

## Downsizing of Voice Prosthesis Diameter in Patients With Laryngectomy

### *An In Vitro Study*

Simone E. J. Eerenstein, MD; Wilko Grolman, MD, PhD; Paul F. Schouwenburg, MD, PhD

**I**n patients with laryngectomy, voice prostheses inserted into a tracheoesophageal fistula (TEF) are widely used for vocal rehabilitation. Gradual dilation of the TEF may cause bothersome leakage around voice prostheses. Prosthesis-related weight and mechanical trauma possibly exacerbate TEF dilation. If prosthesis size were to be decreased, with a concomitant decrease in prosthesis weight and diameter, dilation of the TEF would probably lessen. We performed in vitro tests to study the effects on aerodynamic prosthesis function when the prosthesis size—in particular, the inner diameter—was decreased. The effects on airflow and pressure were specifically studied in the airflow range of patients with laryngectomy. A 1-mm decrease of the regular inner prosthesis diameter from 5 mm to 4 mm showed no significant aerodynamic consequences at the average laryngectomized airflow point. Also, such a 1-mm decrease in diameter involved a prosthesis weight reduction of 18%. In view of these findings, downsizing the standard prosthetic diameter should be considered in future voice prosthesis development.

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In patients with laryngectomy, the implantation of voice prostheses is currently the vocal rehabilitation method of choice. Voice prostheses are 1-way valves inserted into a created tracheoesophageal fistula (TEF) allowing for air shunting from the lungs and trachea into the esophagus where it generates voice.<sup>1,2</sup>

Different types of voice prostheses have been developed and have come into use. These indwelling devices vary in design, insertion methods, and aerodynamics, but their diameters are compatible.<sup>1-9</sup>

Prosthesis size is defined by length and there are several lengths available. In contrast to the variations in length, the prosthetic diameter of the regularly used prosthesis types in Europe is a (relatively) constant 5 mm, and the weight averages 1 g. Although the diameter does not vary between the different lengths, it is a factor that should be taken into account when dealing with prosthesis-related TEF problems.

Two diameters should be taken into account when dealing with these devices: the inner and the outer. The inner diameter is important because it determines the aerodynamic characteristics of the prosthesis by the amount of shunted air allowed from the lungs into the pharyngoesophageal segment where it generates voice. A decrease in inner diameter at a constant phonation pressure automatically decreases the amount of shunted air, whereas the amount of shunted air can be kept at the same level if the pressure is increased. Because phonation is easier for a patient with laryngectomy when a lower pressure is needed, it is important that phonation pressures be kept totally or largely unaltered if prosthesis changes are to be made.

The outer diameter of the prosthesis is important to the TEF because the TEF normally adapts to the outer prosthesis shape. A large outer diameter will enlarge the TEF, whereas a smaller diameter will allow it to shrink. When a constant thickness of the body of the prosthesis is maintained, changes in outer diameter

*From the Department of Otolaryngology-Head and Neck Surgery, Academic Medical Center, University of Amsterdam, Amsterdam, the Netherlands.*

## MATERIALS AND METHODS

A total of 20 *in vivo* voice prostheses of the most commonly used lengths were used for the aerodynamic tests: ten 6-mm and ten 8-mm VoiceMaster prostheses (Entermed BV, Woerden, the Netherlands). All prostheses were taken directly out of their boxes and placed into our specially constructed *in vitro* measuring system. All prostheses were measured after removal of the prosthesis valve to eliminate the effects of the specific aerodynamic characteristics of the valve mechanisms.

The inner diameter of the VoiceMaster prosthesis measures 5.0 mm. Specifically made prosthesis inserts in varying diameters (3.0, 3.5, 4.0, and 4.4 mm) were inserted into the prostheses during the aerodynamic measurements. A 4.5-mm insert could not be manufactured for technical reasons (**Figure 1**). The inner diameter could thus be decreased from the current 5 mm to 4.4, 4.0, 3.5, or 3.0 mm as desired.

Aerodynamic pressure measurements were conducted by placing the prosthesis in a specially built system made up of a pressure controller, mass flow meter, pressure transducer, and a personal computer with data acquisition software.<sup>13</sup> In this system, the pressure needed to maintain a regulated airflow through the prosthesis could be measured.

