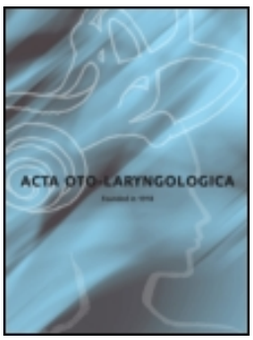

Acta Oto-Laryngologica

ISSN: 0001-6489 (Print) 1651-2251 (Online) Journal homepage: http://www.tandfonline.com/loi/ioto20

In Vivo Aerodynamic Characteristics of the Nijdam Voice Prosthesis

F. J. A. Van Den Hoogen, A. Veenstra, G. J. Verkerke, H. K. Schutte & J. J. Manni

To cite this article: F. J. A. Van Den Hoogen, A. Veenstra, G. J. Verkerke, H. K. Schutte & J. J. Manni (1997) In Vivo Aerodynamic Characteristics of the Nijdam Voice Prosthesis, Acta Oto-Laryngologica, 117:6, 897-902, DOI: 10.3109/00016489709114221

To link to this article: http://dx.doi.org/10.3109/00016489709114221

Published online: 08 Jul 2009.

Acta Otolaryngol (Stockh) 1997; 117: 897–902

In Vivo Aerodynamic Characteristics of the Nijdam Voice Prosthesis

F. J. A. VAN DEN HOOGEN,[1] A. VEENSTRA,[2] G. J. VERKERKE,[2] H. K. SCHUTTE[3] and J. J. MANNI[4]

From the [1]Department of Otorhinolaryngology, Head and Neck Surgery, University Hospital Nijmegen, [2]Centre for Biomedical Technology, University of Groningen, [3]Voice Research Laboratory, Department of Medical Physiology, University of Groningen, and [4]Department of Otorhinolaryngology, Head and Neck Surgery, University Hospital Maastricht, The Netherlands

Van den Hoogen FJA, Veenstra A, Verkerke GJ, Schutte HK, Manni JJ. *In vivo aerodynamic characteristics of the Nijdam voice prosthesis.* Acta Otolaryngol (Stockh) 1997; 117: 897–902.

The Nijdam voice prosthesis is an indwelling valveless voice prosthesis for postlaryngectomy voice rehabilitation. The *in vitro* aerodynamic characteristics are reported to be comparable to that of the low-resistance Groningen voice prosthesis. Owing to the design of the prosthesis the airflow resistance depends on the shaft length of the voice prosthesis in relation to the thickness of the tracheo-oesophageal wall. As tissue characteristics of the patient's oesophageal mucosa could also be of importance, an *in vivo* study was found necessary. To assess *in vivo* characteristics the following parameters were recorded in 10 patients: intratracheal pressure, intraoesophageal pressure and airflow during phonation. At an airflow of 0.15 l/sec the transdevice pressure loss varied from 0.5 up to 7 kPa (mean 3.9 kPa). With an artificial increase of the tracheo-oesophageal wall thickness, transdevice pressure losses up to 13 kPa were found. Significant interindividual as well as intraindividual differences were noted. The airflow resistance of the Nijdam voice prosthesis in relation to the thickness of the tracheo-oesophageal wall was compared with the airflow resistance reported for various other voice prostheses. The *in vivo* aerodynamic characteristics of the Nijdam voice prosthesis found in this study indicate the need to modify the present design in order to improve its airflow resistance and to eliminate the influence of the thickness and tissue characteristics of the tracheo-oesophageal wall. *Key words: laryngectomy, voice rehabilitation, Nijdam voice prosthesis, aerodynamic characteristics, in vivo measurements.*

INTRODUCTION

The concept of voice prosthesis (VP)-assisted tracheo-oesophageal speech is well known and highly successful in rehabilitating the majority of laryngectomized patients (1–3). Since the introduction of a commercially available VP by Blom & Singer in 1979 (4) several other devices have been brought to our attention (5–7). With the presentation of the low-resistance Provox VP (7) the importance of a low airflow resistance again was stressed. Most leading devices (8–10) have been adapted in order to achieve more favourable aerodynamic characteristics. At present an acceptable prosthesis should be an indwelling low-resistance device as this combines a low complication rate with an optimum chance for effortless and fluent speech.

