

ORIGINAL RESEARCH

Voice Restoration With the Advantage Tracheoesophageal Voice Prosthesis

Steven B. Leder, PhD, CCC-SLP, Lynn M. Acton, MS, CCC-SLP, Joann Kmiecik, MA, CCC-SLP, Cindy Ganz, MS, CCC-SLP, and Eric D. Blom, PhD, CCC-SLP, New Haven, Connecticut, Cleveland, Ohio, New York, New York, and Indianapolis, Indiana

OBJECTIVES: To determine whether the Blom-Singer indwelling Advantage tracheoesophageal voice prosthesis (TEP) extends prosthesis life span significantly in patients with documented premature device failure due to fungal colonization.

STUDY DESIGN AND SETTING: Data were collected in a prospective manner on a total of 42 standard indwelling TEP users who exhibited early device failure, that is, between 2 weeks and 6 months, due to fungal colonization of the flap valve despite appropriate use of oral antifungal agents. There were 29 men and 13 women, whose ages ranged from 36 years 10 months to 86 years 8 months.

METHODS: Baseline data were derived from the average number of days 3 previous standard indwelling prostheses functioned before leaking. An Advantage indwelling TEP was placed after the third change, oral antifungal agents stopped, and routine care implemented, that is, flush and brush the device in situ twice each day. Each participant was assigned to 1 of 3 groups. Group 1 had device failure equal to or less than 2 months ($n = 12$). Group 2 had device failure between 2 and 4 months ($n = 19$). Group 3 had device failure between 4 and 6 months ($n = 11$).

RESULTS: Groups 1 and 2 exhibited significantly longer device life span, that is, 77 and 82 days, respectively ($P < 0.01$), and group 3 exhibited device life span that was longer but not significantly so, that is, 12 days ($P > 0.05$), after the change from standard to Advantage TEP. Individual data indicated that the majority of participants, that is, 32 of 42 (76.2%), experienced longer device life span after changing to the Advantage prosthesis. Specifically, 9 of 12 (75.0%) users in group 1, 17 of 19 (89.5%) users in group 2, and 6 of 11 (54.5%) users in group 3 exhibited longer device life span. The combination of using an Advantage

TEP, discontinuing oral antifungal agents, and reducing the number of both TEP changes and clinic visits resulted in overall cost benefits for both the user and the health care system. The cost benefit for group 1 was \$520.00; group 2, \$393.00; and group 3, \$204.25.

CONCLUSIONS: The Advantage TEP extended device life span significantly for standard indwelling device users with documented premature device failure due to fungal colonization, reduced costs associated with tracheoesophageal voice restoration rehabilitation, and enhanced user satisfaction by eliminating use of oral antifungal agents and reducing clinic visits.

SIGNIFICANCE: Use of an Advantage indwelling voice prosthesis is warranted from both cost and user satisfaction perspectives when early and repeated device failure occurs as a result of fungal colonization.

EBM Rating: B-3

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The Blom-Singer tracheoesophageal voice prosthesis (TEP) has undergone continuous design modifications during the past 25 years to make it more effective, anatomically compatible, and easier to use.¹ Introduction of an extended-wear indwelling TEP continued this evolution and was developed for laryngectomees who were either unwilling or unable to perform self-changing of nonindwelling devices. The indwelling TEP was shown to achieve its a priori life span goal of 180 days (6 months) with almost uniform patient preference and without risk of increased complications.²

From the Yale University School of Medicine, Department of Surgery, New Haven, CT (Dr Leder and Ms Acton), the Cleveland Clinic, Head and Neck Institute, Cleveland, OH (Ms Kmiecik), Memorial Sloan-Kettering Cancer Center, New York, NY (Ms Ganz), and Head and Neck Surgery Associates, Indianapolis, IN (Dr Blom).

Supported in part by the McFadden, Harmon, and Mirikitani Endowments. Reprint requests: Steven B. Leder, PhD, Yale University School of Medicine, Section of Otolaryngology, PO Box 208041, New Haven, CT 06520-8041.

E-mail address: steven.leder@yale.edu.

