Multi-institutional Assessment of the Provox 2 Voice Prosthesis

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Objectives: To verify the initial results of a new anterograde replacement method of the second-generation indwelling Provox voice prosthesis, Provox 2 (Atos Medical AB, Horby, Sweden), and to determine its device life.

Design: Nonrandomized, multi-institutional, controlled clinical trial.

Setting: Four academic hospitals and/or comprehensive cancer centers in the Netherlands.

Patients: Two hundred thirty-nine consecutive patients who had undergone laryngectomy and were visiting the outpatient clinic for replacement of their voice prosthesis.

Intervention: Anterograde replacement of the Provox 2 voice prosthesis.

Main Outcome Measures: Evaluation of ease of use by the medical professional and appreciation by the patients, by means of structured questionnaires; comparison of device life between the original Provox and the new Provox 2 voice prosthesis in a subset of patients.

Results: Voice prostheses replaced were Provox (n = 188), Groningen (Medin, Groningen, the Netherlands) (n = 47), and Nijdam (Medin) (n = 4). Anterograde replacement of Provox 2 was always possible. The new anterograde method was preferred by the medical professionals in 97.1% of cases and by 93.7% of the patients, who reported significantly reduced discomfort (P < .001). There was no significant difference in device life between Provox and Provox 2 (median, 125.5 and 104 days, respectively). In 57.5% of patients, the Provox 2 device life was shorter and in 42.5% it was longer (sign test, P = .09).

Conclusions: The results of the initial study concerning ease of use for the medical professionals and decreased discomfort for the patients of the new anterograde replacement procedure of the Provox 2 prosthesis were confirmed. The device life of Provox and that of Provox 2 were comparable, despite the alterations needed to optimize the Provox 2 prosthesis for the anterograde procedure.


The most obvious consequence of total laryngectomy is the loss of laryngeal speech. Of the different methods of speech rehabilitation, the best voice quality is achieved by prosthetic voice restoration. Primary placement of a voice prosthesis at the time of total laryngectomy is the method of choice in the Netherlands. The most commonly used device in this country is the indwelling, low-resistance Provox voice prosthesis. The long-term results obtained with the Provox rehabilitation system are positive. Approximately 80% of the patients report fair to good intelligibility both in face-to-face conversations and in speaking on the telephone. The only maintenance required from the patient is the daily brush-cleaning of the device.

An indwelling voice prosthesis is not a permanent implant, but requires periodic replacement (on average, after 3-5 months). The most frequent indication for replacement of any voice prosthesis is incompetence of the valve, mainly because of Candida overgrowth, causing leakage of fluids through the prosthesis. The replacement method for the original Provox voice prosthesis is a multistep procedure, consisting of the retrograde passage of a special disposable guidewire through the prosthesis in situ, via the pharyngoesophageal segment out of the mouth, removal of the tracheal flange, and subsequent removal of the remainder of this prosthesis with the guidewire via the pharyngoesophageal segment out of the mouth, followed by the introduction of the new prosthesis through
PATIENTS AND METHODS

During a period of 7 months, 239 consecutive patients, visiting the outpatient clinic for replacement of their voice prosthesis, were accrued into a prospective, clinical study assessing the anterograde replacement method and the Provox 2 (Atos Medical AB, Horby, Sweden) device life. For the device analysis, only patients who previously had experienced at least 2 replacements of the voice prosthesis because of incompetence of the valve were included. The study protocol was approved by the medical ethical committees of the 4 participating institutions, all in the Netherlands. Patients were accrued from and treated in the University Hospital Dijkzigt and Dr Daniel den Hoed Cancer Centre in Rotterdam, University Hospital Nijmegen in Nijmegen, University Hospital Maastricht in Maastricht, and the Netherlands Cancer Institute in Amsterdam, after having given informed consent. Minimum follow-up was until the or at least 6 months after the insertion, of the Provox 2 prosthesis.