The Nijdam VP is a valveless voice prosthesis that became commercially available in 1990, and has recently been officially described in the literature (11). We have been using the Nijdam VP since its introduction and have compared it prospectively with the Groningen VP and Provox VP (12, 13).

The aerodynamic characteristics of the Nijdam VP have been a point of discussion because, theoretically, the opening pressure could be unpredictable owing to the design of the valve mechanism, the shaft length of the VP, the thickness of the tracheo-oesophageal wall (TOW) and the pliability of the patient's oesophageal mucosa. As the valveless Nijdam VP forms a barrier mechanism with the oesphageal mucosa the aerodynamic characteristics can only be acccurately defined in a model simulating the *in vivo* situation or in an *in vivo* setting. The effect of the thickness of the TOW in relation to the shaft length of the Nijdam VP has been tested in an *in vitro* model using porcine oesophagus. Aerodynamic characteristics of the Nijdam VP were reported to be comparable to those of the low-resistance Groningen VP (14). Recent biomechanical studies on the Nijdam VP have shown that with increasing intratracheal pressure a tracheo-oesophageal opening is created not only by deflection of the oesophageal flange of the Nijdam VP, but also by deformation of the oesophageal mucosa (15). This suggests that tissue characteristics of the oesophageal mucosa can influence the airflow resistance of this VP. The pliability of the oesophageal mucosa might differ in laryngectomized patients because of prior surgery or radiotherapy. For this reason an *in vivo* study has been designed in addition to the study using porcine oesophagus (14). This article describes the method used and results of these *in vivo* measurements.

MATERIALS AND METHODS

The Nijdam VP

The Nijdam VP is a biflanged valveless medical-grade silicone VP with a completely new barrier mechanism. The Nijdam VP is shown schematically in Fig. 1. The inner surface of the oesophageal flange has an open connection to the lumen of the shaft and the

