

Success and Predictability of Provox Prosthesis Voice Rehabilitation

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Objectives: To determine the success rate and relating clinical factors of voice prosthesis rehabilitation and to analyze the discrimination ability of the multidimensional Harrison–Robillard–Shultz Tracheoesophageal Puncture Rating Scale (HRS Rating Scale).

Design: Prospective clinical study.

Setting: University Department of Otorhinolaryngology, Head and Neck Surgery, University Hospital Inselspital, Bern, Switzerland.

Subjects And Methods: From 1992 through 1998, 87 patients with advanced squamous cell carcinoma of the larynx and/or hypopharynx underwent primary tracheoesophageal puncture after total laryngectomy. Clinician otolaryngologists and speech/language pathologists independently used the HRS Rating Scale for success assessment of voice prosthesis rehabilitation.

Results: Age, sex, tumor localization, tumor stage, and radiation therapy had no influence on the success of voice prosthesis rehabilitation. Overall, voice rehabilitation success rates between 40% and 62% were achieved. Speech/language pathologists and clinician otolaryngologists evaluated the same patient group without significant statistical differences. The HRS Rating Scale analysis showed an equal distribution of the subscale parameter *care* in functional and nonfunctional speakers and a strong correlation between the subscale parameters *quality* and *use*.

Conclusions: Because of its safety and simplicity, tracheoesophageal puncture has become a state of the art method for voice rehabilitation after total laryngectomy. The short-term superiority of voice prosthesis in voice rehabilitation over esophageal speech rehabilitation must be seen in light of comparable long-term success rates of the 2 methods.

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THE LOSS of vocal function is generally considered the most disabling consequence of total laryngectomy. Many innovative surgical and nonsurgical procedures aim to restore the patient's verbal communication. Since the introduction of the first real tracheoesophageal valve prosthesis by Mozolewski in 1972, tracheoesophageal shunt techniques gained increasing acceptance because of the relative simplicity of the operation, the acquisition of speech, and better voice quality.¹ Maves and Lingeman² first described performing the primary tracheoesophageal puncture (TEP) at the time of laryngectomy. More than a dozen shunt valve prostheses were developed in the last 30 years.

With reported success rates ranging from 50% to 90%, the results of surgical rehabilitation by means of voice prostheses are, on the average, better than rehabilitation by esophageal speech, with a success rate of 33%.¹ The wide variability of reported success rates of the TEP procedure

may be explained by the lack of controlled success criteria. Almost every published study used its own success criteria. In 1992, Harrison and Robillard-Shultz introduced the Harrison–Robillard–Shultz Tracheoesophageal Puncture Rating Scale (HRS Rating Scale), a 15-point rating scale incorporating key elements of the definitions of use and quality of speech as well as ability to care for the fistula and the prosthesis from 15 reviewed studies.³ Between 1992 and 1998, we consequently applied the HRS Rating Scale to our laryngectomized and voice prostheses–implanted patients. The purposes of the present study are to determine the success rate and relating clinical factors of voice prosthesis rehabilitation and to analyze the discrimination ability of the multidimensional HRS Rating Scale.

RESULTS

CLINICAL RESULTS

Total laryngectomy was indicated in 30 (34%) cases due to hypopharynx carci-

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PATIENTS AND METHODS

PATIENTS

Between 1992 and 1998, 87 consecutive patients were primarily implanted with a Provox or Provox 2 (Atos Medical AB, Hörby, Sweden) voice prosthesis directly after total laryngectomy.^{4,5} This group consisted of 82 men and 5 women who ranged in age from 44 to 81 years, with a mean age of 62 years.

Before total laryngectomy, patients underwent psychological evaluation and had the opportunity to speak to voice-rehabilitated patients. Patients with anticoagulation and diseases or anomalies prone to putative prosthesis handling problems, such as Parkinson disease, were not considered for voice prosthesis implantation. Each patient received voice prosthesis rehabilitation training by speech/language pathologists 14 days after laryngectomy. The speech/language pathologists observed the patients for about 18 months and during this time assessed their condition using the HRS Rating Scale after 2, 6, 12, and 18 months. The otolaryngologist checked the patients when the voice prosthesis had to be changed, mostly owing to leakage. Before the prosthesis was removed, the patient's condition was scored using the HRS Rating Scale. All patients were independently seen by the speech/language pathologist and otolaryngologist.

