

Evaluation of Customized Prosthesis for Irregularly Formed Tracheostoma After Laryngectomy

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Abstract

Background: After laryngectomy, the tracheostoma forms the functional center for breathing and phonation. An occasionally occurring but typical problem can arise from an oversized and/or irregularly formed tracheostoma, hampering the temporary occlusion necessary for sufficient speech production. As an alternative to a surgical correction of the tracheostoma, an individually adjusted stoma silicone prosthesis may be used.

Materials and Methods: Twenty-one patients suffering from irregularly formed tracheostoma after laryngectomy followed by insertion of a speech valve were provided with a silicone tracheostomal prosthesis. They underwent subjective assessment of voice quality and breathing function according to a standardized general questionnaire and to the Voice Handicap Index (VHI). Furthermore, a clinical evaluation was performed including detection of peristomal leakage and phonation time.

Results and Discussion: Patients described a significant improvement of voice production with the tracheostomal prosthesis (averagely graded as 1.9 with and 3.2 without prosthesis, $P = .0026$). Breathing was also slightly improved by the prosthesis with an average grade of 1.7 compared to 2.3 with a conventional cannula ($P = .063$). There was a strong correlation between self-evaluation and the total score of the VHI after insertion of the prosthesis ($P < .0001$). Minor local skin reactions caused by the adhesive were described by 5 of the 21 patients.

Conclusions: A tracheostomal prosthesis represents an efficient alternative to surgical revision of irregularly formed tracheostoma after laryngectomy, enhancing voice production and breathing function.

Keywords

laryngectomy, speech valve, tracheostomal prosthesis, Voice Handicap Index, voice quality

Introduction

After laryngectomy, the separation of airway and pharynx leads to the loss of the patient's voice function. Inserting a speech valve between trachea and reconstructed pharynx represents the most commonly performed method for voice rehabilitation. For this purpose, the tracheostoma is closed by the fingertip or a self-closing valve during exhalation, allowing air to pass through the speech valve into the pharynx. The airflow leads to vibrations in the pharynx, which can subsequently be modulated by articulation. Therefore, the tracheostoma forms the "functional center" for breathing and voice production. Form and size of the tracheostoma are fundamental factors for both adequate respiration and voice rehabilitation. As a typical problem, the latter can be impaired by an extensive size or irregular form of the tracheostoma, making sufficient mechanical closing

difficult or even impossible. In some cases, surgical modification of the tracheostoma is feasible. As an alternative, the irregularly formed tracheostoma can be corrected by insertion of a customized stoma prosthesis.¹ The evaluation of breathing and voice production under this kind of device was the aim of this study.

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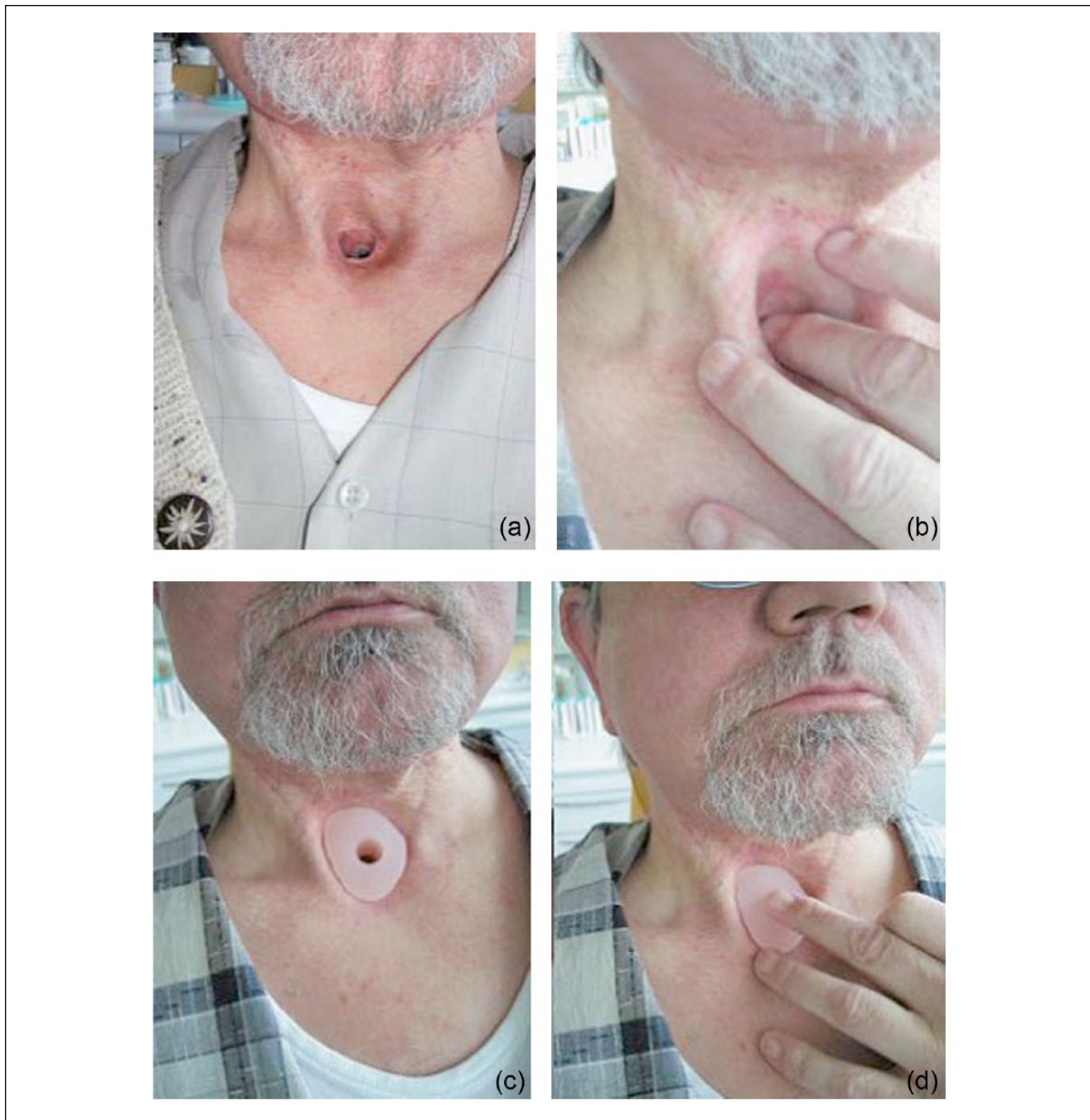