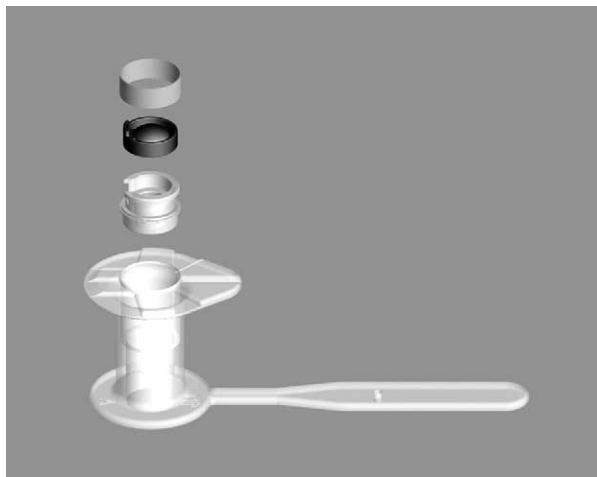


Figure 1 Exploded view of the Advantage tracheoesophageal voice prosthesis (top to bottom): titanium enclosure for valve cartridge; silicone ring flap valve impregnated with silver oxide; plastic valve seat; and soft silicone prosthesis body.

However, a subset of indwelling prosthesis users, reported to be as high as 20%,³ exhibited persistent fungal colonization of the flap valve, resulting in early device failure, that is, within the first month, due to leakage through the TEP despite appropriate use of oral antifungal agents such as amphotericin B lozenges^{4,5} or nystatin oral suspension.^{5,6} In an effort to improve device life span for these users, the Food and Drug Administration recently approved the Blom-Singer indwelling Advantage voice prosthesis (Inhealth Technologies, Carpinteria, CA). This device retains the design improvements and continues the benefits of the extended-wear indwelling TEP with the important addition of 7% silver oxide, a known antifungal substance, incorporated into the silicone matrix of the flap valve. The cartridge assembly system allows the flap valve to be inside the lumen of the voice prosthesis, thereby eliminating direct tissue contact (Fig 1).

The primary purpose of the present study was to investigate whether the Advantage TEP resulted in prolonged in vivo device life span by preventing early flap valve failure due to fungal colonization. In addition, both cost containment and user satisfaction with this style of prosthesis (measured by reduced number of voice prostheses, eliminated need for daily antifungal agents, and reduced clinic visits) were studied.

MATERIALS AND METHODS

Participants

This multicenter study was approved by the Human Investigation Committee of Yale University School of Medicine. Participating institutions included the Cleveland Clinic Head and Neck Institute, Memorial-Sloan Kettering Cancer Center, and Head and Neck Surgery Associates. Data were collected in a prospective manner on a total of 42 standard

indwelling TEP users who exhibited early device failure, that is, device failure occurring between 2 weeks and 6 months, due to fungal colonization of the flap valve. Leakage occurred despite appropriate use of oral antifungal agents, that is, twice-a-day, 5-8 minute nystatin swish-and-swallow protocol. There were 29 men and 13 women, with an age range from 36 years 10 months to 86 years 8 months.

Data Collection Procedures

Baseline data were derived from the average number of days 3 previous standard indwelling prostheses functioned before leaking. An Advantage indwelling TEP was placed after the third change, oral antifungal agents discontinued, and routine care implemented, that is, flush and brush the device in situ twice each day.

Each participant was assigned to 1 of 3 groups. Group 1 had device failure equal to or less than 2 months ($n = 12$). Group 2 had device failure between 2 and 4 months ($n = 19$). Group 3 had device failure between 4 and 6 months ($n = 11$).

RESULTS

Life spans of standard indwelling voice prostheses compared with Advantage voice prostheses are shown in Table 1. Student *t* tests for correlated samples indicated that group 1 and group 2 users exhibited significantly longer device life span, that is, 77 and 82 days, respectively ($P < 0.01$), after the change from standard to Advantage TEP. Group 3 users exhibited device life span that was longer (12 days) but not significantly so ($P > 0.05$) after the change from the standard to the Advantage device.

Individual data (Table 2) indicated that the majority of participants, that is, 32 of 42 (76.2%), exhibited longer device life span after changing to an Advantage prosthesis. Specifically, 9 of 12 (75.0%) users in group 1, 17 of 19 (89.5%) users in group 2, and 6 of 11 (54.5%) users in group 3 exhibited longer device life span.

