Eur Arch Otorhinolaryngol (1997) 254: 1–5

ORIGINAL PAPER

A. Veenstra · F. J. A. van den Hoogen · H. K. Schutte
H. F. Nijdam · J. J. Manni · G. J. Verkerke

Aerodynamic characteristics of the Nijdam voice prosthesis in relation to tracheo-esophageal wall thickness

Received: 6 July 1995 / Accepted: 10 April 1996

Abstract Tracheo-esophageal speech using various prostheses is currently the most successful form of voice and speech rehabilitation for laryngectomees. Main inter-device differences are durability and trans-device pressure loss during speech. The valveless indwelling Nijdam voice prosthesis is a new voice prosthesis. A barrier mechanism is created by a combination of the esophageal mucosa and the umbrella-like "hat" of the prosthesis that covers the esophageal side of the tracheo-esophageal fistula. The Nijdam prosthesis can be used clinically for longer periods of time when compared to such other indwelling voice prostheses as the Provox prosthesis and the low-resistance Groningen prosthesis. However, trans-device pressure loss during speech has been unknown. Adjustment of the shaft length of the Nijdam voice prosthesis to tracheo-esophageal wall thickness was expected to affect trans-device pressure loss during speech. We report the results of in vitro tests to quantify the effect of tracheo-esophageal wall thickness on trans-device pressure loss. In the present study pressure loss was measured at different air flow rates in relation to tracheo-esophageal wall thickness. Findings demonstrated that when shaft length of the Nijdam prosthesis corresponded exactly to tracheo-esophageal wall thickness, trans-device pressure loss was comparable to that of the Provox prosthesis. If a relatively shorter Nijdam prosthesis was chosen to prevent aspiration from occurring, the pressure loss across the prosthesis increased to that of the low-resistance Groningen prosthesis.

Key words Nijdam voice prosthesis · Total laryngectomy · Voice rehabilitation · Aerodynamics

G. J. Verkerke (✉) · A. Veenstra
Centre for Biomedical Technology, University of Groningen, Bloemsingel 10, 9712 KZ Groningen, The Netherlands

H. K. Schutte
Department of Medical Physiology, University of Groningen, Groningen, The Netherlands

F. J. A. van den Hoogen
Department of Otorhinolaryngology, University Hospital, Nijmegen, The Netherlands

J. J. Manni
Department of Otorhinolaryngology, University Hospital, Maastricht, The Netherlands

H. F. Nijdam
Department of Otorhinolaryngology, Westfries Gasthuis, Hoorn, The Netherlands

Introduction

Voice prostheses (VPs) have now been employed over the last 16 years to restore speech after total laryngectomy. The first commercially available prosthesis was developed by Blom and Singer [1] in 1979. VPs are inserted in a surgically created fistula in the tracheo-esophageal wall (TEW). At initiation of voice, the tracheostoma has to be occluded manually or by means of a valve [2]. Expiratory air then flows into the esophagus to activate the pharyngo-esophageal (PE) segment.

Two types of VPs can be distinguished: i.e. non-indwelling and indwelling devices. The former device can be replaced by the patient; the latter remains in place until the end of its clinical usefulness, which is generally indicated by either leakage or increased air flow resistance. The indwelling VP then requires replacement as an outpatient clinic procedure.

The indwelling Nijdam VP is produced and distributed by Medin Instruments (Groningen, The Netherlands) and has been used clinically in the ENT Department of the University Hospital Nijmegen (The Netherlands) since 1988 [5]. This VP differs from other indwelling devices [3, 8] by its unique valveless construction. Its barrier mechanism is created by an umbrella-like silicone "hat" that covers the tracheo-esophageal (TE) fistula on the esophageal side.

It was expected that the shaft length of the Nijdam VP would influence tension between the hat and the esophageal mucous membrane. The trans-device pressure loss during speech would therefore be influenced by adjustment of the shaft length of the VP to TEW thickness. In this study we have examined the influence of TEW thickness on the trans-device pressure loss at physiological air flow. In vitro measurements were performed with a measuring set-up and a dummy TEW that permitted simulated changes in mucosal wall thickness and different air flow rates.