 ISSN 0001-6489

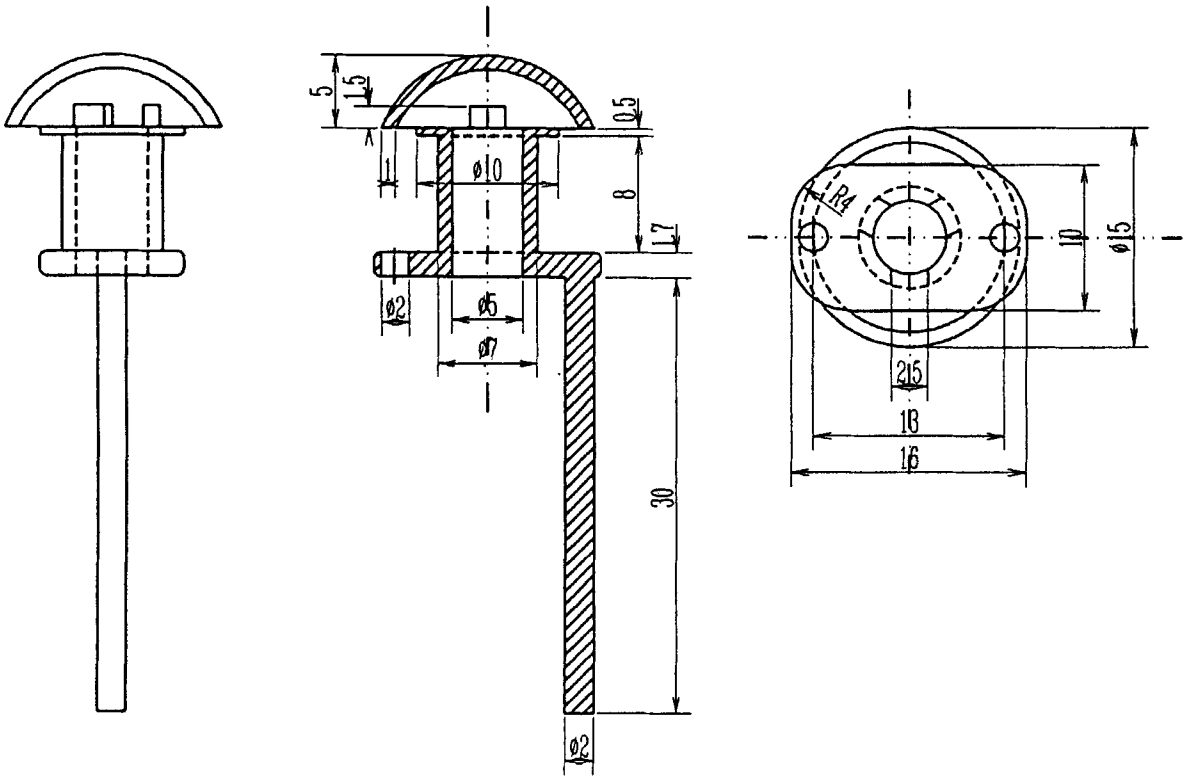

Fig. 1. Schematic drawing and dimensions (mm) of the Nijdam voice prosthesis.

tracheal opening. *In vivo* the edge of the oesophageal flange is in contact with the oesophageal mucosa and thus a barrier is formed. When phonation starts increased intratracheal pressure deforms both the oesophageal flange and the oesophageal tissue, thus opening the barrier mechanism (Fig. 2). Therefore it is important to relate the shaft length of the VP to the TOW thickness. If the prosthesis is too short it will fit too tight, causing an increase in the opening pressure. If the VP is too long leakage may occur.

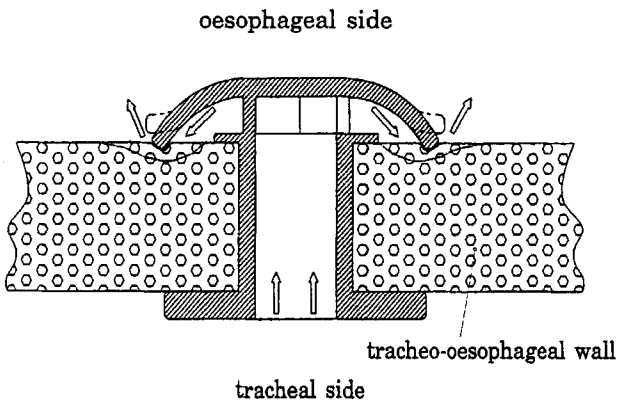

Fig. 2. The Nijdam voice prosthesis *in vivo*. The *arrows* indicate airflow during speech. The deflection of the oesophageal flange and impression of the oesophageal mucosa during speech are represented by the interrupted lines.

The Nijdam VP is available in five shaft lengths, 4–8 mm, and two shaft diameters, 7 and 8 mm. This enables adjustment to individual differences in TOW thickness and diameter of the tracheo-oesophageal fistula.

Experimental set-up

The size of the shaft length in relation to the thickness of the TOW is known to influence the transdevice pressure loss (14). In order to gain insight into this effect *in vivo*, Nijdam VPs with different shaft lengths should be tested, as the TOW thickness cannot be changed. Repeated replacements might cause oedema of the fistula region and oesophageal mucosa. This will influence the transdevice pressure loss as the oesophageal mucosa is part of the barrier mechanism of the Nijdam VP. For this reason and to minimize discomfort the *in situ* VP was replaced at the start of the experiment by a new Nijdam VP, preferably with a longer shaft length than the *in situ* VP. During the experiment the shaft length of the VP in relation to the thickness of the TOW was altered by placing a 1, 2 or 3 mm thick silicone disk between the tracheal flange of the VP and the posterior tracheal wall (Fig. 3). In this way the effect of four different shaft lengths (or TOW thicknesses) on the transdevice pressure loss could be evaluated with only one VP replacement in each participating patient.

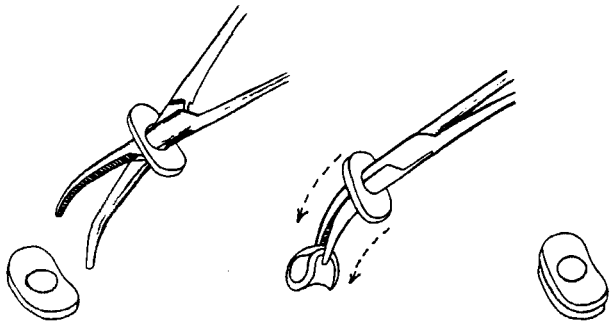

Fig. 3. Placement of a silicone disk between tracheal flange and tracheal mucosa. A forceps is fed through the silicone disk (*left*). The tracheal flange of the *in situ* voice prosthesis is grasped and folded with the aid of the forceps (*middle*), and the silicone disk is pushed over the tracheal flange (*right*).