Patient characteristics are shown in Table 1. Eighty-five percent of patients were male and 15% were female. The mean age was 65.3 years (range, 27-87 years). The median follow-up since total laryngectomy was 4.6 years (range, 1-16 years). Ninety-one percent of the patients underwent locoregional radiotherapy preoperatively or postoperatively. Thirty-seven patients (15.5%) were reported to have had a pharyngeal stenosis. If a patient was using some form of anti-Candida treatment, this medication was not changed and was continued after insertion of the Provox 2 device.

The prostheses removed in this study were 188 Provox devices, 47 Groningen prostheses (Medin, Groningen, the Netherlands),10 and 4 Nijdam prostheses (Medin).11 Patients with a Groningen or a Nijdam device were included, because the outer dimensions of these prostheses are comparable and the retrograde replacement procedure is almost identical. To avoid the use of the guidewire altogether, the Provox device was removed by cutting off the tracheal flange and allowing the remainder to pass through the intestinal tract. The Groningen and Nijdam prostheses, as usual, were removed by pulling the device out of the TE fistula.

The Provox 2 voice prosthesis (Figure 1) is available with shaft lengths of 4.5, 6, 8, 10, and 12.5 mm. Compared with the original Provox voice prosthesis, the Provox 2 has slightly thinner flanges (esophageal flange, 1.5 mm instead of 1.6 mm, and tracheal flange, 1.3 mm instead of 1.6 mm) and the junctions between the shaft and the flanges are more curved. The esophageal flange is thus more rigid than the tracheal flange, therefore diminishing the chance of inadvertent dislodgment into the trachea. These adaptations have been made to optimize the device for anterograde insertion. In addition to this, Provox 2 has a tapered tracheal flange for increasing flexibility, figures on the tracheal flange for length identification in situ, and an enhanced valve construction.

The anterograde replacement procedure, schematically shown in Figure 2, has been published previously and is summarized herein. The insertion tool consists of an inserter and a loading tube. The voice prosthesis is secured with a safety string and placed on top of the inserter (Figure 2, A). Next, the esophageal flange of the voice prosthesis is folded forward between thumb and index finger (Figure 2, B) and pushed into the loading tube (Figure 2, C and D). After removal of the existing prosthesis with a nontoothed hemostat, the loading tube can be inserted into the TE fistula until the back wall of the esophagus is reached (Figure 2, E). Then, with the loading tube in this position, the inserter is pushed forward, enabling the forward-folded esophageal flange to unfold itself in the lumen of the esophagus (Figure 2, F). Next, the loading device is pulled back, locking the esophageal flange against the anterior esophageal wall (Figure 2, G). The loading tube can now be removed and the tracheal flange of the voice prosthesis is positioned. This usually happens spontaneously. In other cases, the tracheal flange has to be unfolded deliberately, either by turning the inserter with the prosthesis around its axis, or by turning and pulling this flange into position with a nontoothed hemostat. The proper position of the voice prosthesis can be checked easily by rotating and exerting slight traction on the tracheal flange, after which the security string of the prosthesis can be cut off (Figure 2, H). X-ray or endoscopic control is not necessary. The Provox 2 voice prosthesis is then ready for use.

Data were collected immediately after the replacement procedure by means of 2 structured questionnaires, 1 to be completed by the patient and 1 by the medical professional replacing the voice prosthesis. The patient questionnaire included items about appreciation of the anterograde method in comparison with the retrograde method, and some general questions concerning the voice prosthesis, eg, cleaning of the device and the use of anti-Candida medication. The questionnaire to be completed by the medical professionals mainly included items to evaluate their experience with the different aspects of this new anterograde procedure, in comparison with the retrograde method. To assess the survival time of the Provox 2 device, an off-study questionnaire also was completed by the medical professional as soon as the Provox 2 voice prosthesis had to be replaced.

Student t test for paired observations was used to compare the appreciation of patients for the retrograde vs the anterograde replacement method. Associations were measured by means of Pearson correlation coefficient. The sign test was used to compare the device life of the Provox and the Provox 2 voice prostheses.

