The Groningen, Nijdam and Provox Voice Prostheses: A Prospective Clinical Comparison Based on 845 Replacements*

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The Groningen, Nijdam and Provox voice prostheses (VP) are all low-pressure, indwelling voice prostheses. Although there are differences concerning the valve mechanism, they have a similar design and are therefore interchangeable. In a prospective study, 845 consecutive replacements were evaluated in 158 patients. Average device lifetime differed significantly from 13 weeks for the Provox VP and 15.8 weeks for the Groningen VP, to 19 weeks for the Nijdam device. Leakage through or around a voice prosthesis was the main replacement indication. Leakage occurred significantly more often with the Provox VP (80.2%) than with the Groningen VP (58.8%) or the Nijdam VP (55%). Increased airflow resistance as a replacement indication occurred significantly more often with the Groningen VP (45.4%) and the Nijdam VP (45.9%) than with the Provox VP (22.7%). Complications during the replacement procedure were rare and usually mild. Replacement was usually an easy outpatient procedure; general anaesthesia was only necessary in 3.0% of 845 replacements, without any significant difference between the three devices. Granulation tissue and hypertrophic scar tissue formation were the most frequent local complications. They occurred in less than 10% of our patients but were significantly more common in patients with a Nijdam VP. Key words: laryngectomy, voice rehabilitation, voice prosthesis.

INTRODUCTION

Since Billroth performed the first laryngectomy in 1873, much has changed in relation to both the surgical technique and postoperative voice restoration. At present, there are three ways of rehabilitating the lost voice of laryngectomy patients. Mechanical sound sources, such as the pneumolarynx and electrolarynx were developed in the late 19th century. They produce voice sounds either by air or electrically induced vibrations but are considered inferior to the other forms of voice restoration. In the same period, oesophageal voice production was recognised as a useful means of voice production after total laryngectomy. The voice rehabilitation process was improved further with the introduction of surgically created tracheo-oesophageal shunts (1, 2). A major step forward was the application of the tracheo-oesophageal puncture with insertion of a silicone voice prosthesis by Blom & Singer (3) in 1979. This also made it possible to deal with shunt stenosis and aspiration which were major complications of the previously unprotected tracheo-oesophageal shunts. Prosthesis-assisted tracheo-oesophageal speech is now generally considered to be superior to any other form of substitute voice production (4, 5, 6).

Voice prostheses have been developed in various countries all over the world, including three in the Netherlands: the Groningen voice prosthesis (VP), the Nijdam VP and the Provox VP. The Provox VP (7) and the Groningen VP (8) are used worldwide and can be considered popular, together with the Blom-Singer VP (10). The Nijdam VP (9, 11) is a valveless design which can have specific advantages in selected patients. The Groningen, Nijdam and Provox voice prostheses are interchangeable. They were compared in a prospective analysis.

Description of the devices

The standard Groningen VP was designed by the Department of Otorhinolaryngology of the University Hospital Groningen and introduced for use in 1981 (8). It consists of a tracheal and oesophageal flange and a shaft of variable length (5–13 mm). This makes it possible to adjust the device to the thickness of the tracheo-oesophageal wall. The Groningen VP has a standard 7 mm or an optional 8 mm shaft diameter. There was a straight slit centrally through the oesophageal flange of the initial device which acted as a valve (Fig. 1a). In 1988 this slit was made semicircular, which reduced the airflow resistance by 50% (12) (Fig. 1b).

The Provox VP has a hinge-type valve and was introduced in 1990 (7) (Fig. 1c). It has a tracheal and oesophageal flange and is available in three shaft lengths (6, 8 and 10 mm). The Provox VP has an outer shaft diameter of 7.5 mm.
The standard Groningen VP with a straight slit-valve (a), the low-resistance Groningen VP with a semicircular slit-valve (b), the Provox VP with a hinge-valve (c). The valveless Nijdam VP (d) with the shaftlength of the VP (mm) printed on the tracheal flange. The barrier mechanism of the Nijdam VP (e); the hatched area represents the tracheo-oesophageal wall.