The intraoesophageal pressure was measured with a 5F Miller microtip pressure transducer (model 350, serial no. 2394, Miller Instruments) inserted through the nose. The microtip was located at the level of the oesophageal flange of the VP, which was approximately 25 cm from the nostril. The location was checked endoscopically and adjusted if necessary. A thin catheter tube was inserted into the tracheostoma and taped to the skin surrounding the stoma. During phonation it was kept in place by the finger occluding the stoma. The catheter was connected to the pressure transducer in the Aerophone mask, designed to measure intraoral pressure, now measuring the intratracheal pressure. Transdevice pressure loss was obtained from a custom-made electronic subtractor by subtracting the momentary values of the intraoesophageal pressure from the momentary values of the intratracheal pressure. The intratracheal pressure transducer and the face mask containing a flow transducer were connected to the Aerophone II system (AP2) (Aerophone II system, model 6800, Kay Elemetrics Corp., USA). The AP2 system was connected to a 486 DX IBM compatable portable computer. An eight-channel writer (type MT 9500 Recorder Astromed), was set at a paperspeed of 5 mm/sec and connected to an intratracheal and intraoesophageal pressure transducer and an electronic subtractor. The intratracheal pressure transducer was used to trigger both the AP2 and the MT 9500 system. The experimental set-up is shown in Fig. 4.

The following *in vivo* parameters were recorded: (i) intratracheal pressure during phonation; (ii) intraoesophageal pressure, at the level of the oesophageal flange of the VP, during phonation; (iii) transdevice pressure loss: calculated by subtracting (ii) from (i); and (iv) airflow during phonation. Before each experiment the complete system was calibrated against a water manometer and a known airflow rate.

Patients

Ten laryngectomized patients, considered to be successful tracheo-oesophageal speakers (2, 13), were selected and invited to participate in the experiment. They were fully informed about the experiment and were free to refuse participation without reason or consequences. Oral consent was obtained from all patients and travel expenses were compensated for.

The *in situ* VP were removed under topical anaesthesia and replaced by a Nijdam VP with a longer shaft length. The patient was asked to swallow some water in order to check for leakage. The intratracheal and intraoesophageal pressure transducers were inserted and fixed. The patient was instructed how to use the face mask with one hand and occlude the tracheostoma with the other. He was allowed to practise a few times while checking for air leakage.

The new VP was inserted approximately half an hour before the actual experiment started in order to let the VP adjust to body temperature and become moist.

The patient was instructed to place the mask airtight to his face, covering the mouth and nose. After leakage of air was checked, the patient was asked to produce a sustained vowel /a/ at a soft, normal and loud sound pressure level. This was done twice. After insertion of a 1, 2 or 3 mm silicone disk the complete procedure was repeated. Leakage of the VP was checked for all instances before each recording. The first leak-proof situation was called TOW increase zero (TOW 0). This corresponds to a situation where the shaft length of the VP and the TOW thickness are approximately equal.

After the experiment a new properly sized Nijdam VP was inserted.

RESULTS

Two patients were using a 10 mm Provox VP before the experiment. One of them could not pass air with the largest available Nijdam VP (8 mm) owing to the thickness of his tracheo-oesophageal wall. As no recordings could be made, he was excluded from the study. Data obtained from the second patient are discussed below

Fig. 5 shows the typical results of the experiment in one patient. The transdevice air-pressure loss for TOW increase of 0, 1, 2 or 3 mm in relation to airflow is depicted. Addition of a 1 mm disk did not cause an increase of transdevice pressure loss, thus confirming that the first measurement was taken with a VP with a shaft length that was too long. Adding a 2 or 3 mm silicone disk increased transdevice pressure loss.

