A Decade of Postlaryngectomy Vocal Rehabilitation in 318 Patients

A Single Institution’s Experience With Consistent Application of Provox Indwelling Voice Prostheses

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Objective: To assess long-term results with consistent use of indwelling voice prostheses (Provox; Atos Medical AB, Hörby, Sweden) for vocal rehabilitation after total laryngectomy.

Design: Retrospective clinical analysis.

Setting: Comprehensive national cancer center.

Patients: Three hundred eighteen patients (261 men and 57 women; mean age, 62 years) from November 1988, through May 1999.

Intervention: Standard wide-field total laryngectomy (287 patients) or total laryngectomy with circumferential pharyngeal resection (31 patients), and 2700 prosthesis replacements. Prostheses remained in situ during 364 339 days (1000 patient-years).

Main Outcome Measures: Device lifetime, indications for replacement (device or fistula related), adverse events, and voice quality.

Results: Median patient-device follow-up was 67 months. Mean actuarial device lifetime for all indications for replacement was 163 days (median, 89 days). Main indications for replacement were device-related, ie, leakage through the prosthesis (73%), and obstruction (4%), or fistula-related, ie, leakage around the prosthesis (13%), and hypertrophy and/or infection of the fistula (7%). Adverse events occurred in 11% of all replacements in one third of the patients, mostly solvable by a shrinkage period, or adequate sizing and/or antibiotic treatment. Definitive closure of the tracheoesophageal fistula tract occurred in 5% of the patients. Significant clinical factors for increased device lifetime were no radiotherapy (P = .03), and age older than 70 years (P < .02). Success rate with respect to voice quality (ie, fair to excellent rating) was 88%, which was significantly influenced by the extent of surgery (P < .001).

Conclusion: The consistent use of indwelling voice prostheses shows a high success rate of prosthetic vocal rehabilitation, in terms of the percentage of long-term users (95%), and of a fair-to-excellent voice quality (88% of patients).


SINCE Theodore Billroth in 1873 in Vienna performed the first laryngectomy for cancer, the loss of the normal voice had been considered the predominating problem after this procedure for more than 100 years. Only after Singer and Blom introduced their first voice prosthesis in 1980, initiating prosthetic tracheoesophageal voice, better and more consistent results with respect to vocal rehabilitation of these patients have been achieved. Of the following 3 rehabilitation methods, ie, tracheoesophageal, esophageal, and electrolaryngeal voice, the first method is considered the most successful mode of restoring communication after a total laryngectomy. The use of various prostheses has become widely accepted in recent years. The following 2 different types of prostheses can be distinguished: nonindwelling devices, which can be removed and replaced by the patient, and indwelling voice prostheses, which have to be handled by a clinician. In 1988, the indwelling Provox voice prosthesis (Atos Medical AB, Hörby, Sweden) was developed in the Department of Otolaryngology-Head and Neck Surgery, the Netherlands Cancer Institute, Amsterdam. This voice prosthesis was designed to meet the criteria of low airflow resistance, optimal retention in the tracheoesophageal party wall, prolonged device lifetime, simple patient maintenance, and comfortable outpatient replacement. Since the last criterion was not optimally fulfilled, there was a need for further innovation. This resulted in a more...
PATIENTS AND METHODS

PATIENTS

From November 1988 through May 1999, 319 patients with laryngectomy underwent rehabilitation with an indwelling Provox voice prosthesis in the Netherlands Cancer Institute. One patient from a foreign country was unavailable for follow-up after replacement during a second-opinion visit. The data on the remaining 318 patients and the 3008 events with or without voice prosthesis are the basis of this retrospective study (the relevant clinical data are summarized in Table 1).

We included 261 men (82%) and 57 women (18%). Ages ranged from 29 to 88 years (mean, 61.9 years). The indication for total laryngectomy was a laryngeal carcinoma in 212 patients (67%), a hypopharyngeal carcinoma in 77 (24%), an oropharyngeal carcinoma in 13 (4%), a carcinoma of the cervical esophagus in 5 (2%), and a thyroid carcinoma in 5 (2%). The indication in the remaining 2% of patients was intractable aspiration after irradiation for a head and neck carcinoma in 4 patients, a tumor of the trachea in 1 patient, and a solitary colon carcinoma metastasis invading the larynx in 1 patient.

