A voice-producing prosthesis for laryngectomized patients

J.W. Tack[1], H.A.M. Marres[2], C.A. Meeuwis[3], E.B. van der Houwen[1], G. Rakhorst[1], G.J. Verkerke[1]

[1] *Department of BioMedical Engineering, University Medical Center Groningen, University of Groningen, Groningen, The Netherlands.*

[2] *Department of ENT, University Medical Centre St. Radboud, Nijmegen, The Netherlands*

[3] *Department of ORL, Head and Neck Surgery, Erasmus Medical Centre, Rotterdam, The Netherlands*

Abstract

Introduction: Despite state of the art tracheo-esophageal (TE) voice-rehabilitation after laryn-gectomy, some patients are unable to produce voice of sufficient quality, because of hypotonicity or atonicity of their pharyngo-esophageal (PE) segment. Furthermore, the TE voice is low pitched, which presents a problem especially for female laryngectomized patients. A voice-producing element (VPE) is developed, based on the double-membrane concept, to supply the laryngectomized patients with a better substitute voice.

Materials and methods: The VPE is comprised of two elastic membranes inside a circular housing that can be inserted in a shunt valve. Four identical prototypes were manufactured and tested in-vitro under physiological conditions.

Prototypes were also tested in 17 female laryn-gectomised patients. An aerodynamic and acoustical analysis was performed, the maximum phonation time, speech rate and intonation capability determined. Finally the voice was perceptual evaluated.

Results: Basic sound, containing multiple harmonics, was successfully produced under physiologic air pressure and airflow conditions. The fundamental frequency and sound pressure level could be controlled by changing the driving pressure, thus enabling sufficient intonation. The obtained frequency range (190 - 350 Hz) is appropriate for producing a female voice. The VPE produced a sound with a low noise-to-harmonics ratio (mean 0.15), the efficiency of sound production ($5.5 \cdot 10^{-5}$) is comparable to normal vocal folds.

The clinical study clearly showed that the pitch and sound intensity were increased without an unacceptable increase in driving lung pressure. The flow rates were lower than normal, leading to significantly longer phonation times. Accumulation of mucus did not interfere with speech production.

Conclusion: Functional restoration of the voice after laryngectomy with a VPE, based on the double-membrane concept, appears a feasible concept for female laryngectomized patients or patients with a hypo- or atonic PE segment.

Keywords: Laryngectomy, Voice rehabilitation, Voice-producing prosthesis, Shunt valve, Artificial organ, Aero-acoustics.

Introduction

Due to an advanced laryngeal cancer sometimes the removal of the complete larynx is necessary; a so-called total laryngectomy. During this surgical procedure the larynx is cut from the trachea, which is sutured to an opening in the skin at the base of the neck for respiration. The most disturbing consequence of this procedure for the patient is the loss of a natural way to produce voice.

For the rehabilitation of the voice, the shunt valve assisted tracheo-esophageal (TE) voice [1] is widely used nowadays. Exhaled air flows via a shunt valve into the esophagus where soft tissue structures start to vibrate thus creating a substitute voice. The mean fundamental frequency of the esophageal voice is usually 60 - 90 Hz [2]. This causes a problem especially for women, since the normal female voice frequency is about 210 Hz. But also males, with a fundamental frequency of about 120 Hz [2] suffer from the esophageal voice. Furthermore, in some laryngectomized patients the tonicity of the soft tissue structures is too low or even absent, which leads to a breathy or even absent TE voice [3-5].

Eureka project "NewVoice" (project 2614, http://www.eureka.be) was set up with the aim to improve the current rehabilitation method. One of the goals was to realise a new sound generating device for improved voice quality. The development and test of the voice-producing element (VPE) will be discussed in this article. The VPE is meant to be placed inside the shunt valve so, when the tracheostoma is closed-off, it can create vibrations by an airflow from the lungs.

To improve the voice quality of laryngectomized patients, several types of a VPE have been developed in the past: Hagen et al. [6] and Hermann [7] developed a VPE with a metal reed. Using this device, patients were able to produce clear voiced sounds, with a higher fundamental frequency. However, as a disadvantage, the reed-based elements produced a sound with a fixed frequency, leading to an unnatural monotonous voice. Furthermore, the element appeared to be sensitive to blockage by tracheal secretions. De Vries et al. [8] developed a different kind of VPE that consisted of a single silicone rubber lip, which periodically interrupted the flow of air from the lungs, creating a voice source. However, in clinical tests Van der Torn et al. [9] observed that it was also sensitive to tracheal secretions.

We have developed a new VPE-concept, based on a double-membrane principle as the sound source. The double-membrane as sound generating principle was developed in a previous study using up-scaled models [10]. The VPE based on this concept consists of two elastic membranes, placed parallel to each other inside a circular housing, see Fig. 1a. To lower the frequency metal weights were placed on the membranes. A constant flow of air from the lungs that is lead between the membranes will start them to vibrate by aerodynamic forces resulting in a complex sound.