In the calculations of the device life of Provox 2, patients whose device was replaced for leakage through the valve were counted as having failed devices; all other patients had their data censored at the date of their last follow-up or removal of the device for other reasons. Time was measured from the date of implant. Proportional hazards regression analysis was used to test associations of different variables with the device life of Provox 2. Survival-type calculations were done by the product-limit method of Kaplan and Meier. A 2-tailed P<.05 was taken to indicate statistical significance.
ryngeal stenosis, have stimulated the development of a second-generation Provox voice prosthesis, the Provox 2, which is designed to allow easy anterograde replacement directly through the tracheostoma. Moreover, the Provox 2 prosthesis can still, if necessary, be inserted into the TE fistula in the retrograde fashion through the pharynx.

In the initial study in 44 patients, the effectiveness and the functionality of the anterograde method were tested, and it was concluded that this method not only simplifies the replacement procedure, but also significantly diminishes the discomfort for the patient (P, .001). In this article, we report the results of a multi-institutional trial conducted to verify the initial results and, since several adaptations had to be made to optimize the Provox 2 voice prosthesis for anterograde insertion, to determine its device life.

## RESULTS

### CLINICAL EXPERIENCE

The outcome of the different steps of the replacement procedure is shown in Table 1. The anterograde replacement method was possible in all patients. The insertion of the voice prosthesis into the instrument and the insertion of the instrument into the fistula were considered uncomplicated in 96.7% and 94.6% of the patients, respectively. In 13 patients (5.4%), the insertion into the fistula was somewhat troublesome because of a narrow stoma and/or a difficult anatomical position of the fistula tract in relation to the stoma. The esophageal flange unfolded instantaneously in 93.7% of patients. In 6% of the patients the esophageal flange of the prosthesis unfolded in the fistula; as a result, the prosthesis did not remain in the fistula and the procedure had to be repeated. The tracheal flange unfolded spontaneously in 172 cases (71.9%), after rotation in 24 (10.0%), and with the use of a hemostat in 42 (17.6%); in 1 patient the tracheal flange unfolded in the fistula and the prosthesis had to be pulled back into the right position. No bleeding or a slight hemorrhage of the fistula (edges) occurred in 62.8% and 31.2% of the patients, respectively, while in 3.8% the bleeding was somewhat more prominent. Statistical analysis showed a strong association between a narrow stoma and/or a difficult position of the fistula and the presence of hemorrhage (P, .001). In only 2 patients the correct position of the esophageal flange was checked by means of flexible pharyngoscopy, while in 232 patients the correct position was checked only by rotation of the voice prosthesis. In the remaining 5 patients, no further checking took place.

In one third of the patients (34%), topical anesthesia was used (4% lidocaine in 5% of the patients and 10%...
lidocaine in 29%). The most frequently used shaft lengths were 6 and 8 mm (n = 104 [43.5%] and n = 102 [42.7%], respectively), 10 patients (4.2%) needed 4.5 mm, 22 patients (9.2%) needed 10 mm, and 1 patient (0.4%) needed a device with a 12.5-mm shaft length.

Forty-six percent of the replacement procedures was performed by otolaryngologists and 54% by residents. The experience level of the medical professional performing the procedure did not have a statistically significant influence on the appreciation by the patients. Based on the above-mentioned positive results, the medical professionals preferred the anterograde over the traditional retrograde procedure in 232 of the cases (97.1%) (Table 3).

PATIENTS’ EXPERIENCE

The patients’ judgment of the retrograde and anterograde replacement procedure, rated on a 5-point scale (ranging from comfortable to very uncomfortable), is shown in Table 4. The retrograde method was considered quite (n = 39 [16.3%]) to very (n = 71 [29.7%]) uncomfortable by almost half of the patients, while 4 patients (1.7%) expressed such a negative opinion on the anterograde procedure. The majority of patients (n = 205 [85.8%]) rated the new anterograde method as more comfortable (Student t test for paired observations, \( P < .001 \)).

