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The Nijdam Voice Prosthesis: A Self-retaining Valveless Voice Prosthesis for Vocal Rehabilitation after Total Laryngectomy

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Voice prosthesis-assisted speech rehabilitation after total laryngectomy has proven to be successful in the majority of patients and exceeds the results of traditional oesophageal speech. Nevertheless 10-30% failure rates are still reported. In part this is due to prosthesis-related problems, in particular ingrowth of *Candida* species in the valve-bearing parts of the devices. A new indwelling, low-resistance and valveless voice prosthesis is described; the Nijdam voice prosthesis. The device has an average device lifetime of 19 weeks which appears to be superior to other indwelling voice prostheses. Replacement indications mainly comprise leakage or increased airflow resistance. Most frequent local complications are granulation tissue and hypertrophic scar tissue formation. These occur in 12% of the patients and can easily be treated. Replacement is a simple outpatient procedure. The prosthesis is interchangeable with other types of indwelling voice prosthesis. *Key words:* laryngectomy, voice prosthesis, voice rehabilitation

INTRODUCTION

Although non-shunt oesophageal voice rehabilitation was the standard for laryngectomees for many years, this has gradually been changing over the past 15 years. Airway shunting to the digestive tract, initially with unprotected shunting techniques (1, 2) allowed fairly natural, fluent speech for the majority of patients. A major drawback was the occurrence of aspiration (of saliva, fluid and food substances) on the one hand and secondary stenosis on the other.

The introduction of the one-way valved silicone prosthesis (3) was a major step forward; it prevented aspiration as well as premature closure of the shunt. Over the past 15 years, several (non-)self-retaining voice prostheses (VP) and low-pressure modifications have been developed for postlaryngectomy voice rehabilitation (3-8). Almost all low-pressure devices presently available have a high voice rehabilitation success rate after total laryngectomy, which ranges from 60-90% (9-11). These different rates are only partly related to the device used. More often there will be a relationship with the extent and technique of surgery. Better results are achieved with primary placement than with secondary placement (12, 13). The majority of patients benefit from pharyngeal plexus neurectomy or myotomy of the cricopharyngeal and lower pharyngeal muscles at primary operation (14-16). In addition, the experience and

postoperative concern of both the surgeon and the speech therapist are likely to effect the final result, as well as patient-related factors such as manual dexterity, intelligence, psychological and sociological factors (17, 18).

Vocal rehabilitation is one of the most important factors that defines the quality of life after total laryngectomy. Therefore, continuous efforts to improve rehabilitation of the lost voice after total laryngectomy are mandatory and should also be directed towards improving existing voice prostheses or developing new ones. Prosthesis-related factors such as aerodynamic properties, early material deterioration, dysfunction of the valve mechanism and a tendency to induce tissue reactions, should all be constantly reconsidered for improvement.

The ideal voice prosthesis, which should be biocompatible, self-cleaning, have a low resistance, be resistant to fungi, leakproof and suitable for primary placement with an unlimited device lifetime, does not exist yet.

We have tried the newly developed, valveless Nijdam voice prosthesis extensively. It comes closer to the above-mentioned goals. Our experience is presented in this paper.

Development and description of the Nijdam voice prosthesis

From long-term investigations on the Groningen VP, it has become obvious that the device lifetime is limited by the ingrowth of fungi in the oesophageal part of the prosthesis (22). This decreases the flexibility of the silicone elastomer and leads to increased

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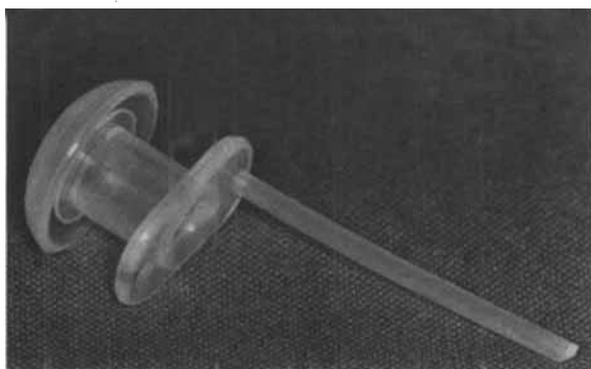


Fig. 1. The valveless Nijdam voice prosthesis.

rigidity of the material. Problems mainly occur in the valve-bearing part of the device and cause leakage through the prosthesis or increase the airflow resistance; both malfunctions indicate the end of the life of the device. Since 1984 efforts have been made to develop a valveless voice prosthesis.