The combination of using an Advantage TEP, discontinuing oral antifungal agents, and reducing the number of both TEP changes and clinic visits resulted in overall cost benefits for both the user and the health care system. A nationwide telephone survey indicated that the average cost for a 48-day supply of nystatin oral suspension, that is, a 480-mL bottle, of which 5 mL is used to swish and swallow for 5-8 minutes twice daily, was \$81.00 (Table 3). The cost difference between a standard (\$91.00) and Advantage (\$150.00) device is \$59.00 (Inhealth Technologies Professional Pricelist, 2004). The professional provider Medicare reimbursement for fee code 92597 (evaluation of patient for voice prosthesis) is approximately \$91.00. Group 1 participants saved 2 professional provider fees plus the cost of nystatin times 4 months plus the cost of 2 replacement standard indwelling devices minus the additional cost of Advantage TEP, for a savings of \$520.00. Group 2 participants saved 1 professional provider fee plus the cost of

Table 1
Group means and standard deviations for life span (days) of standard indwelling voice prostheses (with nystatin) and Advantage voice prostheses (without nystatin) for groups 1, 2, and 3 (N = 42)

Life span (days)	Group 1 ^a (n = 12)		Group 2 ^b (n = 19)		Group 3 ^c (n = 11)	
	Standard	Advantage	Standard	Advantage	Standard	Advantage
\bar{X}	41.25	117.83*	86.05	168.47*	149.45	161.27
SD	13.39	68.62	18.21	182.40	17.23	68.75
Range	9-58	21-216	60-109	77-432	125-189	38-329

\bar{X} , mean; SD, standard deviation.

^aDevice failure due to fungal colonization ≤ 2 months.

^bDevice failure due to fungal colonization between 2 and 4 months.

^cDevice failure due to fungal colonization between 4 and 6 months.

* $P < 0.01$

nystatin times 5 months plus the cost of 1 replacement standard device minus the additional cost of Advantage TEP, for a savings of \$393.00. Group 3 participants saved on nystatin for 5 months minus the \$59.00 for the Advantage TEP, for a savings of \$204.25. If replacement Advantage prostheses are used long-term, additional cost benefits will accrue.

User satisfaction was reported to be uniformly positive as a result of discontinued use of oral antifungal agents and less frequent visits to the clinic for device changing. Even those participants who did not achieve adequate fungal control with an Advantage TEP did not want to resume use of oral antifungal agents. No participant reported difficulty with routine prosthesis care requirements.

DISCUSSION

The indwelling Advantage TEP extended device life span significantly for the majority of users who exhibited persistent fungal colonization despite appropriate use of oral antifungal agents. The most benefit in regard to device life span and cost savings occurred for group 1 users, who exhibited standard indwelling device failure between 2 weeks and 2 months. Group 2 users, with device failure between 2 and 4 months, also exhibited significantly longer device life span as well as excellent cost savings by changing to an Advantage TEP. It was not surprising that changing to an Advantage device did not significantly lengthen

Table 2
Individual mean data for life span (days) of three standard indwelling voice prostheses and one Advantage voice prosthesis for groups 1, 2, and 3 (N = 42)

Group 1 ^a (n = 12)		Group 2 ^b (n = 19)		Group 3 ^c (n = 11)	
Standard	Advantage	Standard	Advantage	Standard	Advantage
40	172	60	79	144	194
42	69	75	84	130	136
28	62	107	189	159	148
35	21	65	259	162	105
9	190	68	189	141	329
36	188	91	161	160	196
55	216	99	77	135	128
58	137	63	112	145	186
58	173	91	194	125	38
41	126	81	168	154	175
52	30	106	172	189	139
41	30	109	129		
		80	432		
		79	163		
		113	92		
		121	204		
		66	97		
		74	312		
		87	88		

^aDevice failure due to fungal colonization ≤ 2 months.

^bDevice failure due to fungal colonization between 2 and 4 months.

^cDevice failure due to fungal colonization between 4 and 6 months.