In this series, only 37 patients (12%) never received radiotherapy. Radiation preceded the total laryngectomy in 143 patients (45%). In most cases, the indication for this surgical procedure was recurrent disease after radiotherapy, with 5 cases of chondroradionecrosis of the larynx, 6 laryngeal or hypopharyngeal primary tumors in a previous radiation field, and 4 cases of intractable aspiration after irradiation for a head and neck carcinoma. Postoperative radiotherapy was given to 138 patients (43%), with a mean dose of 56.7 Gy (median, 60 Gy). Preoperative or postoperative radiotherapy was never considered a contraindication for primary tracheoesophageal puncture (TEP) and immediate voice prosthesis insertion. At the time of analysis (May 1999), 183 patients were still alive. The median survival since the date of operation was 7.0 years. Of the deceased patients, 60 died of recurrent disease, 6 of a secondary malignant neoplasm, and 69 of intercurrent disease.

SURGERY

The type of surgery was a total laryngectomy in 287 patients (90%), and a total laryngectomy combined with a circumferential pharyngeal resection in 31 patients (10%) (including simultaneous esophageal resection in 18). Sixty-six patients underwent surgery before the end of 1988, when the indwelling Groningen prosthesis mainly was used. These prostheses were converted to the Provox device between the end of 1988 and beginning of 1989, when indicated. Between the end of 1988 and 1999, the remaining 252 patients underwent surgery, during which time the indwelling Provox prostheses were used.

Primary TEP with immediate retrograde insertion of the voice prosthesis at the time of laryngectomy was applied in 277 patients (87%) (Provox in 163; Provox2 in 46; and before 1988, Groningen in 66). Of the 41 patients (13%) undergoing secondary TEP with immediate retrograde insertion of the voice prosthesis, a Provox was inserted in 31 (Provox in 23; Provox2 in 8), whereas before 1988, a Groningen prosthesis was placed immediately during the TEP procedure in 10 patients.

Surgical procedures to influence the toxicity of the pharyngoesophageal (PE) segment during total laryngectomy were performed in 142 patients, mainly in those undergoing operation in the last 10 years. A unilateral neurectomy of the pharyngeal plexus was performed in 136 patients (in combination with a cricopharyngeal myotomy in 37), and a cricopharyngeal myotomy only in 6 patients. The 43 myotomies were mainly performed if the surgeon deemed the upper esophageal sphincter to be hypertonic on palpation after removal of the larynx. During follow-up, 18 patients (6%) experienced a clinically relevant hypertonicity of the PE segment, which required treatment. Sixteen patients underwent a secondary long vertical PE myotomy (middle and inferior constrictor and cricopharyngeal muscles). In the last year, 2 patients were treated with botulinum toxin (Botox; Allergan, Nieuwegein, the Netherlands, injections for this indication).

A circumferential reconstruction of the pharynx and/or esophagus was performed in 31 patients, using a jejunal

comfortable anterograde replacement method of the adapted, second-generation device, Provox2, as an alternative for the more uncomfortable retrograde replacement of the original Provox prosthesis, performed using a special disposable guidewire.10,11

We herein assess the clinical experience in our institute during the last decade with the consistent use of both indwelling voice prostheses for vocal rehabilitation after total laryngectomy in a large, unselected cohort of patients. We analyze the favorable long-term results, with special attention to the importance of adequate management of the adverse events inevitably encountered with every prosthetic rehabilitation method.

RESULTS

This retrospective series consists of 318 patients (Table 1) with 3008 evaluable periods. In 1988-1989, there were 164 periods when a Groningen prosthesis was replaced by a Provox device, which were excluded from further analysis. There were 144 periods without voice prosthesis, eg, shrinkage of the TE fistula or temporary or definitive closure. Finally, there were 2700 periods with a Provox voice prosthesis in situ, at the end of which the existing voice prosthesis was replaced by a new device, or was still in situ at the end of follow-up. The median follow-up of the 318 patients in the observation period was 67 months. Of the 183 patients alive at the end of follow-up (May 1999), 173 patients (95%) were still using a Provox or Provox2 voice prosthesis. In total, this series consists of 364339 days with an indwelling voice prosthesis in situ (approximately 1000 patient-years).

Most patients needed several prostheses during the 10-year observation period, with a mean of 8.5 (range, 1-55); one exceptional patient needed 114 prostheses in 10 years. The mean actuarial device lifetime during the complete period was 163 days. Figure 1A shows the mean device lifetime per patient for all replacement indications (in 3-month periods): in 30% of the patients
devices were replaced with a mean device lifetime of less than 3 months; in 40%, from 3 to 6 months; and in 30%, longer than 6 months. The median actuarial device lifetime for the complete period was 89 days. Figure 1B shows the median device lifetime per patient for all replacement indications (in 3-month periods): in 43% of the patients, devices were replaced with a median device lifetime of less than 3 months; in 31%, from 3 to 6 months; and in 24%, longer than 6 months.