The Nijdam VP (Fig. 1) is made of medical grade silicone elastomer. It consists of a biflanged hollow shaft of variable length and diameter. Two shaft diameters (standard 7 mm and optional 8 mm) are available and there are five shaft lengths (4, 5, 6, 7 and 8 mm) in order to enable proper adjustment to the size of the fistula and the variable thickness of the tracheo-oesophageal wall. The oval tracheal flange is equipped with a silicone string and a small perforation, both used for introduction (Fig. 2). The length of the shaft of the prosthesis is printed on the tracheal flange.

In this newly developed silicone voice prosthesis, the round oesophageal flange has open communication with the shaft of the prosthesis. The oesophageal flange covers the oesophageal end of the tracheo-oesophageal fistula like an umbrella. The rim of the oesophageal flange maintains slight pressure against the oesophageal mucosa and forms a barrier to prevent leakage. Thus the barrier mechanism is partially prosthetic and partially biological. As *Candida* decontamination does not influence the flexibility of the mucosa in the oesophagus, it was estimated that the ingrowth of the fungus in the material of the prosthesis would cause fewer problems with the occlusive mechanism.

As voice production is initiated the stoma is occluded and the intratracheal pressure rises with attempted expiration. The oesophageal flange of the prosthesis is lifted off the oesophageal mucosa and air escapes into the oesophagus. This initiates vibrations of the pharyngo-oesophageal (PE) segment needed for speech (Fig. 3). Proper adjustment of the length of the shaft to the thickness of the tracheo-oesophageal wall is mandatory, because a relatively

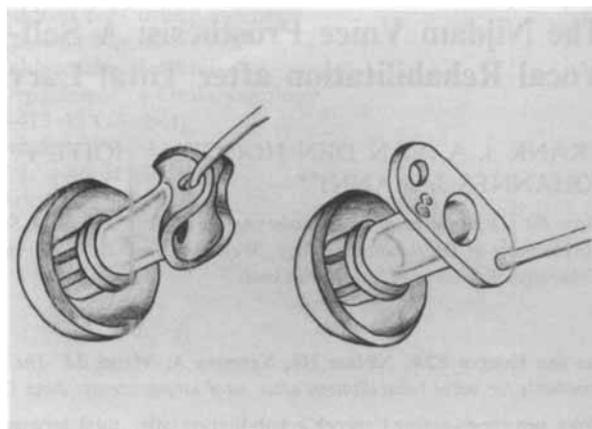


Fig. 2. The tracheal flange can be collapsed with the aid of the introduction string to promote easy passage of the prostheses through the fistula. The size of the prosthesis is printed on the tracheal flange.

long shaft may cause leakage, while a relatively short shaft may result in an increase in airflow resistance. It is our experience that proper adjustment is possible without the need for a measuring device.

The Nijdam VP is interchangeable with other indwelling voice prostheses, such as the low-pressure Groningen VP, Blom-Singer VP (\varnothing 21 French) and the Provox VP.

Surgical technique

The surgical technique for primary as well as secondary placement is similar to that of the low-pressure Groningen VP and Provox VP, which has been described elsewhere (19, 20).

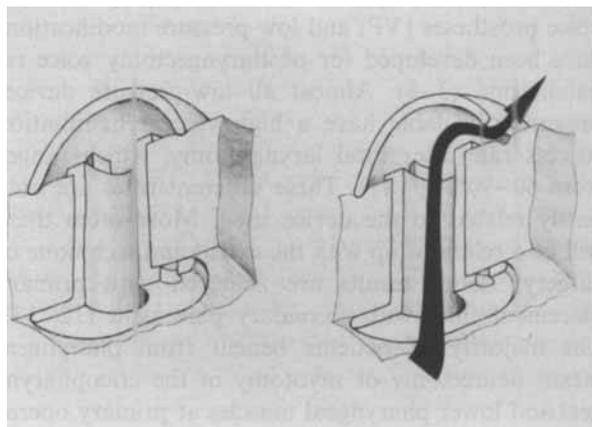


Fig. 3. The barrier mechanism of the Nijdam voice prosthesis. Artist's representation of the *in vivo* situation. The arrow indicates the airflow during speech that lifts the oesophageal flange (prosthetic part of the valve) away from the slightly depressed oesophageal mucosa (biological part of the valve)

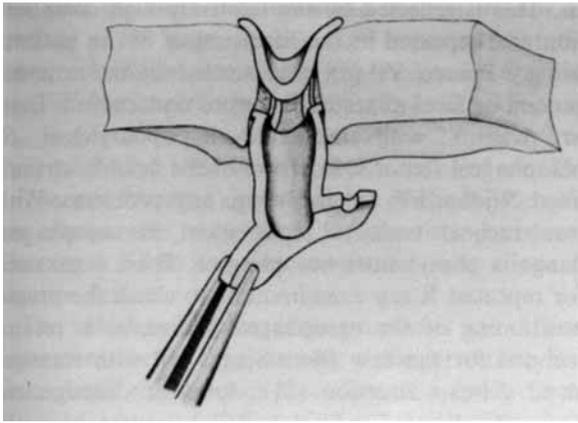


Fig. 4. The flexibility of the Nijdam VP enables transtracheal removal without the danger of damaging the fistula.

