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A comparison of survival lifetime of the Provox® and the Provox®2 voice prosthesis

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Abstract

The Provox® (Atos Medical AB, Hörby, Sweden) voice prosthesis was developed between 1988 and 1990 and has been used at our centre with regular success since 1993. Since 1996, a second generation of Provox® (Provox®2) has been used, which can be inserted by an anterograde technique. The aim of this study is to compare the survival lifetime of both voice prostheses. The survival time of the two voice prostheses were compared retrospectively in 152 devices placed in 38 patients. A Kaplan-Meier analysis was performed to determine the survival lifetimes and a log rank test was performed to compare the two curves. Clinical factors affecting the lifetime were also analysed with a Kaplan-Meier plot.

The median survival lifetime of the Provox® and Provox®2 were 303 and 144 days respectively. The Kaplan-Meier estimation shows that this difference is statistically significant ($p = 0.02$). It is considered an early failure if it occurs within the first three months. There was a larger number of early failures with the Provox®2 than with the Provox® ($p = 0.04$). Neither the gender nor the age affected the lifetime of the devices. Radiotherapy seemed to lengthen the lifetime of the first valve.

The survival lifetime of the second generation Provox®2 valve is shorter than the lifetime of the first generation Provox®. This could be due to the difference in elasticity of these valves that could lead to a different level of colonization and invasion of the valves by micro-organisms.

Key words: Larynx Artificial

Introduction

Since the first Blom-Singer prosthesis,[1] voice restoration using a tracheosophageal fistula has become the treatment of choice for post-laryngectomy speech rehabilitation. Various voice prostheses (VP) have been employed over the past years. The most commonly used types of VPs are the Blom-Singer VP (Inhealth International Health Care Technologies, CA) and the Provox® VP (Atos Medical AB, Hörby, Sweden). They both give a similar voice quality and have a similar lifetime.[2] The main causes of the replacement of these VP are a leakage through, or around, the VP and an increasing effort required to produce phonation, both due to deterioration of the silicon valve by micro-organisms.[3] The lifetime of these prostheses is extremely variable and explains the large differences observed in the mean device lifetime of the Provox® VP described in the literature (from 94 days to 241 days).[2,4–13]

Since 1996, a second generation of Provox® (Provox®2) that has been used at this centre can be inserted by an anterograde technique.[10] This method simplifies the replacement procedure and diminishes the discomfort for the patient.[12] In the literature, only four studies have compared the survival lifetime of the Provox® VP and the Provox®2 VP, although it was not their main goal. Three of them showed a shorter lifetime for the Provox®2 VP, but this difference was not statistically significant. Op de Coul *et al.*[14] showed a statistically significant difference of mean device lifetime of 120 days for the Provox® VP and 98 days for the Provox®2 VP. With our experience, we noticed that more frequent replacements were required with this new VP. We thus compared the survival time of the two voice prostheses retrospectively.

Materials and method

A retrospective analysis of the medical files of all patients managed with a VP Provox® or Provox®2 between March 1993 and November 2000 in our department revealed 159 Provox valves inserted in 38 patients (24 Provox® and 135 Provox®2). Valve failure was defined as a salivary leakage through or around the valve, or the inability to effectively produce a voice using the valve, both necessitating the device replacement. In seven patients, a new valve replacement was necessary within seven days,

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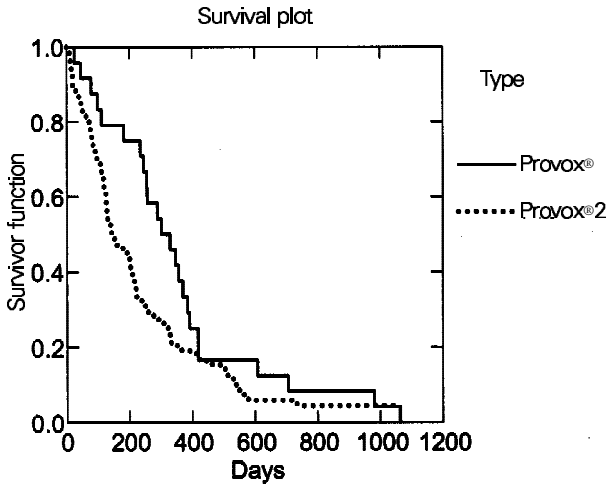