Table 2 gives an overview of the different indications for replacement of the 2700 voice prostheses used in the study period (for Provox and Provox2). At the end of the follow-up, 297 prostheses were still in use, 2396 prostheses were replaced, and in 7 replacements the indication was not known in retrospect. There appeared to be no difference in the replacement indications of the first (primarily) inserted prosthesis vs that of the following device, ie, device- and fistula-related indications occurred at the same frequencies in the first indwelling voice prosthesis.

**VOICE QUALITY**

The assessment of the voice quality was performed at each replacement session, using the following 5-point scale rating: 5 points for excellent, 4 for good, 3 for fair, 2 for poor, and 1 for no voice. Excellent and good indicate a fluent and intelligible voice used under all social circumstances, and excellent was used only when the patient’s voice approached normalcy. Fair indicates a somewhat less satisfactory voice that was still used as the main method of communication. Poor indicates a voice with unsatisfactory quality that was not useful as a primary communication method. To allow the use of the voice quality in multivariate statistical analysis, a mean voice quality (MVQ) score was established by calculating the sum of the individual ratings (1-5) during the whole study period, divided by the number of voice-quality evaluations per patient. Mean scores were rounded (excellent, ≥4.5; good, 3.5-4.4; etc).

**STATISTICAL METHODS**

The main objective of the statistical analysis was to investigate the relation between several patient- and treatment-related factors and lifetime of the Provox device. A Provox was replaced because of device- or fistula-related problems. Both end points were considered separately. Life-times not ending with the particular end point and ongoing lifetimes at the end of the observation period were censored. Since the number of device lifetimes within patients varied from 1 to 114, the within-patient dependency of device lifetimes was analyzed by means of a proportional hazard model including y-distributed frailty. The model was extended by the following covariates: sex, age, myotomy (yes or no), neurectomy (yes or no), type of operation (larynx or laryngopharynx), radiotherapy (no, preoperative, or postoperative), and type of Provox device. The analyses were performed using the frailty function written for S-Plus by Therneau. The association of various covariates with the mean voice quality was tested by means of the Kruskall-Wallis test.

**DEVICE-RELATED INDICATIONS FOR REPLACEMENT**

The main reason for replacement was leakage of fluids through the prosthesis (1746 [73%] of 2396 replacements, in 232 patients [73%]). Improper closure of the valve occurred, invariably due to Candida deposit on the device. Increased pressure, another device-related end point, was less frequently observed (102 times [4%], in 70 patients [22%]). The median time to both device-related problems was 111 days.

Time to device-related problems was longer for the Provox than for the Provox2 device. Median actuarial device-related lifetime was 120 and 92 days, respectively (P < .001). Radiotherapy (preoperative and postoperative) was negatively associated with time to device-related problems. In patients not undergoing irradiation, median device lifetime was 162 days compared with 111 days in patients undergoing preoperative irradiation (P = .03) and 102 days in patients undergoing post-

graft interposition in 8, a gastric pull-up in 18, and a radial forearm flap in 3. Because of flap necrosis, a second reconstruction procedure was necessary in 2 patients; a jejunal graft reconstruction was converted into a gastric pull-up in one patient, and a proximal gastric pull-up necrosis was reconstructed with a radial forearm flap on top of the gastric transfer in the other.

**VOICE PROSTHESSES**

Before 1988, the indwelling Groningen voice prosthesis was used. At the end of 1988, there was a switch to the indwelling Provox, developed in our institute, followed by the indwelling Provox2 in 1996, which replaced the original Provox device in most cases. The replacement of the first 2 devices requires a retrograde procedure, whereas the latter device is replaced in an anterograde manner.

At each replacement session, a special form was used by the otolaryngologist to collect the relevant data of the indications for replacement: technical aspects, size, and serial number of the prosthesis; presence of fistula problems; macroscopic signs of Candida growth on the prosthesis; medications; and voice quality. The indications for replacement of the prosthesis were considered to be device- or fistula related. The device-related indications included leakage through the valve and obstruction of the prosthesis leading to an increased airflow resistance during voicing. The fistula-related indications included leakage around the prosthesis, inaccurate sizing, hypertrophy or infection of the TE fistula, and spontaneous extrusion or loss of the prosthesis. In the fistula-related category, cases were also included in which the prosthesis was removed for definitive closure of the TE fistula, eg, surgical revision of the tracheostoma, a secondary primary tumor in the stomal region, on request of the patient, or because of a severe tracheitis.