Three rehabilitation times of voice prosthesis follow-up were arbitrarily defined: phase I covered months 0 through 9 after implantation; phase II, months 10 through 30; and phase III, months 31 through 72. Speech/language pathologists saw patients only in phases I and II, otolaryngologists in phases I, II, and III. According to the above-mentioned voice prosthesis follow-up procedure, speech/language pathologists saw the patients most often in phase I, while otolaryngologists compiled the most data in phase II. Moreover, all patients were seen in

a tumor follow-up program every 1 to 3 months after the end of the surgical treatment and/or radiotherapy.

For statistical analysis, the Mantel-Haenszel χ^2 test was used. For every patient, all ratings were summarized in a 2×2 cross-classification table, rater by ratings. The Mantel-Haenszel χ^2 test was used in all these tables to analyze the relation between rater and ratings. An unequal number of ratings from the speech/language pathologists and from the otolaryngologists were allowed.

THE HRS RATING SCALE

The HRS Rating Scale³ (**Figure 1**) defined success by the following 3 parameters: (1) *use* (degree to which tracheoesophageal speech is used as the main means of communication), (2) *quality* (the ease of voice production and its effect on intelligibility), and (3) *care* (the patients' independence from professional aid for maintenance of the fistula and the prosthesis). Each parameter was scored on a 1- to 5-point scale. The score of 1 or 2 was considered nonfunctional; a score of 3, marginally functional; and a score of 4 or 5, functional. The 3 scores for the subscale parameters *use*, *quality*, and *care* were then tallied for an overall score that ranged from 3 to 15. A total overall score of 12 or higher was established as the cutoff level for successful voice prosthesis rehabilitation.³ Because the Provox voice prosthesis was not to be self-removed and inserted by most patients, the maximum reachable score of the subscale parameter *care* in these patients was only 4 instead of 5 points. Either way, the cutoff level of 12 or more points for a functional speaker was maintained.

The study used 2 approaches for success assessment: (1) patient independent, ie, every prosthesis was scored according to the above-mentioned criteria and cutoff level and (2) all prostheses used in every single patient were scored according to the above-mentioned criteria and cutoff level. A successful patient voice rehabilitation was defined as successful voice prosthesis rehabilitation in more than 50% of the assessed prostheses.

noma and in 57 (66%) cases due to carcinoma of the larynx. Of the 87 patients in the sample, 8 (9%) had relapsing T2 tumors, 32 (37%) had T3, and 47 (54%) had T4. The N stage distribution included 49 patients (56%) with N0 lymph node status, 11 (13%) with N1, 25 (29%) with N2, and 2 (2%) with N3. While larynx carcinomas had N0 lymph node status in 64 patients (74%), hypopharynx carcinomas had N2 lymph node status in 59 patients (68%). Sixty-six patients (76%) received radiotherapy treatment. The Kaplan-Meier survival curve is shown in **Figure 2**. The 2-year survival rate of all patients was 70%, and the 5-year survival rate was 48%. Patients with hypopharynx carcinoma with N2 or N3 lymph node metastasis showed the worst prognoses.

VOICE PROSTHESIS REHABILITATION RESULTS

Based on the independent evaluation of speech/language pathologists and otolaryngologists, age, sex, tumor localization, tumor stage, and radiotherapy had no significant influence on the success of voice prosthesis rehabilitation. In phase I, the mean voice prosthesis life cycle was 4.2 months (2.14 prostheses in 9 months; 95% confi-

dence interval, 1.55-2.74 prostheses) for successfully rehabilitated patients and 3.6 months (2.5 voice prostheses in 9 months; 95% confidence interval, 1.09-3.91 prostheses) for unsuccessfully rehabilitated patients. In phase II, successfully rehabilitated patients had significantly shorter voice prosthesis life cycles than unsuccessfully rehabilitated patients. The cost to the patient per year after successful voice rehabilitation is estimated to be about \$600 (Euro \$640). Medical complications of voice prosthesis rehabilitation were scarce and showed no correlation with voice rehabilitation success: 1 patient experienced aspiration, 2 patients ingested the Provox prosthesis, 3 patients had aspiration pneumonias due to periprosthetic leakage, and peristomal infections occurred in 4 patients and fistula granulomas in 2 patients. No patient died from a complication or resulting treatment. Inner prosthesis seepage was not considered to be a complication but a normal wear effect. Periprosthetic leakage was observed mostly in the old Provox prosthesis. Spontaneous closure of the tracheoesophageal fistula with prosthesis in place occurred in 14 patients (8 functional and 6 nonfunctional speakers). Five functional and 1 nonfunctional speakers asked for insertion of a new prosthesis. Of the other 8 patients, 5 were