The underlying principle is comparable to the oscillating lips of a musician playing a brass instrument [11], but also to the avian vocal system, the syrinx, in which the membranous sections at the junction of the two bronchi interact with the airflow from the lungs and a frequency modulated sound is produced [12].

To optimize the prototype a scale study was performed [10] and a numerical model was developed [13]. Clinic-ready prototypes of the double-membrane based VPE were tested both in-vitro and clinically.

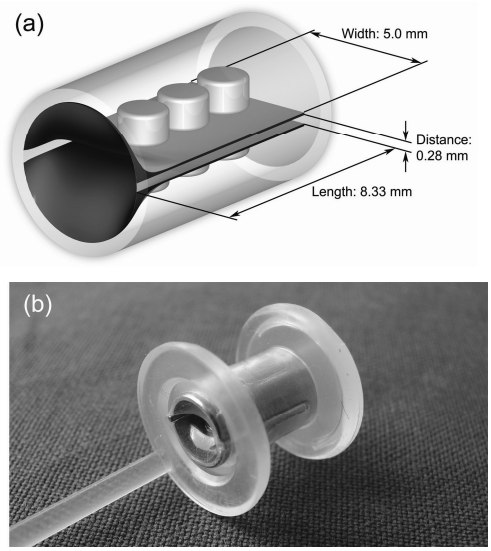

Figure 1: The voice-producing element based on the membrane principle; (a) drawing showing the geometry of the weighted membranes, and (b) photograph of a prototype placed inside a shunt valve, viewed from the upstream side.

Materials and methods

Double-membrane voice-producing element

Four identical prototypes were tested inside the in-vitro experimental set-up. The VPE prototypes consisted of two elastic membranes, fixed inside a circular metal housing (Fig. 1b). Each membrane with a thickness of 0.07 mm is loaded with three identical metal weights to decrease the vibration frequency. The membranes were made out of the medical grade polyurethane Tecothane TT-1085A (Noveon, Inc., Cleveland, OH, USA) by dip molding. The metal discs were made out of steel and also dipped in the polyurethane.

The housing could be placed in the lumen of TE shunt valves, like the Groningen Button or the Provox valve [14].

.

Experimental set-up

The experimental set-up, shown in Fig. 3, is a model of the physiological situation in a patient, and described by Van der Plaats et al. [15]. The model represented the acoustical load of the lungs and trachea. The following aero-acoustic parameters were measured [16]:

Airflow rate & air pressure

The air pressures and flow rates that are necessary for sound production must not exceed the physical capabilities of the patients. The lung pressure varies significantly with the vocal intensity; during laryngeal phonation the pressure ranges from 0.2 to 3.0 kPa. The airflow range is 45 - 350 ml/s under normal speaking conditions [3].

The mean airflow rate (q) was measured by a Lilly flowhead (Mercury Electronics, Glasgow, Scotland), connected to a differential pressure transducer (Honeywell 164DC01D76, Freeport, Ill., USA) and a custom-build amplifier.

The air pressure (p) was measured in relation to the atmospheric pressure with a differential pressure transducer (Honeywell 163PC01D48, Freeport, Ill., USA), connected to a custom-build amplifier.

Fundamental frequency & sound pressure level

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, with the possibility for intonation.

Our intention is that the patient can control the vocal pitch with the 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 3 - 4 semitones [4], with a sound pressure level range of 60 to 80 dB, measured at 30 cm from the mouth [3].

The sound was measured with a condenser microphone (B&K 4134, Copenhagen, Denmark), connected to an amplifier (B&K 2609, Copenhagen, Denmark).

Efficiency of sound production, noise-to-harmonics ratio

The sound quality of the prototype was further quantified by the calculation of the efficiency of sound-production, and the noise-to-harmonics ratio.

The acoustic efficiency was calculated as the ratio of acoustic power to the power provided to produce the sound.

Clinical trial

Finally, the prototypes were evaluated in a clinical trial [17]. In 17 female laryngectomized patients a voice-producing element was placed inside the TE shunt valve. The new voice obtained in this way was compared with the patient's regular TE shunt voice.

An aerodynamic and acoustical analysis was performed, the maximum phonation time, speech rate and intonation capability determined. Finally the voice was perceptual evaluated.

Results

In-vitro results

The airflow rate increased approximately linear with an increase in 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 could be reached easily. Within this pressure range the prototypes functioned normal, and the corresponding average airflow range was 27 - 100 ml/s. The measured *F0* range was about 190 - 350 Hz, which involves almost 11 semitones. Harmonics were observed up to a frequency of 4 kHz. The average *SPL* range was about 57 - 81 dB(A). The noise-to-harmonics ratio lay below the threshold for a normal healthy voice.