Materials and methods

The Nijdam VP

The Nijdam VP is shown schematically in Fig. 1. The VP consists of a tracheal flange and a smaller esophageal flange that are connected by a shaft. On top, a hat is connected to the esophageal flange by three small columns. The prosthesis is made from medical-grade silicone rubber and is molded in one piece. Five shaft lengths are available, varying from 4 to 8 mm, while shaft diameters are either 7 mm or 8 mm. These differences allow the VP to be used under conditions of different TEW thicknesses and fistula diameters. The barrier mechanism of the prosthesis results from increased tracheal pressure on attempted phonation causing deformation of both the hat and esophageal tissue, so that expired air can flow from the trachea through the shaft into the esophagus (Fig. 2).

Experimental studies

The experimental set-up used is illustrated in Fig. 3 and consisted of a housing in which a Nijdam VP was placed. To reproduce the interaction of the hat of the VP with the esophageal tissue, a part of the esophagus of a pig was used that consisted of both mucosal and muscular layers. Experiments were performed within 2 h after sacrificing the pig to maintain tissue freshness as much as possible. Plastic disks were also used to increase the thickness of the TEW to simulate a relatively small VP inserted in the TEW. The housing was equipped with a pressure and flow transducer (Aerophone II system, model 6800, KAY Elemetrics Corp, Pine Brook, N.J., USA) which was connected to a computer. All data were stored on disk. A 4 cm^2 piece of porcine esophagus was pierced with a scalpel. A Nijdam VP with a shaft length exceeding TEW thickness was inserted in the perforation. Both parts were placed into the test housing and a water level of 2 cm was placed above the VP hat to check for possible leakage. If necessary, leakage was controlled by assembling the two halves of one or more plastic disks underneath the esophageal specimen (Fig. 3). The corresponding artificial TEW thickness was used as reference thickness (TEW_{ref}).

Measurements were carried out for increasing TEW thicknesses using plastic disks of 0.5 mm thickness until a maximal increase of 2.5 mm was reached. Human expiratory air was blown through the device at various flow rates, increasing from about 0.05 l/s to 0.5 l/s. Each flow rate was kept constant for a few seconds. The trans-device pressure loss was then measured for each