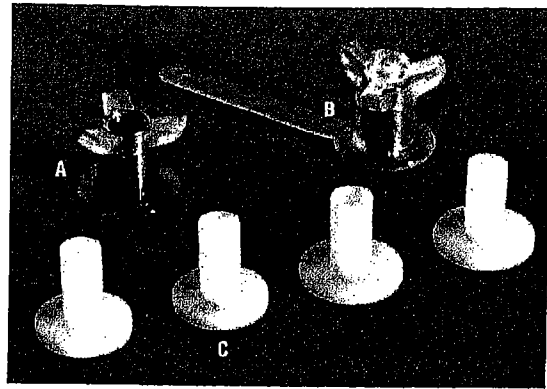
The specific characteristics of the pressure-measuring system are as follows. The pressure controller (Brooks Rosemount, Chanhassen, Minn) was used for the regulation of airflow through the prosthesis to achieve conditions similar to those in patients with laryngectomy. It regulated the airflow in a semi-sawtooth pressure pattern in 1-minute intervals. The airflow used varied from 0 to 0.35 L/s to ensure the full airflow range from 0 to the average 0.15 L/s present in patients with laryngectomy.<sup>14-18</sup>

The mass flow meter (Sierra Instruments, Monterey, Calif) measured flow independently for temperature and pressure changes. The pressure transducer (model 206; Setra Systems Inc, Acton, Mass), a differential pressure-measuring device, was used to measure the pressure drop over the prosthesis. And the personal computer ran on a Pentium 200 MHz chip with an analog-digital/digital-analog converter (National Instruments, Austin, Tex).

Our data acquisition software (Lab View 4 for Windows 95; National Instruments) was used to control the pressure controller, and thus regulate the airflow through the devices, to acquire multichannel input from the sensors, and to perform the data analyses. Each prosthesis was measured 5 times for each of the 5 available diameters after an initial 5-minute period of testing before recording the data from the sensors into the computer. Statistical analysis of the accumulated data was performed using the 2-sample *t* test with a predetermined significance level ( $\alpha$ ) of .01.

automatically involve changes in inner diameter, and vice versa.

Gradual dilation or enlargement of the TEF (into which the voice prosthesis is inserted) is one of the fre-



**Figure 1.** Laryngectomy voice prostheses: A, without valve and B, with valve. C, Prosthesis inserts of various sizes.

quently encountered problems in prosthesis use.<sup>10-12</sup> Due to the dilation of the TEF, persistent and bothersome leakage of fluids from the esophagus into the trachea occurs.<sup>10-12</sup> The peripheral leakage is often treated using temporary surgical or conservative means.<sup>10-12</sup> These solutions include measures such as temporary removal of the prosthesis, permitting the TEF to shrink, or cauterization and injection of collagen into the dilated tissue. Another option often considered in treating peripheral leakage is an increase in prosthesis diameter. However, limitations of the local anatomy at the TEF site, specifically the esophageal lumen, contraindicate a major increase in prosthesis size.

All of the currently used treatments focus on eliminating peripheral leakage, but none focus on the cause of the TEF dilation. The dilation is attributed to several factors, including previous irradiation of the tissue and mechanical fistula damage. Mechanical trauma can be caused by excessive prosthesis size and weight and also by frequent prosthesis replacements, made necessary in many cases by yeast-induced prosthesis dysfunction.<sup>10-12</sup> Currently, methods for decreasing the frequency of prosthesis replacement by diminishing yeast-related prosthetic problems are the topic of many ongoing international research projects. In contrast, we opted for an analysis of the possibility of decreasing prosthesis diameter. A smaller prosthesis diameter with a concomitant lower weight would possibly have a positive effect on TEF dilation. Changes in prosthesis diameter should also influence the aerodynamic characteristics of the device, and we therefore performed *in vitro* tests. The effects on airflow and pressure were specifically studied in the airflow range of patients with laryngectomy.

