{-2} at 102 dB SPL.

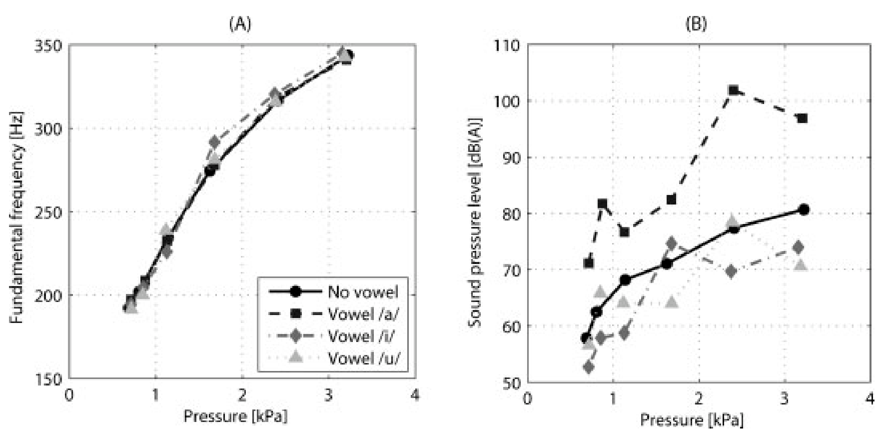

FIGURE 7. The influence of 3 physical vowel models on the fundamental frequency (**A**), and the sound pressure level (**B**), as measured for prototype DM1.

The characteristic behavior of the vibrating membranes was observed with the videostroboscopic recordings. These recordings showed that the sound was produced by the periodical opening and closing of the airway. The membrane vibrations had a wave-like motion; the airway closure propagated from the upstream side to the downstream side. Increased driving pressure caused increased vibration amplitude as well as vibration frequency.

DISCUSSION

Most laryngectomized patients can regain their speech with the shunt valve-assisted TE voice. However, serious difficulties often remain for patients that have a breathy, hypotonic, or atonic voice, and females that have problems dealing with the low pitch of their voice. These patients can benefit from the new substitute voice source presented in this study, on condition that the functioning of these VPEs fit the requirements as imposed by the physiological working environment.

The in vitro tests show (Figure 4A) that the pressures that are necessary to drive the membrane vibrations of the VPE prototypes are in line with the driving lung pressures that can be acquired physiologically. Although the mean vibration threshold pressure is slightly higher than the threshold in laryngeal voicing, 0.7 kPa instead of 0.2 kPa, no problems concerning the controllability of the prosthetic sound source with the driving lung pressure are expected. Additionally, the mean airflow range (27–100 mL/s) is relatively low, but lies within the mean laryngeal flow range (45–350 mL/s). In TE voice production, low airflow rates are not uncommon,[16] but nevertheless a lower permissible flow rate could mean that the patient needs more time to adapt to the new voice source. Furthermore, the differences between the measured prototypes shown in Figure 4 may be related to manufacturing inaccuracies.

Earlier attempts to replace the voice with a VPE, utilizing a metal reed or a silicone rubber lip, resulted in problems related to the interference of mucus from the trachea,[16] and in the case of the metal reed problems also resulted from the unnatural monotonous sound.[13] In this study, the variability of the fundamental frequency is shown (Figure 4B) for the double-membrane prototypes that would allow intonation in the speech of female laryngectomized patients. In spite of the decreased membrane vibration frequency with the added metal weights, the level of the f_0 range (190–350 Hz) still appears to be too high for male phonation (mean 120 Hz). To decrease the current f_0 of these prototypes, we suggest that a complementary study look for other ways to load the membranes. Since the mean f_0 for a female voice is 210 Hz, the prototype's frequency variation expressed in semitones is -2 and $+9$ semitones, which is suitable for a normal speaking range profile.[8,9] Figure 4B also shows the nearly linear increase of the frequency with increasing driving pressure. Combined with the also linear pressure and flow relation (Figure 4A), this means that the behavior of the VPE is linear, which is a favorable result since it means that controlling the voice pitch during speech is made more comfortable.