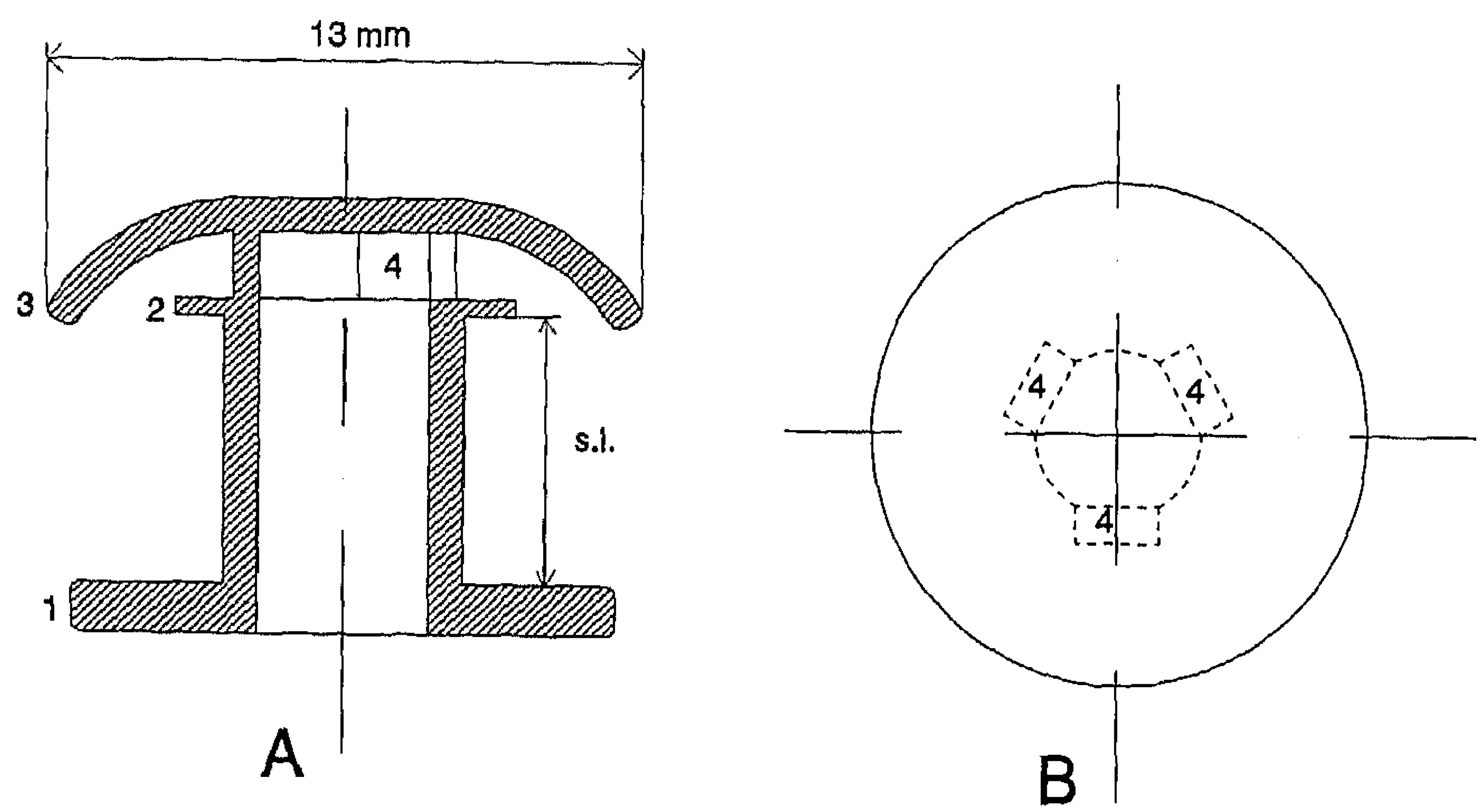

Fig. 1 A, B Schematic representation of the Nijdam voice prosthesis (VP). **A** Cross section, **B** top view, with the *dotted lines* marking the prosthesis columns (*1* tracheal flange, *2* esophageal flange, *3* umbrella-like "hat", *4* column, *s.l.* shaft length)