Figure 1. (a) Laryngectomized patient with an irregularly formed tracheostoma characterized by excessive craniocaudal extension and prominent sternocleidomastoid muscles laterally. (b) Insufficient sealing by fingertip. (c) Customized silicone prosthesis for the tracheostoma. (d) Sufficient sealing of the irregularly formed tracheostoma after insertion of an individually fitted silicone prosthesis.

Materials and Methods

Among the 21 investigated patients were 2 (10%) female and 19 (90%) male individuals with a medium age of 68.5 years (range, 53-81 years). Seventeen patients received laryngectomy due to a laryngeal carcinoma, and 4 patients suffered from hypopharyngeal cancer. All patients developed

an irregularly formed tracheostoma, characterized by a diameter exceeding 2.5 cm, prominent sternocleidomastoid muscles, or irregular margins, and received a silicone stoma prosthesis (Figures 1a, 1b, and 2a). Depending on the individual requirement of the patient, the prosthesis was produced with a simple aperture that can be covered by fingertip (Figures 1c and 1d) or with a bigger aperture including a

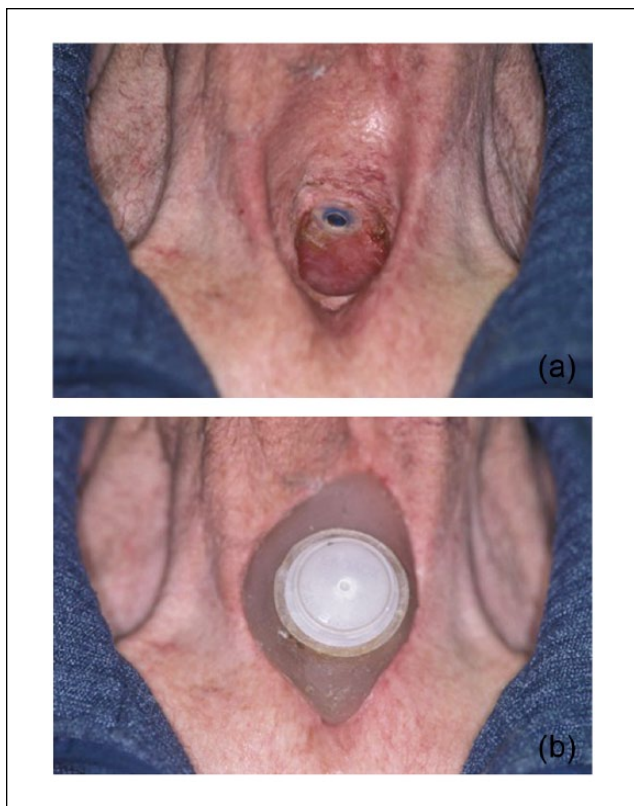


Figure 2. (a) Laryngectomized patient with extensively large tracheostoma with inserted speech valve. (b) Heat and moisture exchanger on top of a tracheostomal silicone prosthesis.

