VHA PROSTHETIC CLINICAL MANAGEMENT PROGRAM (PCMP)

CLINICAL PRACTICE RECOMMENDATIONS TRACHEOESOPHAGEAL VOICE PROSTHESES

I. BACKGROUND

VHA's Prosthetic and Sensory Aids Service Strategic Healthcare Group was directed by the Under Secretary for Health to establish a Prosthetic Clinical Management Program (PCMP). The objectives are to coordinate the development of recommendations for prosthetic prescription practices and contracting opportunities to assure technology uniformity and ease of access to prosthetic prescriptions and patient care that will lead to valid outcome measures and analysis for research purposes.

A work group with input from selected clinicians with expertise in speech devices convened to recommend a policy regarding selection of tracheoesophageal voice prostheses for veterans who have undergone total laryngectomy. A person who has had a laryngectomy breathes only through an opening in the neck called a tracheostoma. This opening leads directly to the lungs.

Tracheoesophageal voice is one of the options available to individuals who have had their larynx removed and are thereby unable to produce normal voice. Tracheoesophageal voice requires the use of a voice prosthesis. The voice prosthesis is a one-way valve that is inserted through a surgically created fistula in the party wall between the trachea and esophagus. When the tracheostoma is occluded, exhaled air passes through the prosthesis, enters the esophagus, and produces esophageal sound that supports speech. The selection of the voice prosthesis is made by matching the features of the prosthesis to the requirements of the patient.

II. POLICY

The purpose of the clinical practice recommendations is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective prescribing.

III. CLINICAL PRACTICE RECOMMENDATIONS

- A. There is no single tracheoesophageal voice prosthesis that is equally suited to every speaker, and it is the responsibility of the clinician to select the prosthesis that has the features that best match the requirements of the patient. (See attached chart: Distinguishing Features of Sample Prostheses.)
- B. The clinician should consider the following before the initial fitting of a voice

prosthesis.

- a. An esophageal retention collar that is small in diameter and narrow in thickness is less abrasive to insert and withdraw, but is easier to dislodge.
- An esophageal retention collar that is larger in diameter and heavier/wider in thickness can be more abrasive to insert and withdraw, but more resistant to dislodging.
- c. Both styles are necessary to meet different patient requirements.
- C. The clinician may consider initially fitting the patient with a 16 Fr. duckbill-type voice prosthesis that is easy to insert and withdraw, requires no special insertion device, and does not require enlargement of the fistula on reinsertion of the device. Such a device would have an esophageal retention collar that is easily flexed. The initial stenting of the fistula can usually be done with a 14 Fr. catheter. The insertion stick comes with the prosthesis. The insertion stick prevents the prosthesis from bending and allows the user to see the entrance to the fistula while seating the prosthesis for insertion. The esophageal tip is bullet shaped for smooth entry and the length of the tip allows the prosthesis to enter and seat into the fistula so it is less likely to slip out when the rest of the prosthesis is inserted. When the prosthesis requires replacement, the new one can be inserted without enlarging the fistula beforehand. A patient who has received training can insert, clean, and replace this prosthesis.
- D. If the patient is using a duckbill prosthesis and:
 - a. The duckbill prosthesis dislodges easily, the patient may benefit by trying a 16 Fr. duckbill that has a firmer esophageal retention collar.
 - b. The patient complains of esophageal irritation or of food appearing to lodge in the area of the esophageal tip, and the prosthesis is not too long, consider changing to a prosthesis with a shorter esophageal tip.
- E. Another style of voice prostheses has a short esophageal tip and is described as a "low pressure" or "low resistance" prosthesis. Low pressure/resistance prostheses are more difficult to insert than the duckbill style because the shortened esophageal tip can slip away from the fistula entrance before it is inserted. If the prosthesis has a delicate esophageal retention collar it is easier to insert than if it has a firm retention collar. A prosthesis with a firm retention collar requires the use of special equipment to fold down the collar so it offers less resistance and insertion is smooth. This equipment may be included with the prosthesis or may require an additional purchase. A patient who has received training can insert, clean, and replace this prosthesis.
- F. If the patient using any style 16 Fr. diameter prosthesis has significantly better esophageal sound with less effort when the prosthesis is removed (open fistula), then a prosthesis with a larger body diameter, e.g., 20 Fr. or more, may be recommended. The clinician should be aware that occasionally a patient using a 20 Fr. low pressure, low resistance prosthesis will complain of an accumulation of

air in the digestive track, often with embarrassing results. The choice is to try another style 20 Fr. low pressure, low resistance prosthesis or return to the duckbill style.

- G. There is a category of voice prostheses that requires insertion and removal by the physician or speech pathologist, and not by the patient. These prostheses are referred to as "indwelling." The body of these prostheses is generally 20 Fr. or larger, and they have large and firm retention collars to prevent dislodging. They are cleaned in place by the patient or designee. They are especially useful for those patients who have good tracheoesophageal voice but are unable or reluctant to care for the prosthesis themselves. These prostheses must have plugs available so that should a leak develop through the prosthesis, the patient can plug the tracheal end and continue swallowing safely. The plugs are of two types. One plug prevents tracheal air from entering the prosthesis, therefore the patient is unable to speak. The other plug is a miniature low pressure, low resistance voice prosthesis that allows the patient to speak and to swallow safely.
- H. Tracheoesophageal voice prostheses and their associated supplies are ordered from Prosthetics Service through CPRS, selecting "Consult" then "New Consult" tabs. In the box for "Consult to Service/Specialty" select "Prosthetics Request." The request should specify the make, model, and stock number of the item.

IV. REFERENCES

American Speech-Language-Hearing Association (1992). Guidelines for Evaluation and Treatment for Tracheoesophageal Fistulization/Puncture. <u>Asha</u>, 34 (March, Suppl.7), 17-21.

Bosone, Z. T. (1999). Tracheoesophageal speech: Treatment considerations before and after surgery. In S. J. Salmon (Ed.), Alaryngeal Speech Rehabilitation (2nd ed., pp. 105-150). Austin, TX: PRO-ED.

APPROVED / DISAPPROVED:

Jonathan B. Perlin, MD, PhD, MSHA, FACP Acting Under Secretary for Health JUN 1 8 2004

Date

DISTINGUISHING FEATURES OF SAMPLE PROSTHESES*

FEATURES Diameter of body	Duckbill Slit valve 16 Fr.*	Blom-Singer Low Pressure Flap valve		Indwelling Flap valve	Provox 2 Indwelling Flap valve	Bivona			
						Duckbill Slit valve		Ultra-Low Flap valve	
		Thick of esoph flange	.457 mm	.508 mm	.508 mm	.965 mm	1.5 mm	.28 mm	.25 mm
Diam of esoph flange	9.91 mm	10.0 mm	11.4 mm	13.34 mm	14.3 mm	9.67 mm	11.1 mm	9.48 mm	12.0 mm
Length of esoph end	8.0 mm	2.54 mm	2.54 mm	0 mm	1.94 mm	8.5 mm	8.5 mm	3.5 mm	5.0 mm
Air Port Optional		Yes				Yes	Yes	Yes	Yes
									
	Measurer					Measurer	" - ,		
Diameter of body	16 Fr.*	20 Fr.*				16 Fr.	20 Fr.		
Thick of esoph flange	.457 mm	.457 mm				.28 mm	.25 mm		
Diam of esoph flange	9.91 mm	10.92 mm				9.65 mm	11.0 mm		
* = Radiopaque									