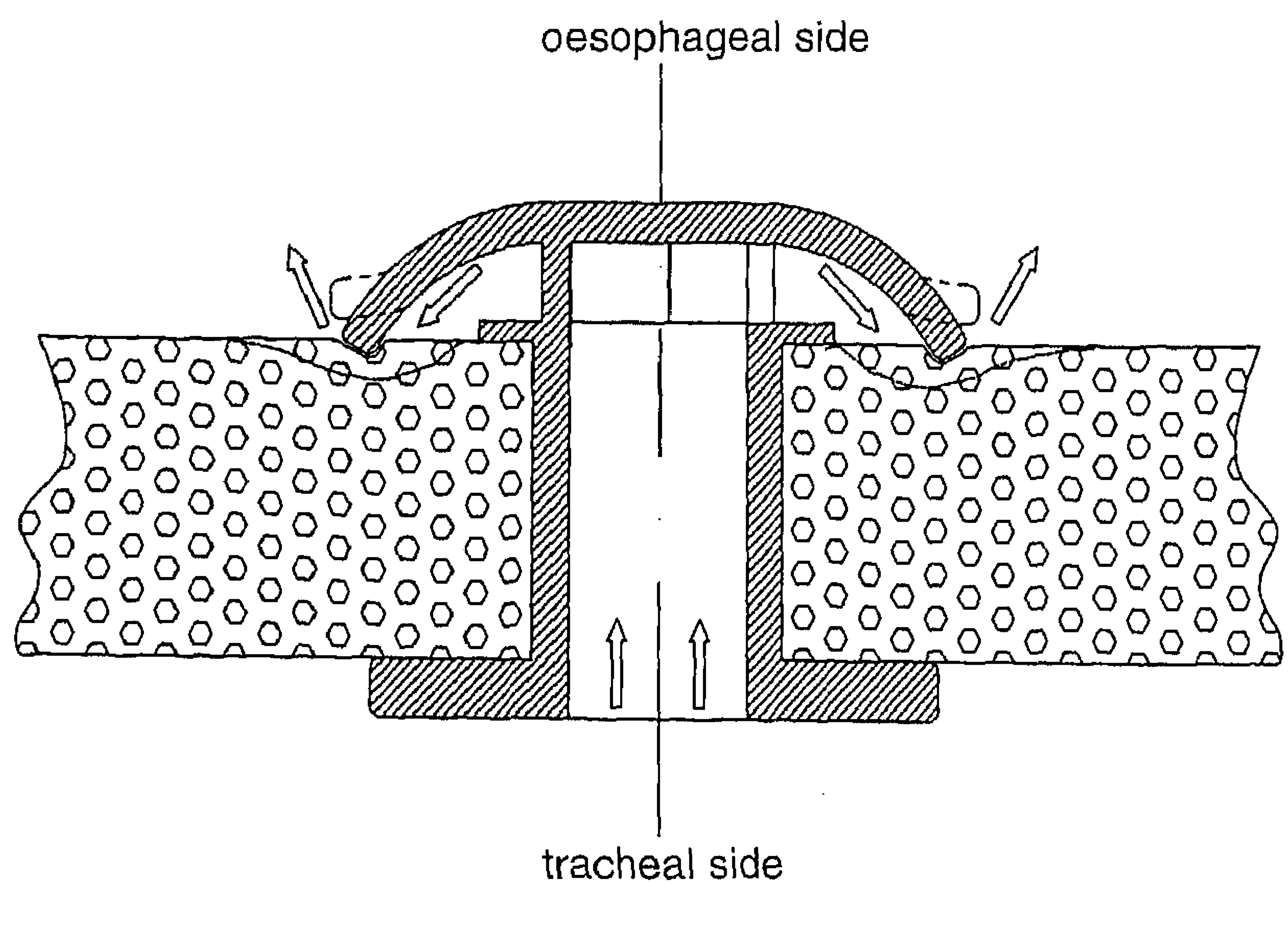

Fig. 2 Nijdam VP in situ. At rest the umbrella-like hat deforms the esophageal mucosa. During phonation deformation of the hat and the mucosa is shown by the *dotted lines*. *Arrows* indicate the direction of air flow during phonation