carrier to install either an HME (heat and moisture exchanger) cartridge or a FreeHands valve (Figure 2b). The prosthesis was fixed to the peristomal skin by an adhesive, for example, Medical Adhesive B, Medical Adhesive B Liquid (Ullrich Swiss, Schweiz, Switzerland), or Blom-Singer Silicone Adhesive (Blom-Singer, InHealth Technologies, Carpinteria, California, USA). The costs of the customized prosthesis were approximately 1700 Euro/\$2000 per case.

We determined the function, durability, and handling of these individually adjusted tracheostomal prosthesis. Patient's assessment of voice quality, breathing function, and handling was analyzed by a questionnaire before and after insertion of the tracheostomal prosthesis as well as the handling. Dichotomous and scaled questions were used. For comparison, the same patients were evaluated using a conventional speech cannula with perforations pointing toward the speech valve and without a sealing pad around it.

Furthermore, to gain a more precise evaluation of voice quality using the prosthesis, the patients were given a German version of the Voice Handicap Index (VHI) questionnaire.^{1,2}

The self-administered VHI questionnaire contains 30 items divided into 3 subscales, measuring physical, emotional, and functional aspects of voice problems. The total

VHI score ranges from 0 to 120. A low denotes VHI value of 0 to 30 points, denoting the absence of voice problems or only slight voice problems; a score of 30 to 60 points indicates a moderate handicap level; and 61 to 120 points represents severe voice disorders.³

The VHI includes 30 situations measuring limitation or disability caused by the voice quality. The 30 questions of self-assessment were subdivided into functional, physical, and emotional aspects.⁴

Additionally, 7 patients were examined clinically, and their individual habits were queried. The examination included an anatomic and functional investigation of the area around the tracheostoma, a phoniatric checkup with and without the prosthesis, and an assessment of maximal phonation time. Subsequently, patients were asked to read a standardized text with and without the prosthesis while the extent of air leakage from the tracheostoma and the whistling (air tones) was recorded and assessed by 2 independent observers using the following scaling system: 0 (no whistling), 1 (little whistling), 2 (audible whistling), and 3 (intense whistling).

Results

Questionnaire

Of the 21 patients, 13 primarily used a conventional speech cannula. Subjective breathing and speaking quality with the speech tube was graded from 1 (very good) to 6 (very bad).

Breathing with the prosthesis was estimated as very good (1) by 9 patients, good (2) by 10 patients, satisfactory by 1 patient (3), and adequate by 1 patient (4). Breathing was slightly better with the prosthesis (average grade 1.7) as compared to a conventional cannula (average grade 2.3; $P = .063$).

Speech function was significantly improved by the prosthesis (1.9 vs 3.2 without prosthesis; $P = .0026$). Eight out of 21 patients rated speaking function with the prosthesis as very good (1), 10 rated good (2), 2 rated satisfactory (3), and 1 inadequate (5). Fifteen patients were able to produce complex sentences, 6 several words or short sentences, and none of the patients only single words.

Medium application time of the prosthesis was 20 hours with a range from 2 to 84 hours. The durability (loss of elasticity, discoloration) was approximately 2 years. Fifteen patients used their finger to seal the stoma (Figure 1c), 4 patients utilized the FreeHands valve (Figure 2b), and 2 patients applied both methods.

Minor local skin reactions caused by the adhesive were described by 5 of 21 patients. Those dermatologic reactions were controlled by temporary interruption or switch to an alternative adhesive. Neck mobility was slightly affected in 3 of 21 patients. One patient was not able to achieve sufficient sealing, 2 reported frequent detachment of the

Table 1. Voice Handicap Index (With Mean and Standard Deviation) in 21 Patients With Prosthesis of an Irregularly Formed Tracheostoma.

Patient	Age	Self-assessment	Emotional Scale	Functional Scale	Physical Scale	Total Score
1	79	1	17	21	20	58
2	67	0	4	9	1	14
3	56	0	8	9	14	31
4	61	1	9	14	11	34
5	73	2	27	23	20	70
6	75	0	0	10	4	14
7	67	0	0	6	0	6
8	63	3	37	36	35	108
9	70	0	0	10	11	21
10	78	2	28	24	19	71
11	58	1	4	5	13	22
12	64	1	13	13	15	41
13	53	0	6	7	15	28
14	64	0	0	4	4	8
15	81	1	9	22	18	49
16	73	1	7	8	13	28
17	76	2	18	18	16	52
18	75	0	10	5	5	20
19	72	0	5	7	6	18
20	65	1	10	14	11	35
Mean	68.5	0.8	10.6	13.3	12.6	36.4
SD	8.0	0.9	10.2	8.4	8.1	25.5

prosthesis, and 1 patient complained about intermittent obstruction by mucus.