The Harrison–Robillard–Shultz TEP Rating Scale

Name: _____ Date of TEP: _____

Date	Months Post TEP	Rating Point	Use	Quality	Care	Overall	Success or Failure
_____	_____	0-11 wk: Immediate	_____	_____	_____	_____	_____
_____	_____	0-11 mo: Short Term	_____	_____	_____	_____	_____
_____	_____	>1 y: Long Term	_____	_____	_____	_____	_____

Reason for discontinued use of tracheoesophageal speech: _____ Date: _____

A. Use
The degree of use of tracheoesophageal speech.

1. Never uses tracheoesophageal speech (0%).
2. Uses tracheoesophageal speech less than 50% of the time.
3. Uses tracheoesophageal speech 50% to 80% of communicative attempts.
4. Uses tracheoesophageal speech manually occluded as main means of communication.
5. Uses tracheoesophageal speech with tracheostoma valve as main means of communication.

B. Quality
The ease of production and intelligibility of speech as determined by fluency and ability to occlude.

1. Unable to get sound; no use of pulmonary air for speech.
2. Voice is too strained or too breathy to permit functional use in conversation (may interfere with intelligibility); includes whispered speech.
3. Stoma, more often than not, is poorly occluded with resultant air escape that interferes with intelligibility or is a distraction to the listener.
4. Voice is mildly strained or mildly breathy, but continuous use in conversation is possible; occlusion is generally good; speech is intelligible.
5. Voice is easily produced; occlusion is good; speech is intelligible.

C. Care
Patient independence of medical or other health care professionals (includes speech/language pathologist, nurse, community worker) for 4 behaviors: (1) remove and insert prosthesis, (2) clean and sterilize prosthesis, (3) recognize problems and seek help immediately if needed, and (4) order supplies.

1. Unable to do any of the 4 behaviors.
2. Independent for any 1 of 4 behaviors.
3. Independent for any 2 of 4 behaviors.
4. Independent for any 3 of 4 behaviors.
5. Independent for all 4 behaviors.

Figure 1. The Harrison–Robillard–Shultz Tracheoesophageal Puncture (TEP) Rating Scale.³

nonfunctional speakers; the 3 functional speakers had learned esophageal speech in parallel and did not want a new voice prosthesis inserted.

EVALUATION BY SPEECH/LANGUAGE PATHOLOGIST

The 87 patients were seen 218 times by speech/language pathologists; 38 patients were seen only in phase I and 49 patients in phases I and II. Phase I includes 160 HRS Rating Scale assessments and phase II includes 58. The results of *voice prosthesis* assessments are given in **Table 1**. Speech/language pathologists observed a successful voice prosthesis rehabilitation for 34% of all voice prosthesis assessments in phase I, 64% in phase II, and 42% in both phases. The overall and corresponding phase I-II results of speech/language pathologist *patient* assessments are given in **Table 2**. Speech/language pathologists found that 29% of the individual patients showed a successful voice prosthesis rehabilitation in phase I, 65% in phase II, and 40% in phases I and II.

EVALUATION BY OTOLARYNGOLOGIST

The 87 patients were seen 425 times by otolaryngologists; 50 patients were seen only in phase I, 22 patients in phases

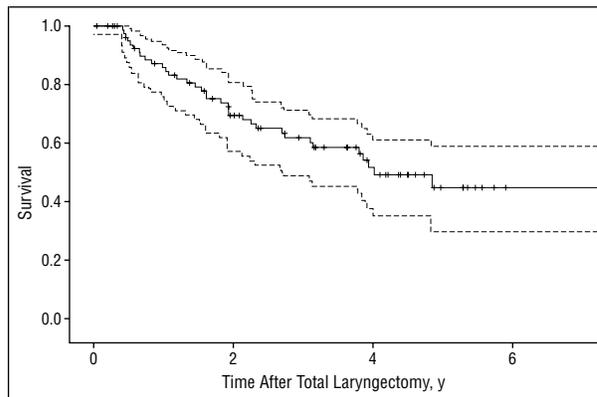


Figure 2. Kaplan-Meier proportion of survival curve with confidence intervals of 87 patients with advanced larynx and/or hypopharynx squamous cell carcinoma after laryngectomy.