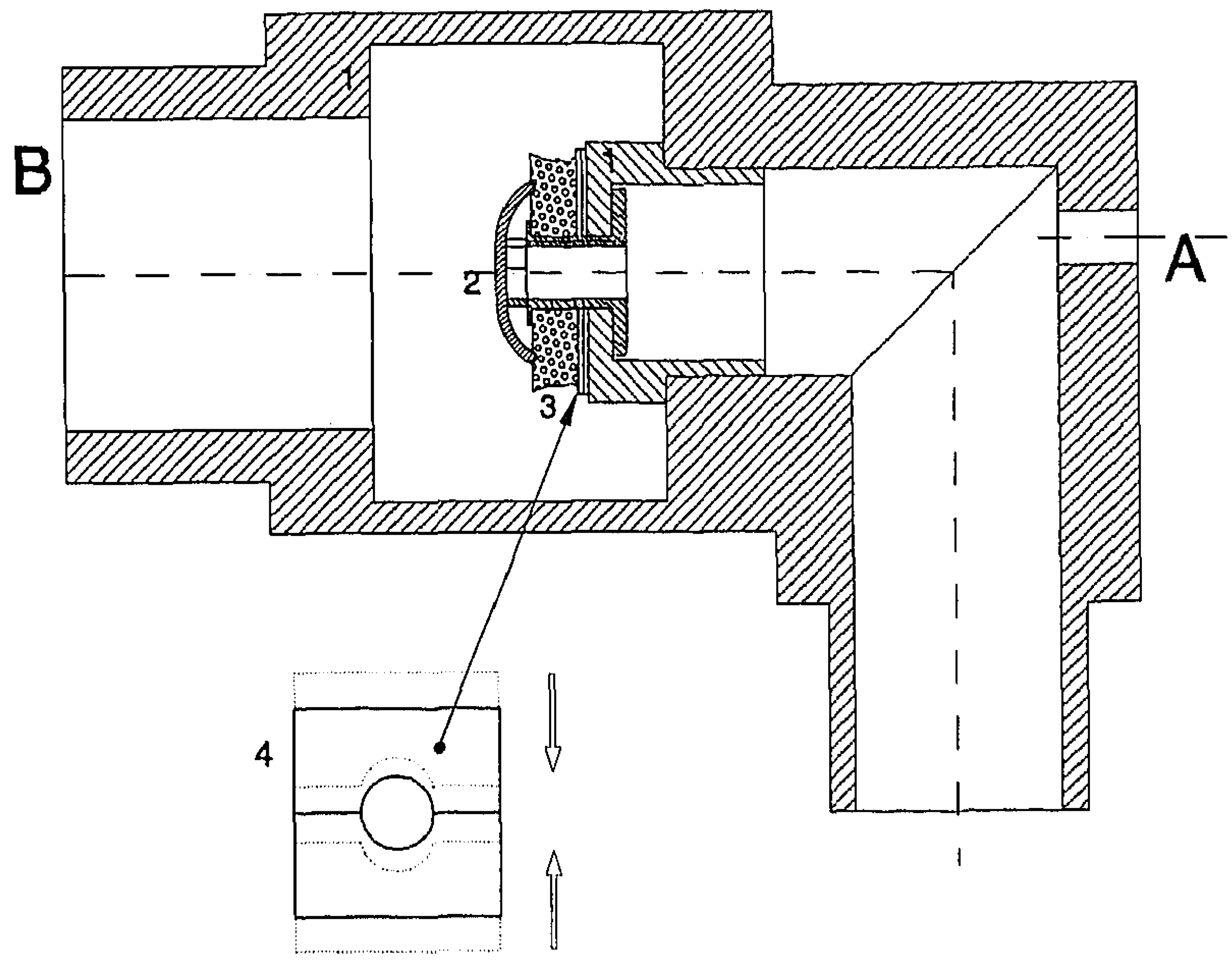

Fig. 3 Experimental setting for testing with connections to the pressure transducer (**A**) and the flow head (**B**) (*1* housing, *2* Nijdam VP, *3* porcine esophagus, *4* plastic disks 0.5 mm thick

