ORIGINAL ARTICLE

# INVESTIGATION OF TRACHEOESOPHAGEAL VOICE PROSTHESIS LEAKAGE PATTERNS: PATIENT'S SELF-REPORT VERSUS CLINICIAN'S CONFIRMATION

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**Abstract:** *Background.* This study investigated the patient's self-report and clinician's confirmation of tracheoesophageal voice prosthesis leakage patterns (through or around) with or without the cough reflex and whether prosthesis diameter affected the leakage route.

*Methods.* Sixty-six consecutive participants with a total of 200 patient-initiated reasons for prosthesis changes were enrolled prospectively. Patient's self-report of leakage and cough reflex were recorded prior to clinician's confirmation.

*Results.* One-hundred eight (54%) of the 200 patient-initiated reasons for prosthesis changes were leakage through or around the voice prosthesis. Leakage was unrecognized in 21 (23%) of 92 instances, even though 15 (71%) of those 21 instances exhibited a cough reflex. Clinician's confirmed leakage in 118 (59%) of 200 patient-initiated reasons for prosthesis changes. Coughing occurred significantly less with leakage around (9 [53%] of 17 instances) than that with leakage through the voice prosthesis (80 [88%] of 91 instances) ($\chi^2$ [1, $N = 108$], $p < .05$). Leakage around the voice prosthesis occurred more with 20-Fr diameter prostheses (16 [76%] of 21 instances).

*Conclusions.* Patient education is important for reliable identification of leakage for prompt prosthesis replacement. Leakage around the voice prosthesis can be minimized or avoided by initially fitting and continuing the use of smaller diameter (16 Fr) voice prostheses. ©2008 Wiley Periodicals, Inc. *Head Neck* **30:** 618–621, 2008

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Clinicians have long recognized that the increase from 16- to 20-Fr (and larger) diameter tracheoesophageal voice prostheses has not been without consequences. Specifically, leakage rate around the first generation 16-Fr voice prostheses that lacked an esophageal flange on the proximal end was approximately 11%,[1,2] but with incorporation of an esophageal flange leakage rates decreased to between 2% and 5%.[3,4] The introduction of 20-Fr diameter voice prostheses witnessed a return to leakage rates approximating 11%,[5] and there are reports as high as 27% with 23-Fr voice prostheses.[6] It was postulated that smaller diameter prostheses, being both lighter in weight and requiring a smaller opening in the tracheoesophageal party wall, might result in less leakage around the voice prosthesis.[7]

There are 2 patterns of leakage. Leakage through a voice prosthesis is predominantly due to valve damage caused by fungal colonization or contact of a duckbill-style device against the posterior esophageal wall; while leakage around a voice prosthesis is due to tracheoesophageal punc-

**Table 1.** Patient-initiated reasons for prosthesis change.

| Reason | No. of patients (%) |
|---|---|
| Leak | 108 (54) |
| Routing change | 31 (15.5) |
| Voice problems | 18 (9) |
| Prosthesis too long | 16 (8) |
| Speech appointment | 10 (5) |
| Medical appointment | 6 (3) |
| Miscellaneous | 11 (5.5) |

*Note: Values based on 200 prosthesis changes.*

ture tract dilation.[8] Both types of leakage are confirmed by direct visualization of the prosthesis in situ while drinking.

There are no prospective reports in the literature regarding patient's versus clinician's determination of leakage incidence or pattern based on prosthesis diameter. It is advantageous to determine leakage as early as possible to prevent potential pulmonary complications and to have optimal timing for device replacement. Therefore, it is recommended that early identification of leakage be done by patient's self-determination at home prior to clinician's confirmation. All voice prosthesis users are instructed to identify leakage independently by either direct visualization or presence of a cough reflex during drinking, but it is unknown if patient's self-determination is as reliable as clinician's assessment. The purposes of the present study were to investigate patient's self-report and clinician's confirmation of leakage incidence and pattern based on visual inspection or elicitation of a cough reflex and to determine if voice prosthesis diameter predisposes leakage either through the voice prosthesis or around the voice prosthesis.