Table 1. Voice Prosthesis Success Rates*

	Phase I	Phase II	Phase III	Overall
Speech/language pathologist	34 (55/160)	64 (37/58)	NA	42 (92/218)
Otolaryngologist	39 (69/176)	77 (136/177)	81 (58/72)	62 (263/425)

*Data are percentage of successful Harrison–Robillard–Schultz Rating Scale assessments (number of successful assessments/total number). NA indicates not applicable.

Table 2. Patient Success Rates*

	Phase I	Phase II	Phase III	Overall
Speech/language pathologist	11 (29)	32 (65)	NA	43 (40)
Otolaryngologist	17 (34)	15 (68)	11 (73)	43 (54)

*Data are number (percentage) of successful voice prostheses rehabilitation in patients. NA indicates not applicable.

I and II, and 15 patients in phase I, II, and III. Phase I includes 176 HRS Rating Scale assessments; phase II, 177; and phase III, 72. The overall and corresponding phase I-II results of otolaryngologist *voice prosthesis* assessments are given in Table 1. Otolaryngologists observed a successful voice prosthesis rehabilitation for 39% of all voice prosthesis assessments in phase I, 77% in phase II, 81% in phase III, and 62% in all phases. The overall and corresponding phase I-II results of otolaryngologist *patient* assessments are given in Table 2. A successful voice prosthesis rehabilitation was seen for 34% of the individual patients in phase I, 68% in phase II, 73% in phase III (not given in Table 2), and 54% in all phases.

The Mantel-Haenszel χ^2 tests comparing all data for each patient independently revealed no significant difference in HRS Rating Scale success assessments by speech/language pathologists and otolaryngologists (phase I, $P = .29$; phase II, $P = .81$). The P values are far from significant, so there is no hint of a difference in ratings between speech/language pathologists and otolaryngologists for phase I, with ratings of 87 patients, and even for phase II, with ratings of only 37 patients. According to

their higher voice prosthesis replacement frequency, patients with successful voice rehabilitation were seen more often by otolaryngologists. The success rate of phase II was statistically significantly higher than phase I in speech/language pathologist and otolaryngologist assessments ($P=.003$), and the success rate of phase III (assessed only by otolaryngologists) was statistically significantly higher than phase II ($P=.02$).

HRS RATING SCALE

Table 3 gives the rating scale distribution for the 3 HRS Rating Scale criteria *use*, *quality*, and *care* for speech/language pathologists and otolaryngologists. The criterion *care* shows a much narrower distribution for both assessors, resulting in a much lower standard deviation than the criteria *quality* and *use*.

Table 4 correlates the successful and unsuccessful event status based on the 3 criteria *quality*, *use*, and *care* to the rating scale sum distribution of 2 criteria: choosing a cutoff line between 7 and 8 points for an evaluation of success seemed to be the most appropriate approach. The contribution of the criterion *care* to an evaluation of success is minimal owing to the uniform rating scale distribution. Eliminating the subscale parameter *care*

Table 3. Rating Scale Distribution for the HRS Rating Scale Criteria Use, Quality, and Care*

HRS Rating Scale Score†	Use		Quality		Care	
	OL	SLP	OL	SLP	OL	SLP
1	17.2	30.3	14.6	19.9	0	3.2
2	11.3	22.0	8.2	23.1	10.8	5.5
3	8.2	6.9	8.5	8.3	9.2	6.9
4	54.5	39.0	31.5	18.1	74.1	81.2
5	8.9	1.8	37.2	30.6	5.9	3.2

*Data are percentage of assessments by otolaryngologists (OL) or speech/language pathologists (SLP) as specified.

†Harrison-Robillard-Schultz (HRS) Rating Scale scores 1 to 5 represent the subscore for each criterion.

would have changed the success status in 0 of 425 prostheses assessed by otolaryngologists and in 1 of 217 prostheses assessed by speech/language pathologists.

The criteria *use* and *quality* correlate strongly. For both otolaryngologists and speech/language pathologists, the Spearman rank correlation between use and quality is higher (correlation factor, 0.8 [otolaryngologists] and 0.87 [speech/language pathologists]) than between use and care (correlation factor, 0.66 and 0.43, respectively) and between quality and care (correlation factor, 0.64 and 0.42, respectively). Lacking either one of the criteria *use* and *quality* does not significantly change the evaluation of a successful voice prosthesis rehabilitation.