In 1990 the valveless Nijdam VP was also introduced (Fig. 1d). It has a completely new innovative barrier mechanism. At the initiation of voice production, the oesophageal flange of the prosthesis is lifted off the oesophageal mucosa and air escapes into the oesophagus which produces the vibrations of the PE segment needed for speech (Fig. 1e). It also has a tracheal and oesophageal flange and a shaft of variable length (4, 5, 6, 7 and 8 mm). The Nijdam VP is available with a standard 7 mm or an optional 8 mm shaft diameter.

Replacement

Replacement is generally a simple outpatient procedure and differs slightly for the three devices (Fig. 2). The trachea and oropharynx are anaesthetized locally, if desired, with 10% lidocaine spray and/or lidocaine oral gel 20 mg/ml to reduce reflexes and minimize discomfort for the patient. The Groningen VP and Nijdam VP can be removed by pulling carefully with a haemostat (Fig. 2a). After the Groningen or Nijdam VP have been removed, a flexible metal guide wire, which can be resterilized, is introduced through the fistula towards the oral cavity (Fig. 2b).

The introduction string of a new prosthesis is connected to the guide wire (Fig. 2c), the prosthesis is swallowed by the patient and pulled into place. Delivery of the tracheal flange is facilitated by the Nijdam design, but positioning can be adjusted using forceps in the Groningen VP. The introduction string is subsequently cut off (Fig. 2d) and the new device is ready for use (Fig. 2e).

Removal of the Provox VP by pulling it out is potentially damaging for the fistula because of its greater stiffness and should therefore be avoided. It can be removed by introducing a disposable guide wire through the shaft (Fig. 2f). The tracheal flange is cut off (Fig 2g) and the oesophageal remnant of the prosthesis is removed transorally by a push-and-pull action of the guide wire which has a stop located halfway (Fig. 2h). The insertion procedure of a new Provox VP is similar to the method described above (Fig. 2c, d and e).

Brushes for daily in situ maintenance have been developed for all three prostheses; plugs are available for temporary occlusion of an intermittently leaking prosthesis.

All three prostheses are made of medical-grade silicone rubber and are considered to be indwelling, low-resistance voice prostheses.

The Provox VP is produced jointly by Atos Medical, P.O. Box 183, S-24222 Hörby, Sweden and Entermed BV, P.O. Box 236, 3440 AE Woerden, The Netherlands. World-wide distribution (outside the Scandinavian countries) is carried out by Entermed BV, while Atos Medical distributes the device in Scandinavia.

The Groningen VP and Nijdam VP are distributed by Medin ENT Instruments, P.O. Box 6201, 9702 HE Groningen, The Netherlands.

MATERIAL AND METHODS

Since January 1991 a voice prosthesis (a Groningen, Nijdam or Provox VP) was chosen at random for placement during total laryngectomy.

We evaluated all the replacement procedures which were conducted between January 1991 and July 1993. A total of 158 patients participated in this study. They had a laryngectomy between February 1981 and February 1993.

Replacement indications were leakage of the device which was objectivated at the outpatient clinic to differentiate leakage through the prosthesis from leakage around it. In the former case, prosthesis replacement was indicated. In the latter, temporary removal of the voice prosthesis was expected to result in shrinkage of the fistula in the majority of patients so that a new prosthesis could be inserted after a few
days. Another indication for replacement of the voice prosthesis was a subjective feeling of increased airflow resistance during speech. There were other less frequent indications for replacement of the voice prosthesis such as excessive granulation tissue formation or loss of the voice prosthesis.

At the end of device life, a voice prosthesis was normally replaced by a new voice prosthesis of the same type. Due to the experience gained during this study it became unavoidable to change to another type of voice prosthesis in some cases. A high airflow resistance during speech could favour changing to a Provox VP, frequent leakage to a Groningen VP or Nijdam VP and periprosthetic leakage to a Nijdam VP. Replacement problems due to hypopharyngeal and/or esophageal stenosis were sometimes avoided by changing to a Nijdam VP. In some cases the type of voice prosthesis was changed without a clear reason.

Every time a VP was replaced, a standardised form was completed stating device lifetime, type and size of the VP being removed as well as of the one being inserted, complications associated with removal and/ or insertion, indication for replacement and local appearance of the fistula. None of the patients used a cannula or other device to treat tracheostoma stenosis. During this period, 845 consecutive replacement procedures were performed in 158 patients.