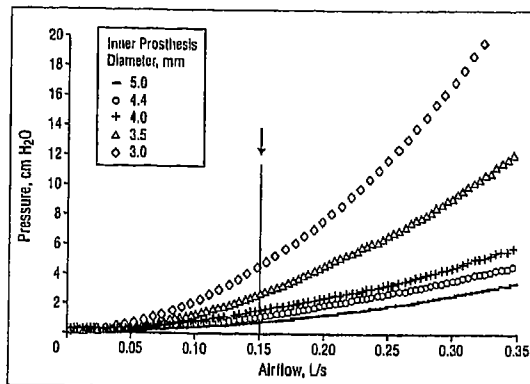
## RESULTS

To allow for comparison of our *in vitro* data with the *in vivo* situation in patients with laryngectomy, all measurements were performed in an *in vitro* system with a wide airflow range that included the average laryngectomized phonation airflow of 0.15 L/s. The results are calculated at the 0.15-L/s airflow level.

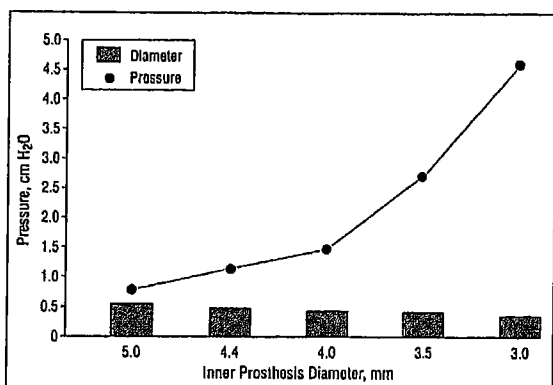
A decrease in inner diameter of the prosthesis from 5.0 through 4.4 to 4.0 mm caused a gradual increase in pressure levels. Decreasing the inner diameter even fur-

**Table 1. Average Pressure per Prosthesis Diameter at Varying Amounts of Airflow**

Airflow, L/s	Pressure at Given Prosthesis Diameter, cm H <sub>2</sub> O				
	5.0 mm	4.4 mm	4.0 mm	3.5 mm	3.0 mm
0.050	0.183	0.243	0.270	0.442	0.713
0.075	0.272	0.382	0.460	0.800	1.344
0.100	0.394	0.583	0.713	1.292	2.177
0.125	0.557	0.829	1.037	1.900	3.270
0.150	0.765	1.117	1.442	2.686	4.603
0.175	0.992	1.482	1.828	3.568	6.043
0.200	1.254	1.863	2.245	4.570	7.679
0.225	1.527	2.280	2.670	5.588	9.539
0.250	1.862	2.662	3.188	6.630	11.790
0.275	2.206	3.090	3.757	7.810	14.187
0.300	2.590	3.579	4.310	9.101	16.268
0.325	2.997	4.038	5.040	10.710	19.789



**Figure 2.** Graph illustrating measured pressure in relation to airflow for varying prosthesis diameters. The average airflow during phonation in patients with laryngectomy is 0.15 L/s (arrow).



**Figure 3.** Measured pressure at 0.15 L/s airflow. The increase in pressure after decreasing the inner prosthesis diameter from 4.0 to 3.5 mm is significant.

ther caused a marked progressive increase in pressure. This is visually demonstrated with a sharp change in the airflow-pressure curve generated when the results are plotted (**Table 1**, **Figure 2**, and **Figure 3**). The 2-sample *t* test *P* values for the differences from 5.0-mm inner prosthesis diameter were .12 for 4.4 mm; .04 for 4.0 mm; .002 for 3.5 mm; and .001 for 3.0 mm.

Statistical analysis of the results shows the visual marked change noted in the plotted airflow-pressure curves to be significant. Whereas the decrease in diameter from 5.0 to 4.4 mm did not cause a significant increase in pressure (*P* = .12), and a decrease from 5.0 to 4.0 mm caused only a slightly significant increase (*P* = .04) (with predetermined significance level of *P* = .01), a decrease from 5.0 to 3.5 mm and 5.0 to 3.0 mm resulted in substantially significant pressure increases (*P* = .002 and *P* = .001, respectively). The aerodynamic results for both groups of measured prostheses (the 6-mm and 8-mm length groups) were the same.