Adverse events were defined as fistula-related problems not manageable by simple prosthesis replacement, ie, leakage around the prosthesis not solvable by downsizing the device, hypertrophy and/or infection of the TE fistula, and spontaneous extrusion or loss of the prosthesis.
operative irradiation ($P<.02$). Age also appeared to be associated with time to device-related replacement. In patients younger than 60 years, median device lifetime was 99 days; in patients aged 60 through 70 years, 111 days; and in patients older than 70 years, 147 days. Device lifetime in patients older than 70 years especially was significantly longer compared with that in the youngest group ($P<.02$). Other factors like sex, tumor type, and stage of disease were not significantly associated with time to device-related problems.

**FISTULA-RELATED INDICATIONS FOR REPLACEMENT**

Replacement was required for leakage around the prosthesis in 315 occasions (13% of 2396 replacements) in 133 patients (42%). Downsizing the prosthesis solved this problem in most replacements (237 times [10%] in 76 patients [24%]). Leakage around the prosthesis not solvable by simple downsizing was observed in 81 replacements (3%) in 57 patients (18%). This adverse event was treated mostly with short-term removal of the prosthesis to allow for spontaneous shrinkage of the fistula tract. One period of shrinkage was applied to solve this problem in 41 of the 57 patients, and in 12 patients, 2 periods were applied. Of the remaining 4 patients, 2 had 3 and 2 had 5 episodes of removal and shrinkage. The median duration of removal of the voice prosthesis was 6 days. In the last few years of the study, applying a purse-string suture around the fistula tract often preceded the option of removal of the prosthesis and shrinkage, and this technique was used in 9 of the patients undergoing recurrent shrinkage. In an additional 4 patients, collagen was injected into the fistula tract according to the technique described by Remacle et al.14 Closure due to untreatable leakage around the prosthesis was ultimately necessary in 19 of these 57 patients (6% of 318 patients). In only 1 patient, this was a definitive procedure, whereas the remaining 18 patients underwent a new TEP procedure.

A less frequent fistula-related reason for replacement was inaccurate sizing (27 times [1%] in 24 patients [7%]). In these cases, patients came back to the clinic because the prostheses felt uncomfortable, which was always solvable by simply upsizing or downsizing the device.

Hypertrophic scarring and/or infection of the TE fistula as indications for replacement were observed 162 times (7%) in 61 patients (19%). These adverse events were solved by upsizing the prosthesis, treatment with antibiotics, and/or resection of granulation tissue during outpatient visit in most cases. On 15 occasions in 14 of the 61 patients, the problem could not be solved by one of these measures and removal of the prosthesis was necessary, which led to a spontaneous closure of the fistula tract. This was a definitive situation in 1 patient, whereas the remaining 13 patients underwent a new TEP procedure.

The last category of adverse events was spontaneous loss of the device, which occurred 14 times (1% of all occasions in 14 patients [4%]). There were no cases of aspiration, and in none of these cases did device loss result in medical complications.

### Table 1. Clinical Data, 1988 to 1999†

<table>
<thead>
<tr>
<th>Characteristic Finding</th>
<th>Patients (N = 318)</th>
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<tbody>
<tr>
<td>Sex, No. (%)</td>
<td>Male 261 (82)</td>
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<td>Female 57 (18)</td>
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<td>Age range (mean), y</td>
<td>29-88 (61.9)</td>
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<td>Indication for laryngectomy, No. (%)</td>
<td>Laryngeal carcinoma 212 (67)</td>
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<td></td>
<td>Hypopharyngeal carcinoma 77 (24)</td>
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<td></td>
<td>Oropharyngeal carcinoma 13 (4)</td>
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<td></td>
<td>Miscellaneous 16 (5)</td>
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<tr>
<td>Treatment, No. (%)</td>
<td>Total laryngectomy 287 (90)</td>
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<td></td>
<td>Total laryngectomy and circumferential pharyngeal resection 31 (10)</td>
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<td></td>
<td>Reconstructions 31 (10)</td>
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<td></td>
<td>Jejunal graft interposition 8 (3)</td>
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<td></td>
<td>Gastric pull-up 18 (6)</td>
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<td></td>
<td>Radial forearm flap 5 (2)</td>
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<td></td>
<td>No radiotherapy 37 (12)</td>
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<tr>
<td></td>
<td>Radiation before total laryngectomy 143 (45)</td>
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<td></td>
<td>Postoperative radiotherapy 138 (43)</td>
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<td></td>
<td>Vocal rehabilitation, No. (%)</td>
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<tr>
<td></td>
<td>No. of periods 3008</td>
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<tr>
<td></td>
<td>With Provox prostheses 2700</td>
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<tr>
<td></td>
<td>Without voice prosthesis 144</td>
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<tr>
<td></td>
<td>With Groningen prosthesis 164</td>
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<tr>
<td></td>
<td>Follow-up Days with Provox device in situ 364 339 (1000 patient-years)</td>
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<tr>
<td></td>
<td>Patients alive with voice prosthesis in situ 173 (of 183 [95%])</td>
</tr>
</tbody>
</table>