The main reasons for grading the retrograde replacement method as uncomfortable were gagging (n = 100 [41.8%]) and/or coughing (n = 104 [43.5%]). Moreover, feelings of pain were noted by 36 patients (15.1%), ranging from a little pain (n = 4 [1.7%]) to moderate pain (n = 22 [9.2%]) and quite a bit of pain (n = 10 [4.2%]). Additional reasons for discomfort as noted by the patients with the retrograde method were feelings of dyspnea and anxiety (anticipation). With the retrograde method, 41 patients (17.2%) reported that they postponed the replacement procedure because they disliked the method. The mean delay was 18.9 days (range, 1 day to 3 months). However, there was no significant association between a pharyngeal stenosis (reported in 15% of the patients) and feelings of discomfort with the retrograde method.

The retention of the Provox 2 prosthesis was, despite the slight changes in dimensions of the flanges, satisfactory. In 3 (1.3%) of the 239 patients the prosthesis was accidentally lost: 2 were pushed into the esophagus by the patient, and 1 was pulled out of the fistula by the patient while cleaning the device with the brush. In none of these patients did aspiration or other clinical adverse events occur, and a new device was inserted without problems.

The last item on the patient questionnaire inquired which method the patient would prefer in the future. As shown in Table 3, 224 patients (93.7%) preferred the anterograde method, while 2 patients (0.8%) preferred the retrograde method and 12 patients (5.0%) did not have any preference. Information on 1 patient’s opinion was missing.

DEVICE LIFE OF THE PROVOX 2 VOICE PROSTHESIS

To assess the device life of the Provox 2 voice prosthesis, 2 criteria had to be met: there had to be at least 2 previous Provox replacements, and the reason for replacement had to be leakage through the prosthesis. Leakage through the prosthesis, mainly caused by Candida de-
posits on the valve, is the most common documented cause of failure of the Provox valve. Patients not having had at least 2 previous replacements were excluded from the device-life analysis (n = 17). Other reasons for replacement of the prosthesis, such as leakage around the prosthesis or other specific fistula problems, such as infection, granulation formation, and hypertrophic scarring, were considered not to be valve failures and, therefore, were also excluded from the device-life analysis (n = 14). This resulted in a population of 157 patients remaining for device-life analysis.

A frequency analysis showed that the median device life of the 2 previous Provox voice prostheses was 102 and 118 days. A combination of those 2 events resulted in a median device life of 125.5 days (range, 10-583 days). To determine the device life of the Provox 2 voice prosthesis, events were censored for other reasons than leakage through the prosthesis or when the prosthesis was still in situ. Leakage around the Provox 2 prosthesis occurred in 2% of the cases. At the date of analysis, the Provox 2 voice prosthesis was still in situ in 21 of the 157 patients (range, 197-372 days). The median device life of the Provox 2 voice prosthesis was 104 days (range, 7-372 days). After censoring, 139 patients remained for device-life analysis. The Kaplan-Meier survival curves of both the Provox and the Provox 2 voice prosthesis are shown in Figure 3. A sign test between the device life of the Provox 2 and the traditional Provox voice prosthesis showed that in 80 patients (57.5%) the Provox 2 survival time was shorter and in 59 patients (42.5%) the Provox 2 survival time was longer than the survival time of the original Provox voice prostheses. This difference was not statistically significant (P = .09).

The maintenance of the voice prosthesis, mainly consisting of cleaning the device with a special brush, was performed by 91.0% of the patients (with a mean of 3 times per day). Furthermore, when the device life of a voice prosthesis is less than 2 months, primarily because of Candida overgrowth, the patient is advised to use anti-Candida medication. Of the 157 patients included in the survival time analysis, 45 patients (28.7%) reported that they regularly used an anti-Candida drug (eg, nystatin, amphoterericin B, or fluconazole). A proportional hazard regression analysis was performed to evaluate whether factors such as age, sex, follow-up time since surgery, radiation treatment, brush maintenance, use of anti-Candida medication, or the regular use of a heat and moisture exchanger or stomafilter influenced the device life of the Provox 2 voice prosthesis. It appeared that none of these factors was statistically significantly associated with the survival time of the prosthesis.