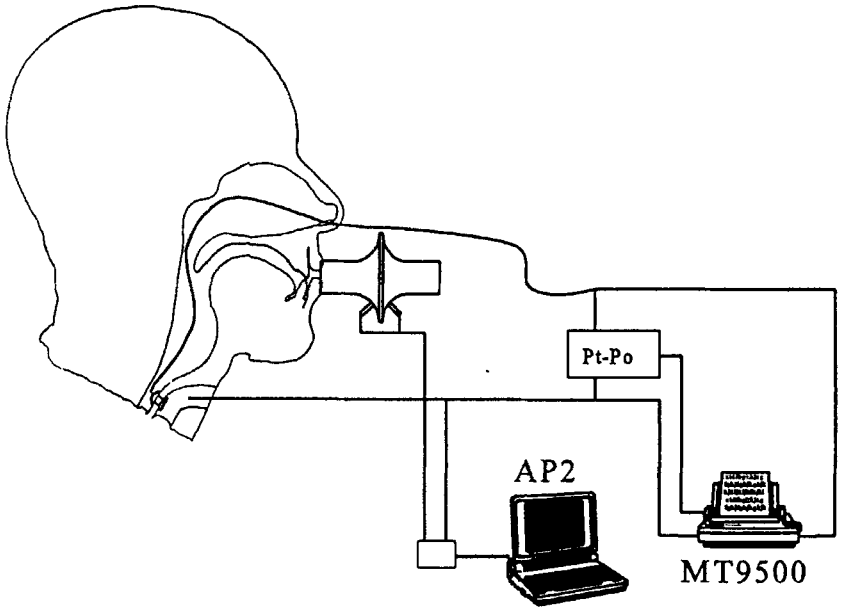

Fig. 4. Arrangement of apparatus used for *in vivo* measurements.

The transdevice pressure loss, at an airflow of 0.15 l/sec (10), as a function of increase of TOW thickness in nine patients is shown in Fig. 6. TOW increase 0 mm reflects the first leak-proof situation during the experiment. If the first leak-proof situation occurred with a 1 mm silicone disk, only TOW increases 0, 1 and 2 mm were reflected (Fig. 6). The mean transdevice pressure loss for TOW increase of 0, 1 and 2 mm was 2.7 kPa, 3.9 kPa and 6.2 kPa, respectively, with SD of 2.1 kPa, 2.0 kPa and 1.9 kPa, respectively.

The line at the top represents the second patient previously fitted with a Provox VP with a shaft length of 10 mm. A Nijdam 8 mm VP (TOW increase 0 mm) was known to be too small for this patient. Adding silicone disks led to very high pressures. Transdevice pressure loss ranged from 6.5 kPa to almost 13 kPa. The results of the *in vitro* study (14) are also shown in Fig. 6. They compare favourably to the *in vivo* results.

Fig. 7 shows the *in vivo* transdevice pressure loss (kPa) against airflow (l/sec) for the Nijdam VP with TOW increase of 0, 1 and 2 mm. Also incorporated in this figure are the values for the Provox VP, low-resistance Groningen VP and the Blom–Singer low-resistance VP that have been reported previously (10).

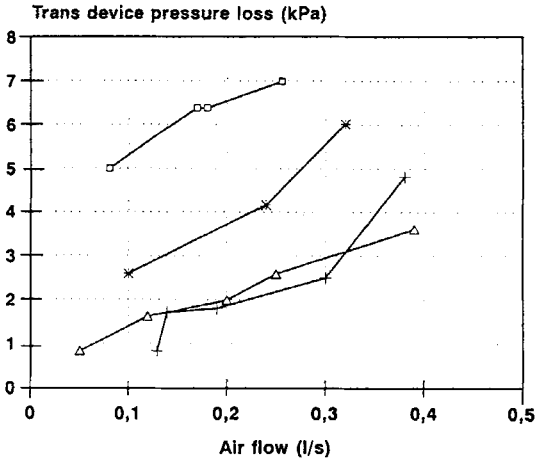

Fig. 5. Example of transdevice pressure loss against airflow in one patient with a Nijdam VP showing the effect of the addition of a (△) 0 mm, (+) 1 mm, (*) 2 mm, or (□) 3 mm silicone disk.