Replacement procedure

At the end of device lifetime, replacement is most frequently indicated by either leakage or increased airflow resistance. Replacement is normally an outpatient procedure. If desired, the trachea and oropharynx can be anaesthetized with 10% lidocaine spray. The Nijdam VP is very flexible and it can therefore easily be removed by pulling it out of the fistula with a haemostat (Fig. 4). A flexible metal guide wire is introduced through the fistula into the oesophagus and pushed upwards towards the oropharynx and brought out through the mouth. The silicone introduction string of the Nijdam VP is fed through the perforation in the tracheal flange and pulled slightly which helps to streamline the prosthesis for easy introduction (Fig. 2). Subsequently the introduction string is connected to the guide wire. The voice prosthesis is swallowed by the patient and pulled into place with the guide wire. The introduction string is cut off and the tracheal flange unfolds. The voice prosthesis is ready for use.

MATERIAL AND METHODS

From 1981 all the patients who underwent laryngectomy at the University Hospital Nijmegen were rehabilitated with a primary-placed indwelling voice prosthesis, unless this was contraindicated. Initially the standard Groningen VP was used at our clinic. Later, this device was replaced by a modification, the low-pressure Groningen VP, in which the valve mechanism was altered from a straight into a semicircular slit, thus reducing the airflow resistance by 50% (7). In 1990, in addition to the low-pressure Groningen VP, the Nijdam VP and Provox VP were introduced and adapted at our clinic.

All prosthesis replacement procedures performed at our outpatient clinic between January 1991 and July

1993 were evaluated prospectively. During the study period, 220 Nijdam VP were replaced in 74 evaluable patients. After every replacement, a standard form was completed stating replacement indication, device lifetime, size of the old and new prostheses, complications of the replacement procedure and the local appearance of the fistula.

Seven laryngectomees who were using the Nijdam prosthesis, were selected at random for intratracheal pressure measurements. The mean device lifetime of the Nijdam prosthesis at the time of measurement was 35 days (range 17–48 days). The laryngectomees were asked to produce a sustained vowel /a/ at varying sound pressure levels, ranging from very soft to very loud. The intratracheal pressure with its corresponding sound pressure level were measured at a mouth–microphone distance of 30 cm. The pressure sensing catheter used to measure the intratracheal pressure was sealed by the patient between the tracheostoma and an occluding finger while producing a sustained /a/. The catheter was connected to a self-designed pressure transducer. The sound level was measured using a sound level meter (Brüel & Kjør, type 2225). From these measurements the intratracheal pressure at a sound pressure level of 70 dB was calculated by interpolation. A sound pressure level of 70 dB at 30 cm mouth–microphone distance is equal to 67 dB at 50 cm distance, which is the mean intensity of the comfortable loudness of tracheo-oesophageal shunt speech.

RESULTS

No complications were encountered with the primary tracheo-oesophageal puncture and placement of the Nijdam VP.

The average device lifetime of the Nijdam VP, based on 220 replacements, was 19 weeks (standard deviation 21.7 weeks, range 1–156 weeks). The most frequent replacement indication was leakage through the voice prosthesis (50%); leakage around the voice prosthesis occurred in only 5% of replacements. Increased airflow resistance was the replacement indication in 45% of the replacements. The aspect of the fistula was normal in the majority of patients. Minor local complications consisted of granulation tissue (12%) and hypertrophic scar tissue formation (10%) which could be treated easily with cauterisation or local resection. Sometimes, a longer voice prosthesis was inserted to avoid this local problem, but it never resulted in permanent removal of the prosthesis.

Complicated removal was often associated with granulation tissue or hypertrophic scar tissue formation. Sometimes, a narrow tracheostoma also caused problems. Loss of the prosthesis and removal under general anaesthesia were classified under the compli-

cated 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. In some cases the introduction string broke during insertion or insertion had to be carried out under general anaesthesia. Complicated removal occurred in 3.6% and complicated insertion in 11.5% of replacements. Replacement complications were mostly of a minor nature. Replacement under general anaesthesia was necessary in 2.3% of our patients, all due to hypopharyngeal or tracheostoma stenosis.

The intratracheal pressure of a sustained /a/ of 70 dB at a distance of 30 cm from the mouth was found to be 4.3 kPa (range 2.8–6.1 kPa).

Subjectively the speech rehabilitation success rates with the Nijdam VP were comparable with those of the Groningen VP (10).