## MATERIALS AND METHODS

**Subjects.** Sixty-six subjects (49 men, 17 women; mean age, 66 years; age range, 44–89 years) participated.

Forty-six subjects had standard total laryngectomy resections, 9 had reconstruction with a pectoralis major flap, 7 had a gastric pull-up, 4 had reconstruction with a radial forearm free flap, and 1 had reconstruction with a latsimus dorsi flap. Sixty-three patients (95%) completed external beam radiation treatment, and 59 (89%) had a secondary tracheoesophageal puncture procedure.[9]

**Procedures.** All patients were seen consecutively and in a prospective manner during either routine 6-month clinic[10] or patient-initiated appointments. Information was recorded regarding prosthesis functioning from patient's report, i.e., leakage status, prior to device assessment by speech-language pathology. Patients were then assessed by drinking up to 60 mL of water to determine leakage status and pattern, ie, leakage either through lumen or around prosthesis. If leakage was noted, the presence or absence of a cough reflex was documented. Following leakage assessment, appropriate prosthesis care was implemented, ie, replacement after the maximum 6 month lifespan or if leakage occurred.

## RESULTS

Table 1 shows patient-initiated reasons for prosthesis change. One-hundred eight (54%) of the 200 patient-initiated reasons for prosthesis changes were leakage through or around the voice prosthesis. Nonleakage reasons accounted for 92 of 200 (46%) patient-initiated reasons for prosthesis change, with routine change (31 [15.5%] of 200), voice problems (18 [9%] of 200), and prosthesis too long (16 [8%] of 200) identified most frequently. Interestingly, 21 instances of leakage (23%) of the of the 92 patient-initiated nonleakage reasons for prosthesis change were unrecognized by the patient, despite the fact that 15 (71%) of that 21 instances exhibited a cough reflex.

Table 2 shows clinician's confirmation of cough status dependent on the leakage pattern. One-hundred eighteen (59%) of 200 patient-initiated reasons for prosthesis change were leakage either through the voice prosthesis or around the voice prosthesis. A chi-square analysis revealed a sig-

**Table 2.** Clinician's confirmation of cough status dependent on leakage through versus leakage around the voice prosthesis ($N = 108$).*

| Cough status | No. of patients (%) | | |
|---|---|---|---|
| | Through the voice prosthesis | Around the voice prosthesis | Total |
| Cough | 80 (88) | 9 (53) | 89 (82) |
| No cough | 11 (12) | 8 (47) | 19 (18) |

*Chi-square, $p < .05$.*
*Note: Values based on 108 reasons for prosthesis changes with 91 through the voice prosthesis and 17 around the voice prosthesis.*
**Ten of 118 instances (6 in which the leakage was into but not out of the prosthesis lumen and 4 in which the leakage was both through and around the voice prosthesis) were excluded.*

nificant difference (chi-square [1, $N = 108$], $p < .05$) in cough response dependent on leakage through versus leakage around a voice prosthesis. Specifically, when leakage occurred through the lumen of the voice prosthesis, a cough was elicited in 80 (88%) of 91 instances. However, when leakage occurred around the voice prosthesis, a cough was elicited in only 9 (53%) of 17 instances. That is, the leakage around the voice prosthesis resulted in significantly less coughing than the leakage through the voice prosthesis.

It should be noted that 3 subjects who exhibited leakage developed an upper respiratory infection severe enough to require hospitalization. No subject without leakage exhibited pulmonary complications.

It is of interest to substantiate that prosthesis diameter and length affected leakage around the voice prosthesis. There were 122 (61%) of 200 reasons for prosthesis changes with 20-Fr devices, and 78 (39%) of 200 reasons for prosthesis changes with 16-Fr devices. The majority of instances of leakage around the voice prosthesis occurred with 20-Fr diameter prostheses (16 [76%] of 21), and 12 (75%) of these 16 were 6 mm in length, ie, 1 of the shortest commercially available sizes for patients with very thin tracheoesophageal party walls. Only 5 (24%) of 21 instances of leakage around the voice prosthesis involved 16-Fr diameter prostheses. These patients needed the prosthesis to be downsized in length or previously wore 20-Fr devices. None of the 21 patients who had always worn and were properly fit with a 16-Fr voice prosthesis exhibited leakage around the voice prosthesis.