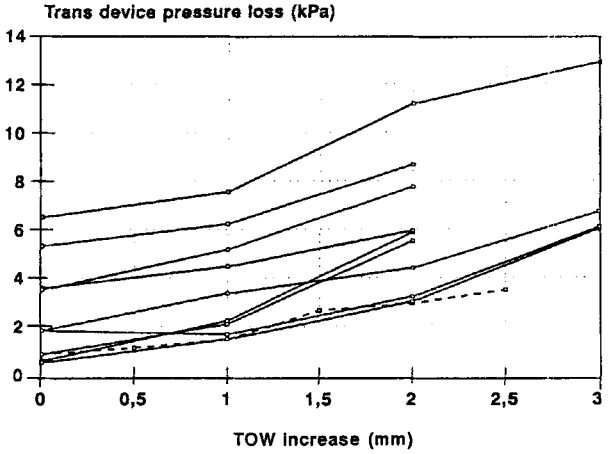

Fig. 6. Transdevice pressure loss against tracheo-oesophageal wall increase for an airflow of 0.15 l/sec for all included patients. Also shown are the results of the *in vitro* measurements reported previously (*dashed line*).

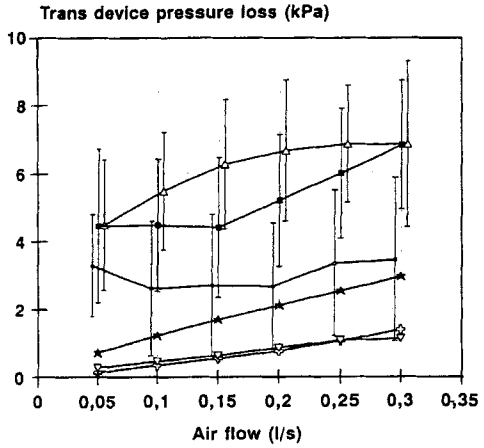

Fig. 7. Mean transdevice pressure loss against airflow for TOW increases of (□) 0 mm, (▨) 1 mm, and (△) 2 mm. *Vertical bars* indicate standard deviations. Comparable values of the low-resistance (☆) Groningen, (▽) Provox and (◇) the Blom–Singer low-resistance voice prostheses. *Vertical lines* indicate SD.

DISCUSSION

The Nijdam VP is a valveless VP that forms a barrier in combination with the oesophageal mucosa. As it is a self-retaining, biflanged VP, the pressure of the oesophageal flange on the mucosa, which in part determines the airflow resistance of this VP, depends on the shaft length of the VP in relation to the TOW thickness. Therefore the shaft length was varied in relation to the TOW thickness during the experiment.

TOW increase 0 mm reflects the first leak-proof situation during the experiment. The question remains of whether the closure for fluids is tight enough to prevent leakage in all circumstances. Therefore the most important values are given for TOW increase 1 mm. In only two patients were test results comparable to the *in vitro* test results of the Nijdam VP measured. In the other patients transdevice pressure losses up to 7 kPa were found under no-leakage conditions. With increasing TOW thickness even higher values, up to 13 kPa, occurred. One patient, previously fitted with a VP with a 10 mm shaft length, was unable to produce a sound with the Nijdam VP.

From these data it can be concluded that, first, the range of shaft lengths presently available is not sufficient to meet individual variations in TOW thickness. Secondly, the *in vivo* aerodynamic characteristics of the Nijdam VP differ essentially and unfavourably from *in vitro* data (14). This is possibly related to the fact that the oesophageal tissue, which plays a role in the barrier mechanism, has unfavourable characteristics in our patients owing to previous irradiation and/or operation.

Furthermore, although the transdevice pressure loss in several patients is within a low-resistance range, the interindividual and intraindividual variation is not acceptable. The risk of a significant increase in transdevice pressure loss with a wrongly sized shaft length seems to be unavoidable in the absence of a measurement instrument for TOW thickness, especially in unexperienced hands. The absence of such a device might also lead to repeated replacements for testing the proper fit.

The Nijdam VP has an innovative design (11) and a new barrier mechanism, but the *in vivo* aerodynamic characteristics of the Nijdam VP are of such nature that further investigations to adapt the design in order to lower the resistance of the Nijdam VP are obligatory.