The results of this prospective study show that the insertion tool needed for the anterograde replacement was easy to handle and that the procedure itself did not present problems. Both otolaryngologists and residents were readily capable of using the method. The method also was considered by the participants to be much less time consuming than the retrograde procedure, which is an advantage in a busy outpatient practice. Proper instruction, nevertheless, is mandatory, as with any new method introduced to the medical field. As results in other clinics have shown, the method is also easily adopted by speech therapists and oncology nurses making the procedure possible for a much wider group of medical professionals than the retrograde method is. In addition, the ability to use the retrograde method with the same prosthesis, using the original guidewire, makes this prosthesis more versatile than other voice prostheses presently available. Especially in the unusual case of a difficult narrow stoma and/or deeply positioned fistula, replacement is still feasible with the retrograde method where anterograde methods may fail. The more flexible Provox 2 will most likely pass a stenotic hypopharynx even more easily.

Nevertheless, in this study population, in patients with a narrow stoma and/or a difficult position of the fistula, the anterograde replacement method was always possible. However, in the latter category of patients, the method may be somewhat more traumatic, given that a slight to moderate hemorrhage of the edges of the fistula did occur significantly more often (P < .001) in these cases. Most hemorrhages occur during anterograde removal of the prosthesis and come from granulations that may be present in the fistula wall. Fortunately, hemorrhage was never a reason for failure of the method or had any clinical relevance, other than the need to reassure the patient of its insignificance.

Replacement of the other 2 prostheses of relevance for this study, ie the Groningen and Nijdam prostheses, by a Provox 2 voice prosthesis was not different from that of the Provox device, because of the comparable outer dimensions. Replacement of a smaller-diameter prosthesis, such as the 16F Blom-Singer (Inhealth Technologies, Carpinteria, Calif) and Bivona (Bivona Medical Technologies, Gary, Ind) devices, may be somewhat less easy. Up to a length of 8 mm, it might be possible to dilate the fistula with the insertion tool, but longer fistula tracts have

![Figure 3](https://example.com/figure3.png)

**Figure 3.** Device life of the Provox and Provox 2 prostheses (Kaplan-Meier curves). There is no significant difference (sign test, P = .09).
to be dilated otherwise before anterograde insertion of the Provox 2 prosthesis should be attempted (R. T. Gregor, MD, PhD, Tygerberg Hospital, Stellenbosch, South Africa, oral communication, February 4, 1998).

For primary insertion of the voice prosthesis at the time of the laryngectomy or for secondary introduction at a later date, the retrograde method by means of the guidewire, as originally introduced with the Groningen device, is still the method of choice. It ensures a tight fit and thus reliable fixation of the prosthesis, without the need for temporary stenting of the freshly created TE fistula, and it diminishes the risk of inadvertent separation of the TE party wall during the procedure. It also allows the earliest possible start of the vocal rehabilitation, without the need for fitting a prosthesis at a time when the surgical field may still feel sore and uncomfortable to the patient.

The correct position of the voice prosthesis could be confirmed in the majority of cases by rotating the device and exerting mild traction. All medical professionals felt comfortable about this. Endoscopic and/or x-ray control, as suggested with the Blom-Singer indwelling prosthesis, was not necessary. Unlike this indwelling prosthesis, the esophageal flange of the Provox 2 device is rather rigid, and the unfolding of this flange is controlled and instantaneous after the device is pushed out of the loading tube. Therefore, there is no waiting time for the dissolving of a gelatin capsule, which helps the medical professional determine that in fact the prosthesis is positioned correctly. Nevertheless, care should be taken to insert the tip of the insertion tool deeply enough into the fistula tract, and to keep the device slightly pressed against the esophageal back wall to ensure the proper unfolding of the flange in the lumen of the esophagus. In case of doubt, the prosthesis might be completely inserted into the esophagus and maneuvered in place with a hemostat, much like in the traditional retrograde procedure, ensuring the reliable position of the esophageal flange at all times.