Voice Handicap Index

On a scale from 0 (no voice handicap) to 120 (maximal voice handicap), the patients achieved a mean value of 37.5 ± 26.5 with the prosthesis (Table 1). The total score varied between 6 and 106. No correlation between age and total VHI score was detected ($r = 0.24$, $P = .34$; Figure 3).

On the voice self-assessment scale, 16 patients were normal (0) or slightly impaired (1), 3 moderately impaired, and only 1 claimed his voice profoundly impaired. A strong correlation between voice self-assessment and total VHI score was detected ($r = 0.87$, $P < .0001$, Figure 4).

Clinical Examination

Clinical follow-up examination was performed on 7 patients in this retrospective analysis. Parameters affecting sufficient tracheostoma sealing during voice production were an oversized stoma in craniocaudal extension (>3 cm) in 6 of 7 investigated patients, prominent sternocleidomastoid muscles in 4 of 7 patients, and a caudal indentation of the stoma in 2 patients.

A maximum phonation time of 12.1 seconds (median) was reached with prosthesis, whereas it ranged from 0 (no

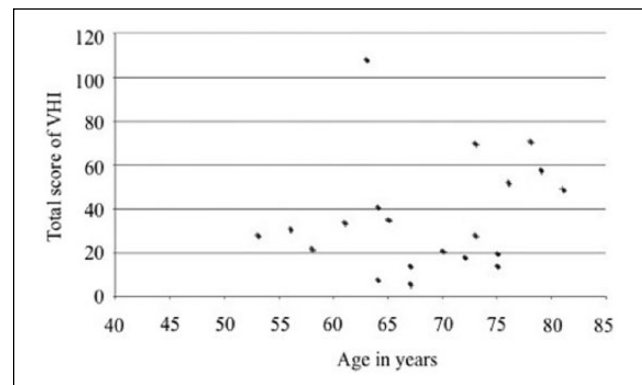


Figure 3. Correlation between age (x-axis) and Voice Handicap Index (VHI; y-axis).

sealing possible) to a maximum of 5.8 seconds without prosthesis. Whistling was considerably reduced using the prosthesis (Table 2).

Discussion

After laryngectomy, the newly created tracheostoma forms a functional center relevant for breathing and voice generation. Form, size, and position of the stoma are crucial factors for a successful rehabilitation and are