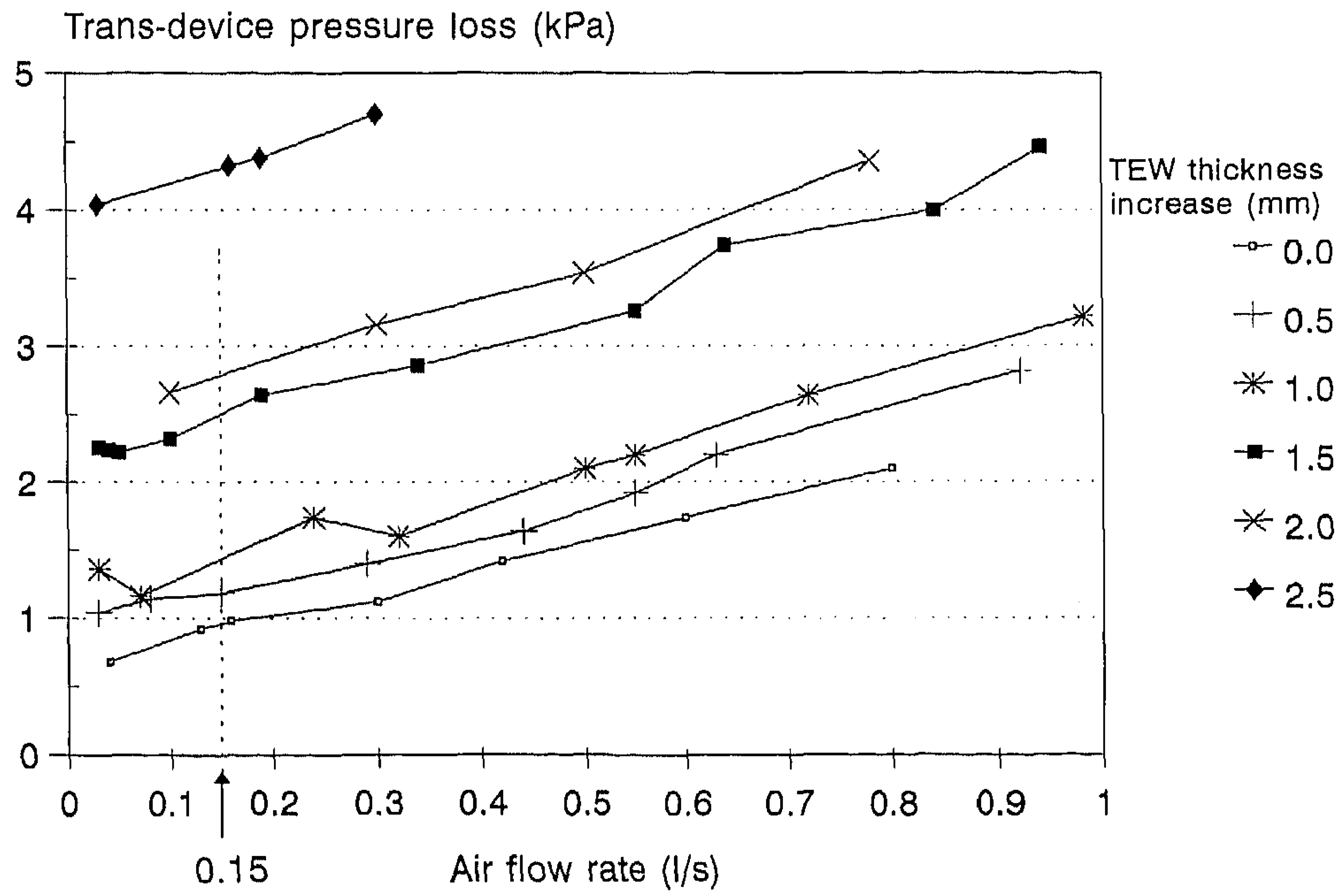

Fig. 4 Trans-device pressure loss versus air flow rate in one experiment. The thickness of the tracheo-esophageal wall (TEW) is increased five times by using 0.5-mm-thick plastic disks

flow rate at various TEW thickness rates and recorded as an X-Y graph. The effect of the TEW thickness increase on the trans-device pressure loss was then studied at a flow of 0.15 l/s, the average conversational flow of TE speakers. The corresponding trans-device pressure loss was obtained by linear interpolation.

Air flow measurements were carried out on three Nijdam VPs, each time using a fresh piece of porcine esophagus. All results were compared to previously published results of the standard Groningen VP, the low-resistance Groningen VP [6] and the Provox VP [3].

Results

Trans-device air pressures losses of one representative experiment are plotted against flow rates for different TEW thicknesses in Fig. 4. The effect of increasing TEW thickness on trans-device air pressure loss at physiological air flow (0.15 l/s) is depicted in Fig. 5. The mean of three experiments and maximal variation is given. Also, trans-device air pressure loss for an air flow of 0.15 l/s of the standard Groningen VP [3], the low-resistance Groningen VP [3] and the Provox VP [3] is shown.

The first leakage-proof situation (TEW_{ref}) showed a mean pressure difference of 0.86 kPa (at a flow rate of 0.15 l/s) and was comparable to that of the Provox VP (0.67 kPa). When the TEW thickness was increased, the mean pressure difference increased from 1.1 kPa ($TEW_{ref+0.5}$) to 1.5 kPa ($TEW_{ref+1.0}$). The pressure loss of 1.5 kPa ($TEW_{ref+1.0}$) was comparable to that of the low-resistance Groningen VP (1.68 kPa). Further enlargement of TEW thickness caused a mean trans-device pressure