As our measurements for decreasing diameter were performed with the aid of prosthesis inserts with decreasing diameters inserted into a regular prosthesis, we could not measure the exact influence the changes would have on the weight of the device. However, on the as-

**Table 2. Calculation of Percentage of Weight Loss With Decreasing Diameters of the Prosthesis\***

Inner Diameter, mm	Area, mm <sup>2</sup>	% of Weight Compared With 5-mm Device	% of Weight Decrease Compared With 5-mm Device
5.0	8.60	100	...
4.4	7.69	89	11
4.0	7.07	82	18
3.5	6.28	73	27
3.0	5.49	64	36

\*All calculations were made with the assumption that the standard thickness of the prosthesis wall (difference between outer and inner diameter) is 1 mm. Formula used for calculation was  $\frac{1}{4} \times \pi \times (\text{outer diameter})^2 - \frac{1}{4} \times \pi \times (\text{inner diameter})^2$ . The percentage of weight for prostheses of decreasing diameter was calculated in comparison with the original 5-mm inner prosthesis diameter given a known standard relative weight.

sumption that a standard thickness (1 mm) of the prosthesis wall is maintained with decreasing inner diameter, it is possible to calculate the percentage of weight loss with the use of the formula  $\frac{1}{4} \times \pi \times (\text{outer diameter})^2 - \frac{1}{4} \times \pi \times (\text{inner diameter})^2$ . With this formula and a standard relative weight of any used material, the weight of any size prosthesis and the percentage of weight loss in comparison with the standard 5-mm device can be calculated. These calculations, as provided in **Table 2**, show a 4.4-mm inner diameter prosthesis to be 89% of the weight of the original 5.0-mm device. This represents a weight loss of 11%, while a decrease to a 4.0-mm inner diameter leads to a weight loss of 18%.

#### COMMENT

The results of the aerodynamic tests illustrate that a decrease in prosthesis diameter would be a viable option if TEF dilation-inducing factors such as prosthesis size and prosthesis-induced mechanical trauma were to be dealt with. We focused on the influence of a smaller diameter on the prosthesis aerodynamic characteristics. All valve mechanisms were removed from the prostheses before the measurements; the results are thus not influenced by

the specific characteristics of the VoiceMaster type and are applicable to all types of voice prostheses.

We found no difference between the 6-mm and 8-mm lengths. If aerodynamic principles are taken into account, length should influence the aerodynamics. However, given the short length of the tested prostheses (6 and 8 mm, respectively), length did not affect the results.

As illustrated in the aerodynamic tests, the decrease in prosthesis diameter influences the aerodynamic characteristics of the voice prosthesis. If the in vitro results are extrapolated to the in vivo situation in patients with laryngectomy, the altered aerodynamic prosthetic characteristics eventually lead to a necessary increase in phonation pressure. As a large airflow range was tested for all measurements, amply covering the average laryngectomized airflow used for phonation, extrapolation of our results is possible. Currently, in vivo aerodynamic measurements are being conducted in our clinic to assess the influence of diameter decrease on phonation pressure.

Although our material (ie, standard-size prostheses with inserts of decreasing diameter) does not allow for direct measurements of weight decrease, our calculations of the effect on prosthesis weight show weight decrease percentages that should not be dismissed. Given the in vitro aerodynamic results, decreasing prosthesis diameter seems a feasible option, and one wonders if it could also be technically achieved. Current technology within voice prosthesis production allows for changes in dimension, rendering a decrease in prosthesis weight and diameter a realistic possibility. Given the possible impact of a decreased diameter on TEF dilation-induced peripheral leakage, we believe decreasing initial prosthesis size should be further explored in prosthetic development.

In conclusion, TEF dilation causes bothersome leakage around voice prostheses. It is suggested that the mechanical trauma of present-day voice prostheses is a factor that contributes to this unwanted dilation. As a consequence, smaller-diameter prostheses might cause less trauma owing to a lesser weight and a smaller defect in the tracheoesophageal wall. Reduction of the outer diameter of the prosthesis demands that the inner diameter also be reduced. This in vitro study has shown that it is possible to reduce the effective inner diameter of voice prostheses to 4.0 mm without significant aerodynamic consequences within the average phonation airflow range for patients with laryngectomy. Such a decrease in diameter would lessen prosthesis weight by 18%. These findings are of importance to prosthesis development should manufacturers consider a decrease in prosthesis size.

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Corresponding author: Simone E. J. Eerenstein, MD, Department of Otolaryngology-Head and Neck Surgery, Academic Medical Center, University of Amsterdam, PO Box 22700, 1100 DE Amsterdam, the Netherlands (e-mail: S.E.Eerenstein@AMC.UVA.NL).

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