†November 1998 through May 1999. PE indicates pharyngoesophageal.

Miscellaneous indications occurred 30 times (1%) in 27 patients (8%). These indications included tracheitis, stoma revision, and endoscopic dilations.

### ADVERSE EVENTS

Some patients experienced 1 or more of these adverse events at different times during their follow-up. The 57 cases of leakage around the prosthesis, the 61 cases of hypertrophy and/or infection, and the 14 spontaneous losses occurred in 102 patients (32%). In 2 patients, this led to a definitive closure of the TEP. Two hundred fifty-seven replacements (11%) were considered due to adverse events, including 81 instances due to leakage around the prosthesis not solvable by downsizing, 162 due to hypertrophy and/or infection events, and 14 due to spontaneous losses. In Figure 2, an overview is given of all patients with respect to fistula-related adverse events.
No significant difference between Provox and Provox2 in the incidence of the various indications for replacement could be observed (Table 2). However, the occurrence of fistula-related indications for replacement with Provox2 was significantly earlier than that for Provox (57 vs 78 days after replacement; \( P = .02 \)). The association of radiotherapy with device lifetime regarding fistula-related indications was not consistent. Although previous radiotherapy seemed to be associated with this \( (P = .05) \), time to replacement after postoperative radiotherapy was not affected compared with no radiotherapy. Other factors such as sex, age, tumor type, stage of disease, myotomy, or neurectomy showed no statistically significant association with fistula-related indications for replacement.

**SIZING OF THE VOICE PROTHESIS**

On 1530 occasions (64%), the size of the replacing prosthesis was the same as the one removed. A device 1 size shorter was inserted on 343 occasions (14%), 2 sizes shorter on 57 occasions (2%), and 1 or 2 sizes longer on 466 occasions (19%).

**DEFINITIVE CLOSURE OF THE TE FISTULA**

During the study period, 17 patients (5%) had a definitive closure of their TE fistula. As mentioned above, 1 patient had a surgical closure because of untreatable leakage around the prosthesis. Another patient had a definitive spontaneous closure after a period of severe hypertrophy of the tissue around the fistula tract. Recurrence or second primary tumor around the TE fistula was the reason for closure in 4 patients; good communication by electrolaryngeal or esophageal speech, in 5 patients. One patient requested a permanent closure because of the necessity for frequent replacements due to uncontrollable Candida overgrowth. In 2 patients, a stenosis or spasm of the PE segment was the reason for closure. In 3 patients, the reason could not be identified in retrospect.

**VOICE-QUALITY ASSESSMENT**

Voice-quality assessments were available for 268 patients (range of assessments, 1-113), allowing calculation of an MVQ score. In 3% of the patients, the MVQ score was excellent; in 51%, good; and in 34%, fair. In 7% of the patients the MVQ score was poor, and in 5% no voice was achieved. Owing to the small numbers, the voice results in patients who underwent a secondary myotomy (n=16) or chemical denervation of the constrictor pharyngeus muscles with Botox (n=2) were not analyzed separately. The improved ratings after the treatment are included in their overall MVQ score.

The MVQ scores were significantly related to age; patients older than 70 years had a lower MVQ score (3) than patients younger than 60 years (4) and than patients aged 60 to 70 years (4) \( (P < .001) \). The MVQ score also showed a significant relation with the extent of the surgery. Patients who underwent a total laryngectomy only had a better voice quality (MVQ score, 4) compared with patients needing a circumferential pharyngeal reconstruction (MVQ score, 3) \( (P < .001) \). Sex, radiotherapy, and tonicity control procedure showed no significant relation with the MVQ score.