Fig. 2. The transtracheal-transoral replacement procedure (a-b-c-d-e; see text). Removal of a Provox VP (f-g-h; see text).
RESULTS

In the 845 replacement procedures, 453 Groningen VP were used, 172 Provox VP and 220 Nijdam VP. Before 1990, all our laryngectomy patients were fitted with a Groningen VP because the other two were not yet available. This accounts for the difference in replacement numbers. The number of replacements per patient during study period ranged from 1 to 35 (Fig. 3).

In 80% to 90% of the replacements, the shaft length remained the same indicating no change in the thickness of the tracheo-oesophageal wall (Fig. 4). In 75%–91% of the replacements, the prosthesis was replaced by a device of the same type (Table I). The Nijdam VP was replaced significantly more often by a Groningen VP or a Provox VP, which indicated that there were prosthesis-related problems, and a different device was expected to be a possible solution.

The Nijdam VP needed to be replaced after an average of 19 weeks. This was significantly longer than the average lifetime of the Groningen VP of 15.8 weeks ($p < 0.04$) and longer than the average lifetime of 13 weeks of the Provox VP ($p < 0.004$) (Fig. 5).

In general, the main replacement indications were increased airflow resistance, often due to deterioration of the prosthesis by *Candida albicans*, and leakage either through the prosthesis or around it if the fistula had become too wide.

In our patients, leakage was the main reason for replacement of the prosthesis (Fig. 6); leakage occurred much more often through the VP (80–90%) than around it (10%). It was necessary to replace 80.2% of the Provox VPs because of leakage. This percentage was significantly higher than the percentages for the Groningen VP and the Nijdam VP for this indication: 58.8% and 55%, respectively ($p < 10.6$).

Increased airflow resistance was the reason for replacement of 22.7% of the Provox VPs. For the

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Table I. Replacement by the same or another device

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<th>Nijdam (%)</th>
<th>Groningen (%)</th>
<th>Provox (%)</th>
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<tbody>
<tr>
<td>in</td>
<td>75.4%</td>
<td>16.4%</td>
<td>8.2%</td>
</tr>
<tr>
<td>out</td>
<td>4.4%</td>
<td>90.9%</td>
<td>4.7%</td>
</tr>
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Comparison of the Groningen, Nijdam and Provox voice prostheses

Table II. Local appearance of the fistula at replacement

<table>
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<tr>
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<th>Nijdam</th>
<th>Groningen</th>
<th>Provox</th>
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<tbody>
<tr>
<td>Normal</td>
<td>73%</td>
<td>82%</td>
<td>79%</td>
</tr>
<tr>
<td>Granulation</td>
<td>12%</td>
<td>6%</td>
<td>6%</td>
</tr>
<tr>
<td>Hypertrophia</td>
<td>10%</td>
<td>4%</td>
<td>4%</td>
</tr>
<tr>
<td>Infection</td>
<td>0%</td>
<td>0%</td>
<td>2%</td>
</tr>
<tr>
<td>Other/not stated</td>
<td>15%</td>
<td>16%</td>
<td>17%</td>
</tr>
</tbody>
</table>

Nijdam VP and the Groningen VP these percentages were significantly higher: 45.9% and 45.4%, respectively ($p < 10.6$) (Fig. 6).

During replacement there was no evidence of any local problems with the Nijdam VP, Provox VP, or Groningen VP in 73%, 79% and 82% of the users, respectively. The most frequent local complications were formation of granulation tissue and hypertrophic scar tissue (Table II). These complications occurred significantly more often in combination with the Nijdam VP than with the Groningen VP ($p < 0.01$).