Table 3
Nationwide telephone survey (January-February 2005) of cost of nystatin oral suspension (480-mL bottle)

City, State	Cost (US dollars*)
New Haven, CT	\$89.00
Washington, DC	\$95.00
Miami, FL	\$89.00
Atlanta, GA	\$80.00
Lafayette, LA	\$69.00
Ann Arbor, MI	\$74.00
St. Louis, MO	\$90.00
Jackson, MS	\$66.00
New York, NY	\$116.00
Oklahoma City, OK	\$66.00
Charleston, SC	\$77.00
Dallas, TX	\$76.00
Madison, WI	\$65.00
\bar{X}	\$81.00
Range	\$65.00–\$116.00

\bar{X} , mean.

*rounded to nearest dollar.

life span for group 3 users, that is, those experiencing device failure between 4 and 6 months, since the upper limit of use was capped at approximately 6 months, even if the device was functioning appropriately, for hygienic purposes and to prevent tissue overgrowth. (The only exceptions were 3 participants who refused to have their functioning devices changed until day 259, 312, and 329, respectively.) However, even group 3 users had good cost savings after changing to an Advantage TEP.

The *Candida* species and *Staphylococcus aureus* were reported to be the most common microbial colonizers causing device failure for Blom-Singer prostheses.⁷ Inspection of the individual data (Table 2) indicated that the addition of 7% silver oxide to the silicone matrix of the flap valve was beneficial for the majority of participants (76.2%). It was not unusual to find that some participants continued to exhibit premature device failure even after changing to an Advantage prosthesis because silver oxide does not cover all types of microbes.⁵ It is appropriate, however, to try an Advantage TEP after repeated, say 3 to 4, early standard indwelling prosthesis failures in order to reap potential cost savings and user satisfaction benefits.⁷

Early Advantage device failure due to fungal colonization, that is, failure in less than or equal to 2 months, usually resulted in return to a standard indwelling TEP and resump-

tion of oral antifungal agents because cost savings were negligible. However, if the life span of an Advantage prosthesis was greater than 2 months, the combination of cost benefits and enhanced user satisfaction may warrant replacement with another Advantage TEP despite the additional cost for the device itself. It should be noted that recent price increases have influenced cost savings slightly; that is, Advantage (\$195.00) – standard indwelling (\$115.00) = \$80.00, versus \$59.00 based on 2004 prices (Inhealth Technologies Professional Pricelist, 2005).

Enhanced user satisfaction with the Advantage TEP resulted from the combination of longer device life span, substantial cost savings, elimination of oral antifungal agents, and less frequent clinic visits. Routine device care was not burdensome and was easily accomplished by all participants.

CONCLUSION

The Advantage TEP extended device life span significantly for standard indwelling device users with documented premature device failure due to fungal colonization. Furthermore, changing to an Advantage device reduced costs associated with tracheoesophageal voice restoration rehabilitation and enhanced user satisfaction by eliminating use of oral antifungal agents and reducing clinic visits.

REFERENCES

- Blom ED, Singer MI, Hamaker RC. Tracheostoma valve for postlaryngectomy voice rehabilitation. *Ann Otol Rhinol Laryngol* 1982;91:498–502.
- Leder SB, Erskine MC. Voice restoration after laryngectomy: experience with the Blom-Singer extended wear indwelling tracheoesophageal voice prosthesis. *Head Neck* 1997;19:487–93.
- Ackerstaff AH, Hilgers FJM, Meeuwis CA, et al. Multi-institutional assessment of the Provox^R 2 voice prosthesis. *Arch Otolaryngol Head Neck Surg* 1999;125:167–73.
- Mahieu HF, van Saene JJM, den Besten J, et al. Oropharynx decontamination preventing *candida* vegetation on voice prostheses. *Arch Otolaryngol Head Neck Surg* 1986;112:1090–2.
- Neibart E, Gumprecht J. Antifungal agents and the treatment of fungal infections of the head and neck. *Otolaryngol Clin No Am* 1993;26:1123–31.
- Izdebski K, Ross JC, Lee S. Fungal colonization of tracheoesophageal voice prosthesis. *Laryngoscope* 1987;97:594–97.
- Palmer MD, Johnson AP, Elliott TSJ. Microbial colonization of Blom-Singer prostheses in postlaryngectomy patients. *Laryngoscope* 1993;103:910–4.