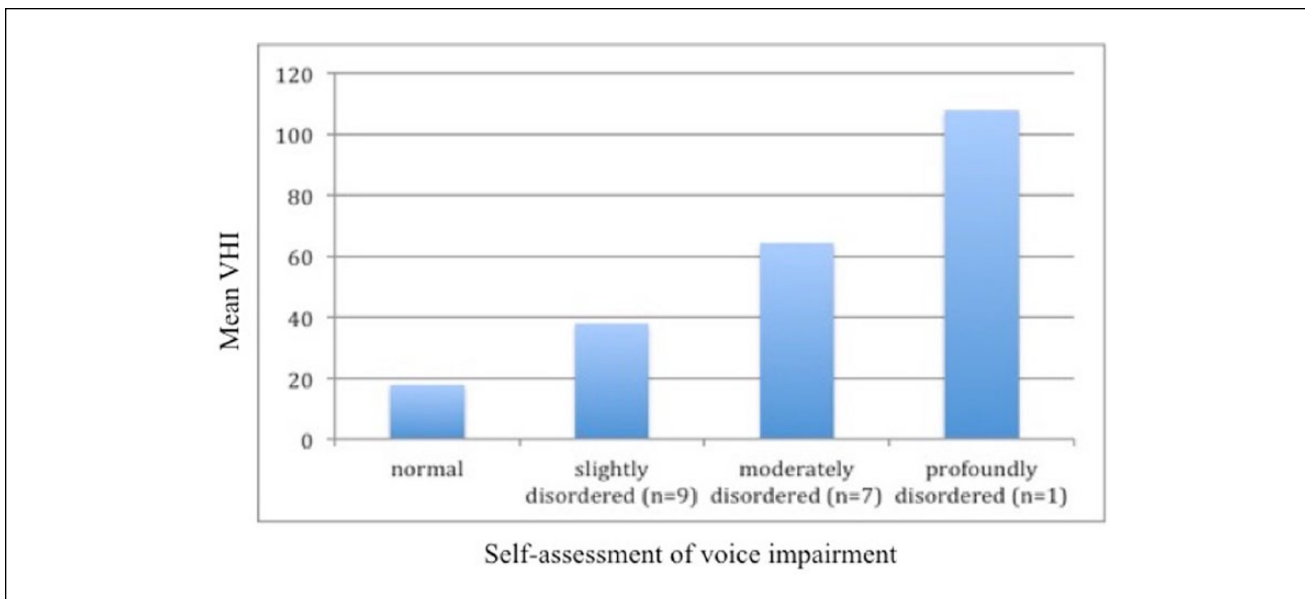


Figure 4. Self-assessment of voice impairment (x-axis) and mean Voice Handicap Index (VHI; y-axis).

Table 2. Results of the Phoniatic Investigation Showing Maximal Phonation Time and Whistling in 7 Patients With Irregularly Formed Tracheostoma (With Prosthesis on the Left Side, Without Prosthesis in the Middle, With a Speech Cannula on the Right Side).

Patient No.	Epithesis		Finger		Speaking Tube	
	Tone (s)	Whistling	Tone (s)	Whistling	Tone (s)	Whistling
1	13	0	3	1	11.5	3
2	11.5	0	2.3	3	1.8	3
3	9	0	5.8	3	5.8	2
4	12.8	0	0	3	—	—
5	7	1	0	3	—	—
6	14.3	1	16	1	—	—
7	17	0	12.5	2	—	—
Ø	12.1	0.29	5.7	2.29	6.4	2.67

influenced by variables like tracheal diameter, tumor location, extent of resection, and different operation techniques.³ The best stoma diameter for an appropriate breathing function and a good access to the tracheoesophageal shunt is stated as 2 to 2.5 cm.⁵ An oversized and/or irregularly formed stoma does not allow sufficient closure and thus impairs voice production. An alternative to surgical intervention is the application of a customized silicone prosthesis.^{6,7} Lewin⁸ describes alternative non-surgical approaches for irregularly formed tracheostomas. They state that extensively large tracheostomas are difficult to handle and are sometimes fixed by bizarre and impractical constructions like using a ping-pong ball. There is no mentioning of the herein described silicone prosthesis, and he concludes that there is a definitive need for sustainable solutions.⁸

Laryngectomized patients with an irregularly formed tracheostoma received a tracheostomal prosthesis and were compared to standard care with a speech cannula. With a prosthesis, they achieved a longer phonation time without alteration of their breathing function. Side effects consisted of a local skin reaction against adhesive, controllable by change of the adhesive or pausing the application.

The tracheostomal prosthesis led to a significant improvement in voice production without negatively affecting breathing.

Although a moderate variability was noticed in the answers determining the VHI, a significant correlation between the self-assessment of the voice quality (range, 0-3) and the total score of the VHI (range, 0-120) became apparent in our study. The average VHI determined by patients with a customized prosthesis was 37.5. This is

comparable to results from other studies with carriers of a speech valve and a shuntless tracheostoma.^{9,10} Though there was no statistical significance, patients with a prosthesis were able to speak longer sentences. This may be due to their prolonged maximum phonation time. Additionally, their voice was usually less affected by whistling.

This is the first study evaluating the efficiency of a customized tracheostomal prosthesis in laryngectomized patients.

The costs of the prosthesis are approximately 1700 Euros, and it has to be considered that a replacement is necessary approximately every 24 months.¹¹ In contrast, a surgical revision of the tracheostoma is durable but bears the general risks of an operation. The cost of a single operation is about 3000 Euros, if no following interventions are necessary. However, the effectiveness of such operations aiming to modify an irregularly formed tracheostoma has not been evaluated systematically with respect to voice production. Instead, some studies showed that surgical attempts like cleaving the sternocleidomastoid muscles in order to form a flatter tracheostoma are not efficient.¹² Other non-surgical methods are not as effective and sustainable. For example, the widely applied use of a fenestrated soft laryngectomy tube often causes irritation of the tracheal mucosa leading to granulations. The application of intraluminal devices that are fixed at the lip around the stomal edge is difficult as well, especially in irradiated patients. Here the skin has lost its elasticity and is further dilated through the button.⁸

Conclusion

According to the current study, a customized tracheostomal prosthesis is a safe adjuvant in laryngectomized patients with irregularly formed tracheostoma. Its efficacy was demonstrated by an improved voice function without negative effects on breathing. Therefore, the tracheostomal prosthesis represents an effective alternative to surgical revision.

Declaration of Conflicting Interests

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