Replacement was a quick and easy outpatient clinic procedure and complications were usually mild and rare. Complicated removal was often associated with granulation tissue or hypertrophic scar tissue formation. Occasionally, a narrow stoma was also a problem. Loss of the prosthesis and removal under general anaesthesia were counted under complicated removals. Complicated insertion was often related to hypopharyngeal or oesophageal stenosis. To find the tract, sometimes retrograde insertion of a nasogastric tube was necessary as a first step to replace a prosthesis. Retrograde insertion was included among the complicated insertions. Also breakage of the introduction string occurred during insertion and in some cases insertion was necessary under general anaesthesia. Complicated removal was reported in 3.6% of the patients with a Nijdam VP, in 2.9% with a Groningen VP and in 6.0% with a Provox VP. These differences were not significant. Complicated insertion was recorded in 11.5% of the patients with a Nijdam VP, in 9.4% with a Groningen VP and in 18.5% with a Provox VP. The latter percentage was significantly higher ($p < 8.8 \times 10^{-6}$). 3.0% of the replacements were done under general anaesthesia. There was no significant difference between the three devices. Replacement under general anaesthesia occurred in 4.0% of the Provox VP replacements, 2.3% of the Nijdam VP replacements and 2.7% of the Groningen VP replacements.

DISCUSSION

The Groningen, Nijdam and Provox VPs are all low-resistance, indwelling voice prostheses. Average device lifetime differed from 13 to 19 weeks. It may be possible to prolong the lifetime by the proper use of the brushes and plugs in cases of unexpected or temporary leakage. The devices are interchangeable and replacement is an easy outpatient clinic procedure. Replacement complications were rare and usually mild, which made replacement under general anaesthesia necessary in only 3.0% of the 845 replacements. Granulation tissue and hypertrophic scar tissue formation were the most frequent local complications. They occurred in less than 10% of our patients.

This study revealed that the Nijdam VP was replaced significantly more often by a Groningen VP or a Provox VP than vice versa. This seemed to be related to the barrier mechanism of the Nijdam VP. The Nijdam VP is a valveless prosthesis. To prevent leakage, close contact is necessary between the oesophageal flange of the Nijdam VP and the mucosa of the oesophagus, which is reflected in the length of the shaft. If the shaft is too short, it may result in an increase in airflow resistance and granulation tissue formation. If the shaft is too long, it can cause early leakage through the prosthesis. Both complications can be prevented by choosing a correct shaft length for the Nijdam VP. We think that in our patients such complications often led to an unnecessary change to a Provox VP or Groningen VP.

The significantly longer lifetime of the Nijdam VP seemed to be related to the absence of a valve. Deterioration of the valve of the Groningen VP and
the Provox VP, usually due to Candida albicans ingrowth, was the main cause of reduced lifetime.

Another possible advantage of the oesophageal flange of the Nijdam VP is its "umbrella effect". Even if the tracheo-oesophageal fistula is a little too wide, the oesophageal flange will cover it as an umbrella and prevent leakage around the shaft of the prosthesis. Other options in this event would be temporary removal of the voice prosthesis with reinsertion after a few days when the fistula has shrunk. Also Gax-collagen injection has been mentioned as a solution to correct an enlarged tracheo-oesophageal fistula (13).

The stiffness of the Provox VP, which is enhanced by the valve mechanism in the shaft, causes difficulties during replacement, particularly under less favourable conditions, such as hypopharyngeal stenosis. In these cases, the Nijdam VP is easier to replace because of its flexibility and special design of the tracheal flange.

A major advantage of the Provox VP is the fact that it has dramatically diminished the number of patients with increased airflow resistance as a replacement indication. If there is a recurrent early increase in airway resistance, changing the patient to a Provox VP should be considered.

If a patient with a VP wishes to travel (abroad), they can regain part of their independence by carrying a complete Provox replacement set, even if they are normally using another device because the devices are interchangeable. The complete set, including an instruction manual, makes it possible for any experienced otorhinolaryngologist to replace the device if necessary.

Financial costs may form an important reason for choosing the cheaper Groningen VP or Nijdam VP in favour of the more expensive Provox VP.

The present study indicates that the Nijdam VP has advantages over the Groningen VP and Provox VP, especially with regard to its lifetime. Choosing the correct length of the Nijdam VP is very important.

The interchangeability of the devices is a great advantage. Specific prosthesis-related problems in individual patients can very often be solved by knowing and making use of the mentioned differences between the three Dutch voice prostheses. We have found that simultaneously using the Groningen, Nijdam and Provox VPs has definitely contributed to successful voice rehabilitation in our laryngectomy patients.

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