Local anesthesia to dampen the coughing reflexes, now only applied in the tracheostoma, was thought necessary in only one third of the cases. In the majority of cases there was apparently no need for topical anesthesia, underscoring the ease of use and low irritation level of the anterograde method.

From the patients’ point of view, this anterograde procedure clearly diminished and/or prevented uncomfortable side effects, such as coughing, gagging, pain, and/or anticipation anxiety. Furthermore, it is noteworthy that a stenosis of the pharyngoesophageal segment, which interfered with the retrograde procedure in 13% of the patients, is not a problem any longer with the anterograde replacement of the prosthesis.

The results of the device-life analysis show that the survival curves of the original Provox and the Provox 2 voice prostheses are similar. Consequently, no statistically significant difference could be found. A delay with the retrograde method on average of 19 days was reported by 41 of the patients. From the survival curve it can be deduced that the original Provox fails slightly less frequently during the first 200 days, while after that period the Provox 2 seems to last longer. None of the tested covariates, such as age, sex, follow-up time since total laryngectomy, radiation treatment, brush maintenance, antifungal therapy, or the use of a stomafilter was statistically significantly associated with the survival time.

With respect to radiotherapy, there are some indications that this might accelerate failure of the valve, and study results by de Carpentier et al showed that this holds true especially for the first valve, but not for subsequent valves. The lack of evidence of an association between irradiation and device life of the prosthesis in this study might, in part, result from the fact that 90.8% of patients had radiation therapy at some time during their treatment, leaving too small a sample in the nonirradiated group. The finding that cleaning the voice prosthesis with a special brush did not positively influence the device life may also be because almost all patients (91.0%) performed this maintenance procedure, leaving few patients in the non–brush-user group.

It is widely accepted that antifungal treatment can improve the device life of a voice prosthesis considerably. Therefore, it might be somewhat unexpected that in this study antifungal treatment did not statistically significantly affect the survival time of the prosthesis. However, the study was not designed to evaluate this aspect in a controlled way, but it still seems fair to assume that these data point to the possibility that by using anti-Candida medication, the device life of the valve can be prolonged to approximately the same period as is usual for patients who do not use antifungal drugs. In the participating clinics, it is common practice that only patients with repeatedly rapid (within 2 months) valve failures caused by Candida overgrowth are advised to use anti-Candida medication on a daily basis, either by swishing and swallowing the liquid medication or by applying it directly into the prosthesis with the cleaning brush. In the study population included in the device-life analysis for Provox 2, this was the case with 28.6% of the patients (26.7% for the total group). This means that most patients apparently do not need any antifungal medication. The advice of some authors to prescribe antifungal medication to all patients using an indwelling device, therefore, does not seem to be applicable to the Provox devices and might lead to overmedication.

The median survival time of the Provox 2 voice prosthesis, established in this multi-institutional study in the Netherlands, is 104 days. This is probably not representative of all countries or geographic areas. In a study from France, the device life of the original Provox voice prosthesis was substantially longer than in the Netherlands. In determining the device life of voice prostheses, it has to be kept in mind that almost all patients in the Netherlands are fully reimbursed by their health care insurance for everything needed in postlaryngectomy rehabilitation. Consequently, there is hardly any threshold for the patient to request replacement of a voice prosthesis, even if the problems are still minor. Besides this aspect, many other factors, such as differences in dietary habits between countries and populations, probably have a major role in the device life of a voice prosthesis.
This multi-institutional trial confirmed the results of the initial study concerning ease of use for medical professionals and appreciation by the patients of the anterograde replacement procedure of the Provox 2 prosthesis. The discomfort for the patient has been significantly reduced. The method is easily adopted by other clinics. The device lives of Provox and Provox 2 are comparable, despite the alterations that were made to optimize the device for the anterograde method.

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