## DISCUSSION

The combination of a significantly high incidence of leakage in the absence of a cough reflex, ie, 47% with leakage around the voice prosthesis, and patient's lack of identification of leakage despite the presence of a cough reflex, ie, 71%, demonstrates the importance of teaching the patient about self-evaluation of leakage. It is recommended that patients drink a colored liquid, eg, grape juice, on a weekly basis and determine visually with a mirror if leakage occurs. This allows for prompt assessment by a speech-language pathologist or otolaryngologist and, if needed, prosthesis replacement to prevent potential pulmonary complications. Further research on the success of prosthesis wearers to self-monitor by using a colored liquid to improve identification of leakage is warranted. In addition, even when some patients coughed, they did not realize the cough was due to leakage, eg, a cough during drinking was incorrectly attributed to habitual coughing on tracheal secretions. Education, therefore, is needed to improve patient identification of both leakage and cough as a consequence of leakage.

An explanation for significantly more coughing dependent on leakage pattern may be the manner in which the tracheal mucosa is stimulated. When leakage occurs through the lumen of a voice prosthesis, a drop or multiple drops of liquid fall onto the tracheal mucosa. This is in contrast to leakage around the voice prosthesis, which tends to seep between the posterior tracheal wall and tracheal flange of the prosthesis. In addition, volume of leakage varied, and future research should investigate whether the amount of leakage, either through the voice prosthesis or around the voice prosthesis, affected cough reflex status.

Leakage around a voice prosthesis occurred significantly more frequently with larger, ie, 20-Fr diameter, devices. Although the trend over the years has been toward using larger devices, the current data show that fewer complications due to leakage around the voice prosthesis occur with smaller diameter prostheses. Therefore, it is recommended that a 16-Fr diameter voice prosthesis be used for both initial fitting and long-term use.

In addition to prosthesis diameter, leakage around may be associated with other factors, eg, poor nutrition, hypothyroidism, recurrent disease, or steroid use. Future research should investigate both these and other potential factors to determine if systemic changes contribute to tissue integrity issues and if medical management strategies can reduce frequency of leakage around the voice prosthesis.

## CONCLUSIONS

Patient education is important to promote early and reliable identification of prosthesis leakage patterns. This allows for prompt prosthesis changing and prevention of potential pulmonary consequences. The data suggest that leakage around a voice prosthesis can be minimized or avoided by initially fitting and continuing the use of smaller diameter (16 Fr) voice prostheses.

## 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. Wetmore SJ, Johns ME, Baker SR. The Singer–Blom voice restoration procedure. Arch Otolaryngol 1981;107:674–676.
3. Garth RJ, McRae A, Rhys-Evans PH. Tracheo-esophageal puncture: a review of problems and complications. J Laryngol Otol 1991;105:750–754.
4. Izdebski K, Reed CG, Ross JC, Hilsinger RL. Problems with tracheoesophageal fistula voice restoration in totally laryngectomized patients. Arch Otolaryngol Head Neck Surg 1994;120:840–845.
5. Blom ED. Some comments on the escalation of tracheoesophageal voice prosthesis dimensions. Arch Otolaryngol Head Neck Surg 2003;129:500–502.
6. Laccourreye O, Menard M, Crevier-Buchman L, Couloigner V, Brasnu D. In situ lifetime, causes for replacement, and complications of the Provox voice prosthesis. Laryngoscope 1997;107:527–530.
7. Eerenstein SEJ, Grolman W, Schouwenburg PF. Downsizing of voice prosthesis diameter in patients with laryngectomy. Arch Otoloryngol Head Neck Surg 2002;128: 838–841.
8. Blom ED, Hamaker RC. Tracheoesopageal voice restoration following total laryngectomy. In: Meyers EN, Suen J, editors. Cancer of the head and neck. Philadelphia: W. B. Saunders; 1996. pp 839–852.
9. Singer MI, Blom ED. An endoscopic technique for restoration of voice after laryngectomy. Ann Otol Rhinol Laryngol 1980;89:529–533.
10. Leder SB, Erskine MC. Voice restoration after laryngectomy: experience with the Blom–Singer extended-wear indwelling tracheoesophageal voice prosthesis. Head Neck 1997;19:487–493.