ACKNOWLEDGEMENTS

F. J. H. Hilgers MD PhD is acknowledged for supplying some of the data necessary to produce Fig. 7. A. Dik was king enough to draw Fig. 3.

REFERENCES

1. Singer MI, Blom ED, Hamaker RC. Further experience with voice restoration after total laryngectomy. Ann Otol Rhinol Laryngol 1981; 90: 498–502.
2. Manni JJ, van den Broek P, de Groot MAH. Voice rehabilitation after laryngectomy with the Groningen prosthesis. J Otolaryngol 1984; 13: 333–6.
3. Hilgers FJM, Balm AJM. Long term results of vocal rehabilitation after total laryngectomy with the low-resistance, indwelling Provox voice prosthesis system. Clin Otolaryngol 1993; 18: 517–23.
4. Blom ED, Singer MI. Surgical-prosthetic approaches for postlaryngectomy voice restoration. In: Keith RL, Darly FL, eds. Laryngectomee rehabilitation. Houston, TX: College-Hill Press, 1979: 251–76
5. Panje WR. Prosthetic vocal rehabilitation following laryngectomy. The voice button. Ann Otol Rhinol Laryngol 1981; 90: 116–20.
6. Nijdam HF, Annyas AA, Schutte HK, Leever H. A new prosthesis for voice rehabilitation after laryngectomy. Arch Otolaryngol 1982; 237: 27–33.
7. Hilgers FJM, Schouwenburg PF. A new low-resistance, self-retaining prosthesis (Provox) for voice rehabilitation after total laryngectomy. Laryngoscope 1990; 100: 1020–7.
8. Smith BE. Aerodynamic characteristics of Blom–Singer low-pressure voice prostheses. Arch Otolaryngol 1986; 112: 50–2.
9. Zijlstra RJ, Mahieu HF, van Lith-Bijl JT, Schutte HK. Aerodynamic properties of the low-resistance Groningen button. Arch Otolaryngol Head Neck Surg 1991; 117: 657–61.
10. Hilgers FJM, Cornelissen MW, Balm AJM. Aerodynamic charactheristics of the Provox low-resistance indwelling voice prothesis. Eur Arch Oto-Rhino-Laryngol 1993; 250: 375–8.
11. Van den Hoogen FJA, Nijdam HF, Veenstra A, Manni JJ. The Nijdam voice prosthesis. A self-retaining valveless voice prosthesis for vocal rehabilitation after total laryngectomy. Acta Otolaryngol (Stockh) 1996; 116: 913–7.

12. Van den Hoogen FJA, Oudes M, Nijdam HF, Manni JJ. The Groningen, Nijdam and Provox voice prostheses: A prospective clinical comparison based on 845 replacements. Acta Otolaryngol (Stockh) 1996; 116: 119–24.
13. Van den Hoogen FJA, van den Berg RJH, Oudes MJ, Manni JJ. A prospective study of speech and voice rehabilitation after total laryngectomy with the low-resistance Groningen, Nijdam and Provox voice prostheses. J Speech Hear Res (submitted).
14. Veenstra A, van den Hoogen FJA, Verkerke B, Schutte H, Nijdam HF, Manni JJ. Aerodynamics characteristics of the Nijdam voice prosthesis in relation to the tracheo-esophageal wall thickness. Eur Arch Oto-Rhino-Laryngology 1997; 254: 1–5.
15. Verkerke GJ, de Vries MP, Schutte HK, van den Hoogen FJA, Rakhorst G. Finite element study of the Nijdam voice prosthesis. In: Algaba J, ed. Surgery and prosthetic voice restoration after total and subtotal laryngectomy. Amsterdam: Elsevier, 1996; 199–201.

Submitted October 30, 1996; accepted January 20, 1997

Address for correspondence:
F. J. A. van den Hoogen, MD
Department of Otorhinolaryngology
Head and Neck Surgery
University Hospital Nijmegen
P.O. Box 9101
NL-6500 HB Nijmegen
The Netherlands
Tel: +31 24 361 4450
Fax: +31 24 354 0251