COMMENT

Over the past 2 decades, TEP has grown to become a state-of-the-art method for voice rehabilitation after total laryngectomy. In contrast to esophagus speech rehabilitation, TEP allowed patients speech and clear communication already by the fifth postoperative week after laryngectomy.⁶ The safety and simplicity of the surgical and follow-up procedure are confirmed by our data. Handling of the fistula and prosthesis can be learned well and often turns the motivated patient into a voice prosthesis expert. A prosthesis life cycle of about 4 months can be expected in successfully rehabilitated long-term patients. In our population, an in situ longevity of 10 or more months as described by Laccourreye et al⁷ was exceptional and mostly observed in unsuccessfully rehabilitated patients.⁸ As in other mechanical valves, use-induced wear may shorten voice prosthesis longevity. In several patients, a suddenly decreasing voice quality in functional speakers was correlated with local or metastatic tumor relapse.

The HRS Rating Scale was applied without problems by the 2 independent tester groups. No differences were observed in the results. The cutoff level proposed by Harrison and Robillard-Shultz is observed to be correct. Due to a narrow distribution in our patient group,

Table 4. Correlation of Voice Prosthesis Rehabilitation Success Status Based on 3 Criteria to the Rating Scale Subscore Distribution of 2 HRS Criteria*

HRS Rating Scale Score†	Use/Quality				Quality/Care				Care/Use			
	OL		SLP		OL		SLP		OL		SLP	
	+	-	+	-	+	-	+	-	+	-	+	-
1	0	0	0	1	0	0	0	0	0	0	0	0
2	0	59	0	43	0	0	0	6	0	0	0	6
3	0	14	0	20	0	37	0	9	0	39	0	10
4	0	21	0	30	0	25	0	8	0	25	0	12
5	0	16	0	8	0	20	0	35	0	27	0	45
6	0	32	0	17	0	21	0	37	0	38	0	38
7	0	20	1	6	0	36	0	16	2	27	6	9
8	100	0	33	0	98	23	26	12	204	6	79	5
9	132	0	504	0	147	0	64	2	51	0	7	0
10	31	0	4	0	18	0	2	0	6	0	0	0

*Data are number of 3 HRS criteria-based successful (+) or unsuccessful (-) event status assessments by otolaryngologists (OL) or speech/language pathologists (SLP) as specified.

†Harrison-Robillard-Schultz (HRS) Rating Scale scores 1 through 10 represent the combined subscore of 2 of 3 criteria.

the subscale parameter *care* did not really contribute to the evaluation of success of voice prosthesis rehabilitation. The excellent prosthesis handling and care attitude in our population could be a local geographical phenomenon. Also, the almost identical distribution of the subscale parameters *use* and *quality* may be attributed to our study group. More data are needed to evaluate the validity of the individual subscale parameters.

Success rates for voice prosthesis rehabilitation vary from 50% to 90% in the literature. The success variety may be explained by a bonus factor for the new method, a heterogeneous patient population, and a different and deficient evaluation system.⁹⁻¹⁸ The present study is the first to have applied the published multiparametric voice prosthesis HRS Rating Scale to TEP evaluation.^{19,20} The same approach is used by 2 independent tester groups. Moreover, the rated success is correlated with the individual patient and with the single prosthesis. Speech/language pathologists and otolaryngologists evaluated the same patient group without statistically significant differences. The overall *patient* success rates of our assessment groups are 40% (speech/language pathologists) and 54% (otolaryngologists), and the overall *voice prosthesis* success rates are 42% (speech/language pathologists) and 62% (otolaryngologists). Short-term success reports dominated the studies of the 1980s. Interestingly, in the literature, the long-term success is slightly lower than the short-term success. We observed no such decrease but instead found a learning curve with an increase of success over time. This complies with a shorter voice prosthesis longevity in the advanced functional speaker compared with the beginner. The 50% overall success rate of voice prosthesis rehabilitation is not far removed from the 33% success rate of esophageal speech rehabilitation, the classic long-term approach for voice rehabilitation.¹ However, 24% of functional speakers with spontaneous closure of the fistula renounced a new prosthesis implant and preferred esophageal speech rehabilitation of "less hassle." Their esophageal speech abilities developed in parallel to voice prosthesis rehabilitation.

In our estimation, voice prosthesis rehabilitation is the essential first step in voice rehabilitation after total laryngectomy. A functionally rehabilitated voice prosthesis speaker may more easily switch to esophageal speech. A special effort is required on the part of the speech/language pathologist to perform both the TEP as well as the esophageal speech rehabilitation.

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