An audible and intelligible voice is also necessary for comfortable speech. The SPL of the elements can be considered fair (Figure 4C), reaching up to ca 80 dB at a driving pressure of 3 kPa, measured with a 0.15 m microphone distance. These levels of the sound pressure, however, varied greatly with the type of acoustical load applied. From Figure 7B, it can be seen that with the vowel model /a/ the SPL increases, while the models for the vowels /i/ and /u/ generally cause an SPL decrease. The models corresponding to the vocal tract shapes /i/ and /u/ have a smaller "mouth" opening than the vowel /a/. As a consequence, less sound is radiated at the "mouth," and more sound energy is reflected back into the vowel model.[26] In vivo, this effect may be less pronounced than these rigid physical vowel models predict. Without applying an acoustical load, the relation between the driving pressure, f_0 (Figure 4B) and SPL (Figure 4C) is fixed, suggesting difficulty in producing an audible voice with a low pitch. However, as shown in Figure 7B, each individual vowel has a certain leveling effect on the SPL that varies with the driving pressure and actually depends on the f_0 of the sound produced (Figure 7A). The SPL increases when the f_0, or an integer multiple of this frequency, approaches or coincides with the formant frequency of the vowel model, in which case the acoustic feedback is strong. For example, consider the vowel /a/ that shows a strong acoustic feedback at about 0.9 kPa, which relates roughly to an f_0 of 200 Hz. In this case, the third and fifth harmonic would have increased in strength, as the first and second formant frequencies of the vowel model are 600 and 1000 Hz, respectively. Please note that the formants of the vowel models have fixed frequencies and that their values are slightly lower than normally found in the physiological situation.

Nevertheless, the vowel models provide a good estimation of how the substitute voice will be perceived and, more importantly, they can show the dependency of the pitch on the acoustical load applied. For the latter case, Figure 7A shows that the f_0 of the prototype is not drawn to the various formant frequencies of the vowel models, and thus shows a "willful" behavior[31] that is important for pronouncing the different vowels at an appropriate speech rate. The presence of harmonics in the sound signal (Figure 6) enabled the pronunciation of the different vowels. Moreover, because of the filtering of the sound signal by the different vowel models, the harmonic strength in relation to the noise level increased, leading to increased clarity of the substitute voice.

The performance of the double-membrane concept with regard to sound production can be evaluated by considering the NHR and the efficiency values. On the basis of the NHR parameter (Figure 4D), the quality of the sound can be considered good compared to a normal laryngeal voice. Schutte[8] measured the overall efficiency of the laryngeal voice in 45 normal subjects. At an intensity level of 60 dB, the efficiency varied from about 0.15×10^{-5} to 2×10^{-5}, and at 80 dB from 4×10^{-5} to 30×10^{-5}. Without the application of a vowel model, the mean efficiencies of the VPE prototypes (0.6×10^{-5} at 60 dB and 5.5×10^{-5} at 80 dB) lie well within this range. The VPE efficiency with the vowel /a/ is about 50% higher than the maximal laryngeal efficiencies measured by Schutte, as derived from his efficiency figures. Given the relatively small size of the elements, the prototype's performance is very good. Moreover, like the vocal folds,[28] the double-membrane concept has the remarkable property that the acoustic power, and thus the efficiency, increases approximately in a quadratic way with the energy (pq) that is supplied to vibrate the membranes (Figure 5).

Furthermore, it is expected that mucus from the trachea can pass between the membranes through the VPE without disturbing its functioning. Nevertheless, clinical tests will be necessary to assess the performance of the elements in situ. The double-membrane prototypes presented in this study are ready for clinical application. Before the application of these VPEs can become an established technique for voice restoration, however, further research is necessary on the VPE manufacturing method, the durability, and the method used by patients to clean the device.

In conclusion, the evaluation shows that functional restoration of the voice after laryngectomy with a VPE, based on the double-membrane concept, appears to be feasible for female laryngectomized patients. The prototypes only need a small amount of airflow from the lungs, but function appropriately under physiological conditions. By varying the driving air pressure, several acoustic parameters can be controlled—eg, the f_0 and the SPL—thus providing the means to speak with intonation. The sound quality is considered appropriate for producing an audible voice with sufficient intelligibility.

The performance of the prototypes is promising, and their functioning might encourage further VPE developments, especially with regard to male voice rehabilitation. Although the working environment was taken into account during the prototype development, further clinical research is necessary on the performance of the elements in situ.

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