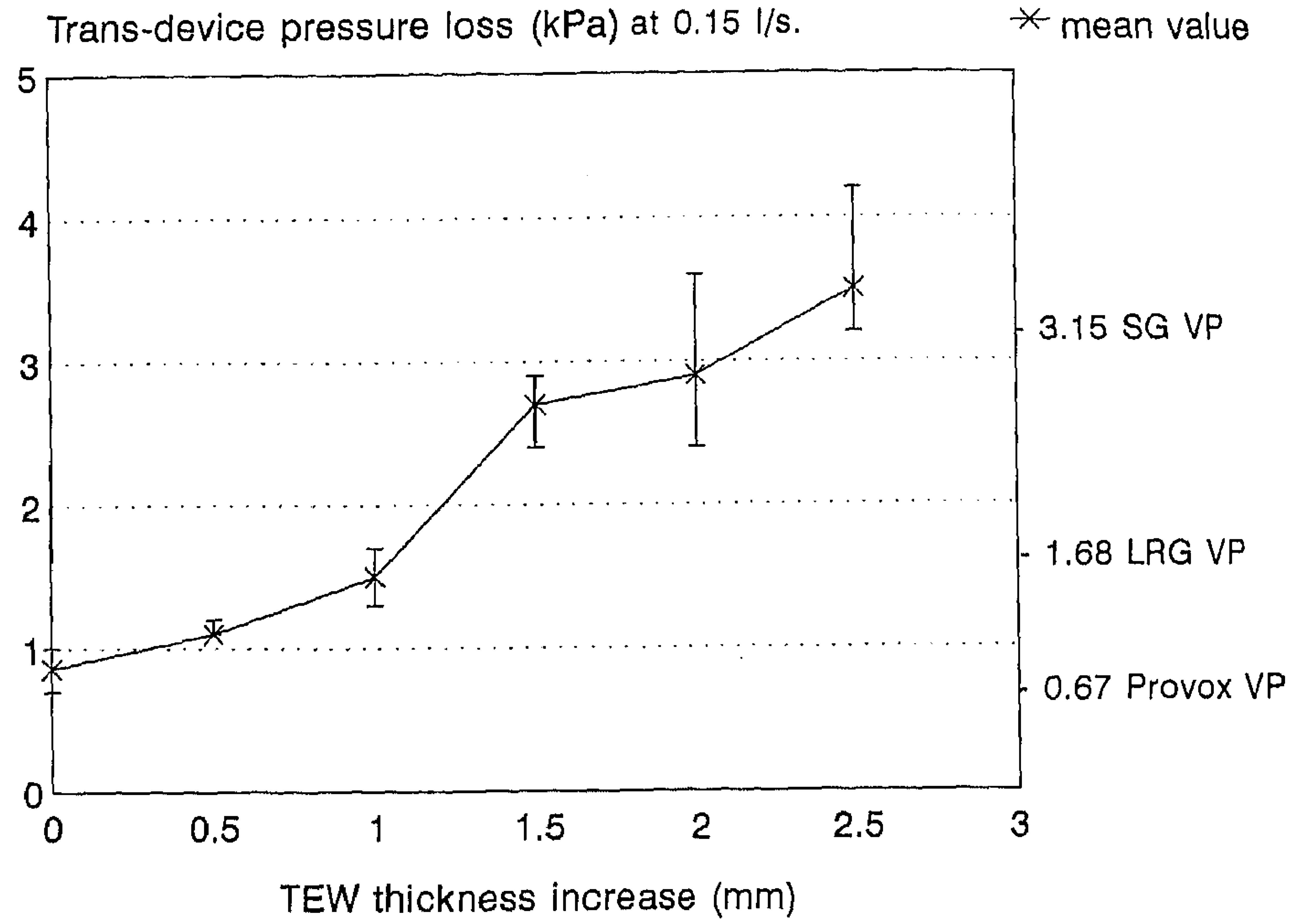

Fig. 5 Trans-device pressure loss at a physiological air flow rate of 0.15 l/s related to TEW thickness increase. Trans-device air pressure loss is shown at an air flow rate of 0.15 l/s in the standard Groningen VP (*SG VP*), low-resistance Groningen VP (*LRG VP*) and Provox VP [3]

loss from 2.7 kPa ($TEW_{ref+1.5}$), 2.9 kPa ($TEW_{ref+2.0}$) to a maximum of 3.5 kPa ($TEW_{ref+2.5}$). The pressure difference of $TEW_{ref+2.0}$ (2.9 kPa) was comparable to that of the standard Groningen VP (3.15 kPa).