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**Table 2. Indications for Replacement of Voice Prosthesis**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Prosthesis Type</th>
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<tbody>
<tr>
<td></td>
<td>Provox</td>
</tr>
<tr>
<td>Leakage through prosthesis</td>
<td>1213 (73)</td>
</tr>
<tr>
<td>Increased pressure</td>
<td>79 (5)</td>
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<tr>
<td>Leakage around prosthesis</td>
<td>218 (13)</td>
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<tr>
<td>Inaccurate size</td>
<td>19 (1)</td>
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<tr>
<td>Hypertrophy and/or infection</td>
<td>107 (6)</td>
</tr>
<tr>
<td>Spontaneous loss</td>
<td>11 (1)</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>21 (1)</td>
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<tr>
<td>Subtotal No.</td>
<td>1668</td>
</tr>
<tr>
<td>No. missing</td>
<td>7</td>
</tr>
<tr>
<td>Prosthesis still in situ</td>
<td>138</td>
</tr>
<tr>
<td>Total No.</td>
<td>1813</td>
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</tbody>
</table>

*Data are given as number (percentage) unless otherwise indicated.*
A decade of consistent application of indwelling voice prostheses (Provox) has resulted in a substantial series of patients and a wide range of informative clinical observations, confirming the high probability of successful long-term speech acquisition after total laryngectomy. Although this patient population is clinically comparable to those in many other reports on prosthetic voice rehabilitation, to our knowledge, this is the largest series in the literature. Most other studies consist of fewer than 100 patients, and few reports describe more than 100 patients. During the observation period of 10 years with a median follow-up of 67 months, which is far longer than the average of 2 years in most other reports, indwelling voice prostheses were in situ during 364,339 days (1,000 patient-years).

The success rate of prosthetic voice is not uniformly assessed in the literature. Some have based their assessment on a combination of whether the prosthesis was used at all, the quality of speech, and whether the voice prosthesis was used as a primary means of communication (initial success rate, 84%; long-term, 74%). Others have used the criteria proposed at the 1988 Third International Congress on Voice Prosthesis and reported 95% with functional speech. Others have used the criteria proposed at the 1988 Third International Congress on Voice Prosthesis and reported 95% with functional speech. However, in our study, only 5% of the patients had a definitive closure of the fistula for different reasons, which means that in 95% of the cases the device stayed in situ long term. Based on a mean voice quality score, the success rate (88% fair to excellent voice) equals the better results reported by others and confirms the previously described results of this institute.

However high the success rate of vocal rehabilitation, as with any use of prosthetic appliances in the human body, the use of indwelling prostheses may give rise to adverse events. In the few reports in the literature carefully evaluating complications of prosthetic vocal rehabilitation, only 1 distinguished between failure of the prosthesis and fistula-related problems. They used the term prosthesis-related complications, which included more or less the same indications as our fistula-related adverse events, such as granulation, hypertrophy, widening of the fistula, leakage around the prosthesis, and loss of the voice prosthesis. Since we separated the results in device- and fistula-related indications for replacement, we shall discuss them in the same order.

**DEVICE-RELATED INDICATIONS**

Leakage through the prosthesis was the reason for replacement in three quarters of both replacements and patients, and was most likely to be associated with *Candida* deposits on the valve, as has been reported by many others. This was a clinical diagnosis in the beginning of the series often substantiated by microbiological cultures. Although it was not documented, we have observed some improved device lifetimes in individual cases by prescribing antifungal agents such as nystatin and fluconazole (Diflucan), as described by others. The negative influence of radiation on the device lifetime, due to possible microbiological pharyngeal alterations that potentially promote *Candida* growth, as suggested previously, can still be supported by the present study.

The differences found in the device lifetimes of Provox and Provox2 in our retrospective study are statistically significant and more pronounced than the findings in a recent prospective multi-institutional trial. However, in that study, there was a trend toward a shorter device lifetime for Provox2. These differences are difficult to explain merely on the basis of design changes necessary to make an easy anterograde replacement of Provox2 possible. We believe that the success of the replacement system undermines the device lifetime to some extent. Because the retrograde replacement procedure is uncomfortable for many patients, the alternative of the anterograde Provox2 replacement will not restrain the patient from coming to the outpatient clinic for a quick and more comfortable solution to a leaking prosthesis. The fact that there is a full reimbursement

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Figure 2. Overview of adverse events with respect to leakage around the prosthesis and hypertrophy and/or infection problems. Among patients with hypertrophy and/or infection, leakage around the prosthesis, or spontaneous loss (n=14 events; not shown in figure), adverse events occurred in 102 (32%) of the patients (257 [11%] of all replacements).
not be done too rapidly and should not exceed more than 1 shaft length, to prevent too much pressure on the tissues.