DISCUSSION

The development of the low-resistance, valveless Nijdam VP has brought us some steps closer to an ideal VP. The innovative design of this flexible device, that can be streamlined for easy introduction, with a completely new barrier mechanism, more resistant to *Candida*-induced malfunctioning, means an improvement over existing voice prostheses.

The average device lifetime of the Nijdam VP ($n = 220$) of 19 weeks is significantly longer than the 15.8 weeks that we found for the Groningen VP ($n = 453$) or the 13 weeks of the Provox VP ($n = 172$). In our opinion, this is related to the valveless design of the Nijdam VP, with a barrier mechanism that is less sensitive to *Candida*-induced malfunctioning. Deterioration caused by *Candida* species is the most important factor for reducing device lifetime (22).

The valveless Nijdam VP is an indwelling device. Indwelling devices require little patient care. This seems to be an advantage, as complications have been reported in association with removal, cleaning and reinsertion of non-indwelling devices by the patient.

Complications of the primary tracheo-oesophageal puncture were not encountered with the Nijdam VP. Replacement of the Nijdam VP is a simple outpatient procedure because it is very flexible. It can therefore be removed easily by carefully pulling it out. Removal of other more rigid voice prostheses in this way should be avoided because it may traumatize the fistula, cause shunt insufficiency and subsequent periprosthetic leakage. Transoral removal of these devices, as well as reinsertion, can cause problems in patients with hypopharyngeal or oesophageal steno-

sis. This is reflected by the relatively high complication rate reported in the literature of 8% in patients using a Provox VP (5), who needed dilatation under general or local anaesthesia before replacement. Even in patients with moderate hypopharyngeal or oesophageal stenosis, insertion of the flexible, streamlined Nijdam VP did not cause any problems. With transtracheal-transoral replacement, the oesophageal flange is always intra-oesophageal. There is no need for repeated X-ray examinations to check the proper positioning of the oesophageal flange, as is recommended for the new Blom-Singer VP with transtracheal gel-cap insertion (21). Anterior dislodgement and aspiration of a Nijdam VP have not been observed in our series.

The "umbrella effect" of the Nijdam VP, in which the oesophageal flange protects the oesophageal end of the fistula from leakage around the prosthesis, may explain why leakage around the prosthesis as a replacement indication only occurred in 5% of the Nijdam VP replacements. This compares favourably with the reported 20.5% of Provox users who need some sort of treatment because of widening of the fistula and leakage around the voice prosthesis (11). Occasionally, a Nijdam VP can be used to replace a Groningen VP or a Provox VP if there is leakage around the device and temporary removal with reinsertion of the prosthesis after shrinkage of the fistula is considered to be too long-winded. Gax-collagen injection as a treatment option to correct an enlarged fistula is said to have good results as well (23), although the advised tolerance test does seem to interfere with the acute nature of leakage around a voice prosthesis.

Although the intratracheal pressure during voice-prosthesis-assisted tracheo-oesophageal speech is only partly caused by the prosthesis itself, it is a strong indicator of the aerodynamic characteristics of a device. We compared the intratracheal pressure of the Nijdam VP to that reported for other shunt valves.

During comfortable speech, the mean intratracheal pressure of the standard Groningen VP (24), the low-resistance Groningen VP (25) and the Provox VP (5) were 9.3 kPa (4.0–16.2 kPa), 3.3 kPa ($P_{2.5} = 2.4$ kPa and $P_{97.5} = 4.6$ kPa) and 1.9 kPa (1.0–3.8 kPa), respectively. The airflow-resistance of the Blom-Singer low-pressure VP is comparable with that of the low-resistance Groningen VP (7).

The mean intratracheal pressure of the Nijdam VP was 4.3 kPa (2.8–6.1). This is significantly lower than that of the standard Groningen VP, but the latter is not considered to be a low-resistance VP and should therefore be avoided. When interpreting these data, it should be realized that our measurements were not done immediately after the insertion of a new Nijdam VP

but after the voice prosthesis had been *in situ* for an average of 35 days. It has been reported that the intratracheal pressure of the low-resistance Groningen VP increases from 3.3 kPa ($P_{2.5} = 2.4$ kPa and $P_{97.5} = 4.6$ kPa) to 4.7 kPa ($P_{2.5} = 2.6$ kPa and $P_{97.5} = 8.5$ kPa) after three to four months of use (25).

The aerodynamic characteristics of the Nijdam VP are comparable with those of the low-resistance Groningen VP so it can be considered to be a low-resistance device.

The valveless Nijdam voice prosthesis has advantages over the existing devices: a longer device lifetime, simple replacement procedure, less sensitivity to *Candida*-induced malfunctioning and infrequent periprosthetic leakage caused by enlarged fistulas. The main disadvantage is the need for some amount of experience with adjusting the shaftlength of the prosthesis so that it conforms with the thickness of the tracheo-oesophageal wall.

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