Maximum standard error in all measurements was ± 0.2 kPa. In none of the cases did leakage appear. That the relation between increase in TEW thickness and increase in trans-device pressure loss was not linear (Fig. 4) indicated an effect of the visco-elastic properties of the applied soft tissue.

Discussion

Most laryngectomized patients can regain their speech using a VP for TE speech. The VP is inserted in a surgically created TE fistula, enabling air flow from the trachea into the esophagus when the tracheostoma is occluded. This air flow causes vibration of the PE segment, which leads to phonation. The VP prevents leakage from the esophagus into the trachea and stenosis of the fistula. Although most laryngectomized patients have been very enthusiastic about rehabilitation with VPs, certain drawbacks still remain.

First, the clinical lifetime of the VP is limited, especially when contaminant organisms (such as candida or yeast) adhere to the valve [7]. This causes leakage and/or increased pressure loss, requiring replacement of the VP by a physician. This takes time and money and is unpleasant for the patient. Secondly, the high intra-tracheal pressure needed for phonation can tire certain patients. This intra-tracheal pressure is mainly caused by both the PE segment and the VP. Thus, trans-device pressure loss must be low to decrease intra-tracheal pressure.

As found clinically, device durability and in vivo air flow resistance vary. In general, the Nijdam VP can be qualified as a good VP having a mean lifetime of 19 weeks [4]. The mean lifetime of the Provox VP and the low-resistance Groningen VP is 13 and 15.8 weeks, respectively. The relatively long device lifetime of the Nijdam VP is probably due to the composition of the barrier mechanism (esophageal mucous membrane versus silicone rubber) being less disturbed by candida and yeast-induced deterioration.

When considering trans-device pressure loss it appeared that when the shaft length of the Nijdam prosthesis equalled the thickness of the TEW, the in vitro properties of the Nijdam VP during speech resembled the Provox VP characteristics. One can question whether this adjustment is possible in vivo and, if so, whether it will result in a leakage-proof situation under changing conditions, as when swallowing. However, we have also shown that when the shaft length of the Nijdam VP is decreased by 1 mm (comparable to the situation of $TEW_{ref+1.0}$), this tighter fit will still result in a very acceptable air flow resistance, resembling the low-resistance Groningen VP. Aspiration will most probably not occur in this situation.

Only when the shaft length of the Nijdam VP was 2 mm shorter ($TEW_{ref+2.0}$) compared to the first leakage-proof situation did air flow resistance rise to a level comparable to that of the standard Groningen VP, which is now considered undesirable. The shaft length of the Nijdam VP appears to be critical for the air flow resistance of the barrier mechanism. This causes intra-individual trans-device pressure loss differences during speech, which does not occur when other VPs are applied. As such, applying the proper VP size to each individual is essential for optimal functioning of the Nijdam VP. Our findings have now shown that in addition to the experience of the physician, a measuring device to measure TEW thickness before placement of a VP is helpful.

In conclusion, when the size of the Nijdam VP corresponds optimally to TEW thickness, the trans-device pressure loss of the VP during speech is comparable to the Provox VP. However, to prevent the risk of aspiration a smaller version of the Nijdam VP should be inserted. This will result in an acceptable trans-device pressure loss, which is comparable to the low-resistance Groningen VP. Inserting an even smaller Nijdam VP will result in an unacceptable pressure loss comparable to the standard Groningen VP and therefore should be avoided.

Acknowledgements This study is part of the Eureka "Artificial Larynx" project and is financially supported by a research grant (BTIP) from the Department of Economic Affairs of the Dutch Government. The physician participating in the present study was F.J.A. van den Hoogen.

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