Removal of the prosthesis to allow the fistula to shrink was reported in some studies, but an indication of how long the fistula should be left alone or whether to close the tract was not given.\textsuperscript{17} One shrinkage period (median, 6 days) was sufficient in most of our cases; recurrence of this problem was only seen in a few. During the shrinkage period, the patient needs a nasal feeding tube and, sometimes, a cuffed tracheal cannula. Little success was obtained by injection of collagen.\textsuperscript{18} More recently, a submucosal purse-string suture around the TE fistula tract in recurrent cases precedes the shrinkage option. This is a relatively simple procedure, using an atrumatic 3 × 0 polyglactin 910 (Vicryl) suture under local anesthesia and providing an instant solution, which avoids nasogastric tube feeding and use of a cannula. Ultimately, a surgical closure of the TE fistula because of un-treatable leakage around was needed in 19 of these 57 patients, but only in 1 patient was no repuncture performed afterward. The surgical procedure in all cases consisted of a separation of the tracheoesophageal party wall via an incision at the cranial mucocutaneous border of the stoma, a sectioning of the fistula tract, and, without interposing grafts, closure of the esophagus in 2 layers and the trachea in 1 layer.

Although the device lifetime of the Provox2 in this series was shorter than that of the first model, the relative incidence of the indication of leakage around of Provox2 equaled that of Provox. This supports our suggestion that there is no widening of the fistula tract by the anterograde replacement of the prosthesis. Even the increased frequency of replacements did not intensify the number of cases of atrophy or hypertrophy and/or infection of the fistula wall. The earlier occurrence of the fistula-related adverse events with Provox2 still might be explainable by the decreased discomfort of the anterograde replacement method, which may have motivated the patient to report to the clinic earlier.

Hypertrophy, scarring, and/or infection of the TE fistula (19%) were seen in a comparable percentage in our population as was atrophy (18%). Manni and Van den Broek\textsuperscript{20} reported granulation and infection in 23 of their 132 patients (17%), and Aust and McCaffrey\textsuperscript{23} handled partial retraction, granulation tissue, and localized cellulitis in 21% of their patients. Comparable in all studies was the minimal number of patients in whom the fistula had to be closed definitively. The fistula closures in our infection cases were all spontaneous after removal of the prosthesis from the TE fistula tract.

The frequency of these adverse events could have been underestimated in our study, as our data are based on carefully and uniformly registered replacements, whereas hypertrophy solved by antibiotics or cautereization only was not registered separately. However, once the TE fistula had the tendency to granulate or to retract into the mucosa during regular follow-up visits, or when the patient complained about higher pressure during speech as a result of esophageal mucosal swelling, we upsized the prosthesis to prevent actual granulation formation or infection. Because hypertrophy was registered as the indication for replacement, and actually this

**Figure 3.** Size of replacement prostheses relative to the original. 1 indicates same size (65%); 2, 1 size shorter (14%); 3, 2 sizes shorter (2%); and 4, 1 or 2 sizes longer (19%).

for these devices in the Netherlands may also contribute to this phenomenon.

Frequent replacement as a result of valve dysfunction by Candida overgrowth could have dietary reasons. Busscher et al\textsuperscript{29} reported a prolonged device lifetime during in vitro experiments with a daily intake of buttermilk, although in vivo results, aside from some anecdotal reports by patients, are still lacking. In our retrospective study, it was not possible to address this issue.

**FISTULA-RELATED INDICATIONS AND ADVERSE EVENTS**

Concerning the fistula-related indications leading to replacement, leakage around the prosthesis appeared to be a relatively minor problem (13% of all replacements), despite being seen at some time in the follow-up in 42% of the patients. The few studies mentioning this issue report this problem in 7% to 27% of the replacements.\textsuperscript{17,18,24,30,31} Leakage around the device as a replacement indication was not seen more frequently in the first prosthesis inserted during surgery. It could be assumed that the immediate insertion of an indwelling device during the TEP procedure, as is the custom in many European clinics for the past 20 years,\textsuperscript{7,21} would lead to more frequent replacements due to leakage around the device. However, it is clear from our data that the normal subsiding of the surgical edema and consequent shortening of the fistula tract did not cause more problems in this respect in the first device.