Overall, the efficiency varied from approximately $0.6 \cdot 10^{-5}$ at 60 dB to $5.5 \cdot 10^{-5}$ at 80 dB, at a distance of 15 cm from the sound source.

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

Clinical results

Voice measurements clearly showed the increased voice pitch (f_0 was 3.5× higher on average; f_0 = 205–305 Hz), whereas the sound intensity also increased significantly for these patients (the sound pressure level, SPL, increased on average by 4 dB; SPL = 64–76 dB[A] measured at a 0.33 m distance from the mouth).

The VPE did not lead to an unacceptable increase in driving lung pressure. The flow rates were lower as compared to regular TE shunt voice for most patients, leading to significantly longer phonation times in one breath. Accumulation of mucus did not interfere with the proper functioning of the voice-producing element during the measurements.

Conclusions

The results from the in-vitro measurements were in agreement with the expectations from previous studies which involved the up-scaled models. In conclusion, the prototypes' performance was according to the stated end-user requirements, with regard to voice restoration for female laryngectomized patients.

The clinical prototype 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 under physiological conditions. By variations of the driving air pressure, several acoustic parameters can be controlled, e.g. the *F0* 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.

Especially laryngectomized patients suggestive of a severely hypotonic or atonic PE segment, having a weak and whispering TE shunt voice, can benefit from a melodious, loud and clear voice by the application of the newly developed voice source.

Acknowledgements

This study was part of Eureka project Newvoice 2614, financed by grant TSIN 1015 of Senter.

References

1. Singer MI, Blom ED: An endoscopic technique for restoration of voice after laryngectomy. Ann Otol Rhinol Laryngo **89** (1980), 529-533
2. Blood GW: Fundamental frequency and intensity measurements in laryngeal and alaryngeal speakers. J Commun Disord **17** (1984), 319-324
3. Schutte HK: The efficiency of voice production. University of Groningen, Groningen, PhD Thesis, 1980
4. 't Hart J, Collier R, Cohen A: A perceptual study of intonation: an experimental - phonetic approach to speech melody. Cambridge University Press, Cambridge, 1990
5. Cheesman AD, Knight J, McIvor J, et al.: Tracheo-oesophageal 'puncture speech'. An assessment technique for failed oesophageal speakers. J Laryngol Oto **100** (1986), 191-199
6. Hagen R, Berning K, Korn M, et al.: Stimmprothesen mit tonerzeugendem Metallzungen Element; A experimentelle und erste klinische Ergebnisse. [Voice prostheses with sound-producing metal reed element--an experimental study and initial clinical results]. Laryngorhinootologie **77** (1998), 312-321
7. Herrmann IF, Arca Recio S, Algaba J: A new concept of surgical voice restoration after total laryngectomy: The female voice. In: Herrmann IF, ed. The Second International Symposium on Laryngeal and Tracheal Reconstruction 263-266, 1996
8. de Vries MP, van der Plaats A, van der Torn M, et al.: Design and in vitro testing of a voice-producing element for laryngectomized patients. Int J Artif Organs **23** (2000),:462-472
9. van der Torn M, de Vries MP, Festen JM, et al.: Alternative voice after laryngectomy using a sound-producing voice prosthesis. Laryngoscope **111** (2001), 336-346
10. Tack JW, Verkerke GJ, van der Houwen EB, et al.: Development of a double-membrane sound generator intended for application in a voice-producing element for laryngectomized patients. Ann Biomed Eng **34** 2006, 1896-1907
11. Fletcher NH: Excitation Mechanisms in Woodwind and Brass Instruments. Acustica **43** (1979), 65-72
12. Fletcher NH: Bird song - a quantitative acoustic model. J theor Biol **135** (1988), 455-481
13. Thomson SL, Tack JW, Verkerke GJ: A numerical study of the flow-induced vibration characteristics of a voice-producing element for laryngectomized patients. J Biomech **40** (2007), 3598-606
14. Hilgers FJ, Schouwenburg PF: A new low-resistance, self-retaining prosthesis (Provox) for voice rehabilitation after total laryngectomy. Laryngoscope **100** (1990), 1202-1207
15. van der Plaats A, de Vries MP, Eerden FJM: Development of an in-vitro test set-up for evaluating a voice producing element under physiologic acoustic conditions. Ann Biomed Eng. **34** (2006), 893-900
16. Tack JW, Rakhorst G, Houwen EB van der, et al.: In-vitro evaluation of a double-membrane based voice-producing element for laryngectomized patients. Head Neck **29** (2007), 665-674
17. Tack JW, Schutte HK, Kooijman PGC, et al.: Clinical evaluation of a membrane-based voice-producing element for female laryngectomized patients. Head Neck **30** (2008), 1156-1166

Corresponding author:
GJ Verkerke
University Medical Center Groningen
A. Deusinglaan 1
9713 AV Groningen, The Netherlands
Email: g.j.verkerke@med.umcg.nl