In our experience, simple downsizing of the voice prosthesis was the solution in most of the “leakage around” cases. Therefore, it is important never to replace the voice prosthesis automatically with one of the same size, but to check the proper length first, avoiding the pistoning effect of too long a prosthesis. As can be concluded from the results shown in **Figure 3**, one third of the replacements required another size. In our experience, downsizing should not be done too rapidly and should not exceed more than 1 shaft length, to prevent too much pressure on the tissues.
was not (yet) the case, this could have resulted in some overestimation.

Overlooking the fistula-related indications, 32% of our total population (representing 11% of all replacements) occasionally experienced an adverse event, which definitively led to fistula closure in only 2 patients (0.6%). As discussed above, these results are comparable to those of other studies. However, accurate sizing and an adequate approach to infection problems with the use of antibiotics and/or antifungal medication can prevent many adverse events. One of the problems discussed in recent years is the existence of gastroesophageal reflux disease in patients undergoing laryngectomy. Although there seems to be a relation to postoperative wound healing problems,31 there is at present no clear evidence that gastroesophageal reflux disease has an influence on prosthetic- or fistula-related device lifetime.

DEVICE LIFETIME

As discussed before, there are many influencing factors in the assessment of the device lifetime of voice prostheses. However, interpretation of the results can be difficult, as device lifetimes have not always been calculated in a consistent manner. In the past, authors have reported on mean device lifetime.18,19,23-26 However, it is probably more realistic to report on median survival times. Especially when interpreting such a high number of patients and replacements, the distribution of the data has to be taken into account. In addition, as also mentioned by others, the last valve has to be censored, since the exact lifetime of that valve is not yet known, ie, the valve has not failed at the time of analysis.17 In our study, the mean value (163 days) is comparable to that reported by others (range, 148-311 days)18,19,23,24,26 and to the 141 days reported earlier.25 The median value of 89 days is lower than the values reported earlier.11 Again, the issue of reimbursement should be taken into account. The fact that, in the Netherlands, costs of prostheses will be covered by most of the insurance companies will not stimulate an increased device lifetime either.

VOICE QUALITY

Tracheoesophageal speech is considered the first method of communication in patients who have undergone laryngectomy and far superior to esophageal voice. Subsequently, the rating of voice quality is of less concern in these patients and is still somewhat difficult to quantify.38 The voice quality assessment used in our institute is simple but consistent, as there is a relatively intensive follow-up performed by the same otolaryngologists, using a standard form to collect the relevant data. The 88% fair-to-excellent voice quality found in our study is also well in concordance with the 84% fair-to-good result reported by the patients in an earlier study.33 Despite the consequent assessment, we have to consider the results with some reservation. Perceptual analysis is considered the gold standard, but it is rather labor intensive and not very suitable for everyday practice. Compared with our rather simple subjective assessment, Delsupehe et al33 described a more elaborate evaluation of prosthetic voice, analyzing 4 objective and 8 subjective voice variables. With their method, they also found that the extent of surgery, total laryngectomy vs laryngectomy combined with partial pharyngectomy, influenced the voice quality. We subscribe to the explanation that the preservation of the hypopharynx, which means a larger vibrating mucosa segment, results in a better voice.

In contrast to the device lifetime and the incidence of adverse events, the voice quality is somewhat reduced in the group of patients older than 70 years. This result contradicts previous findings by Hilgers and Balm,25 although the age limit used then was 80 years, and the statement was also referring to device lifetime and adverse events, which still are not different in the different age groups. Using nondwelling prostheses, Shultz and Harrison22 associated this age factor (age >60 years in their study) with the difficulty of stomal occlusion, and with a combination of hearing loss and stomal noise during speech. In addition to hearing loss, a decreased ability or willingness to learn is another possible explanation.39 A solution to the deterioration of the dexterity with age could be the use of the valved Provox HME,37 which has been shown to improve the ease of digital stomal occlusion, and thus the voice quality.38,39

CONCLUSIONS

The results of our 10-year follow-up study demonstrate that the consistent application of indwelling prostheses such as the Provox system can result in a high percentage of successful vocal rehabilitation. In rating successes, it is important to differentiate between device-related indications for replacements and replacements due to fistula-related adverse events, and to evaluate possible influencing factors. By an intensive and consequent multidisciplinary approach to problems, most of the inevitable adverse events can be solved adequately, minimizing the discomfort for the patient who has undergone laryngectomy and uses an indwelling voice prosthesis.

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