FIG. 1

The Kaplan-Meier survival curves for the two types of voice prosthesis. The log-rank test shows a statistical significant difference ($p = 0.017$) for the two curves with the Provox® 2 having a shorter lifetime.

it was then considered as a failure of the replacement and not as a failure of the valve itself. These valves were then not considered for the survival time analysis. Therefore, we retrospectively studied 24 Provox® and 128 Provox®2 inserted in 38 patients (from one to 13 valves per patient).

Only 11 patients had their total laryngectomy before 1996 and received the Provox® VP once or several times. They all received a Provox®2 VP after 1996. Twenty-seven patients received only the Provox®2 VP, as the first prosthesis and also as a further one, if any. At the time defined as the end of the study time, 24 Provox®2 were still inserted (all the Provox® had been removed). There were 36 men and two women with ages ranging from 46 to 84 years.

Because some Provox®2 were still inserted at the end of the study time, the Kaplan-Meier analysis was performed to determine the survival lifetime of the two voice prostheses, then a logrank test was performed to compare the two curves. Kaplan-Meier plots were also performed to analyse the survival time of the first VP inserted, the subsequent ones and to determine the influence of the number of previous VPs inserted. Kaplan-Meier curves and logrank tests were also performed to analyse the role of some clinical factors (i.e. gender, age and radiotherapy) on the device lifetime. A two-tailed p-value of 0.05 was taken to indicate statistical significance.

An early failure was defined as a failure within three months. We analysed the 152 VP with a Kaplan-Meier survival curve and censored all times at three months in order to compare the early failures in the two groups.

Results

The lifetime of the Provox® VP ranged between 25 days and 1 065 days with a median lifetime of 303 days. The lifetime of the Provox®2 VP ranged between nine days and 735 days with a median lifetime of 144 days. The Kaplan-Meier survival plot is shown in Figure 1. The logrank test made to compare both curves shows a $p = 0.017$. The device lifetime of the Provox®2 is shorter than the lifetime of the Provox® VP. The median lifetime of the first valve of every patient is 246 days for the Provox® (11 patients) and 222 days for the Provox®2 (27 patients). This difference is not statistically significant ($p = 0.3$), although the numbers of the patients are small. The median lifetime of the subsequent valves is 358 days for the Provox® (13 VP) and 141 days for the Provox®2 (101 VP). This difference is statistically significant ($p = 0.02$). The median lifetime of the first valve is then shorter than the next ones for the Provox® VP and longer for the Provox®2. This difference is not statistically significant, neither for the Provox® VP ($p = 0.3$) nor for the Provox®2 VP ($p = 0.08$). The Kaplan-Meier analyse also shows that the number of previous VP carried out by the patient does not influence the lifetime of the device.

The early failure of the devices was also analysed. There were three early failures (out of 24) for the Provox® VP (13 per cent) and 34 early failures (out of 104) for the Provox®2 VP (33 per cent). Twenty-four Provox®2 were still inserted at the end of the study. The Kaplan-Meier plot with a logrank test performed on the 152 VP with all times censored at three months show a $p = 0.04$. There is therefore a larger number of early failures with the Provox®2 VP.

The clinical features analysed were the gender, the age and radiotherapy. Their distributions were equivalent in the two groups of VP (demonstrated by the Chi square test). Amongst the 38 patients, two were female. No statistical analysis was then

TABLE I

THE MEDIAN LIFETIME OF THE VALVES ACCORDING TO DIFFERENT CLINICAL FEATURES

Clinical feature	Provox®		Provox®2	
	Median lifetime (days)	N (24)	Median lifetime (days)	N (128)
VP on non-irradiated patients	–	0	254	16
VP on patients during radiotherapy	465	6	551	8
VP on irradiated patients	318	18	207	104
Age $\leqslant$ 60	340	17	217	63
Age > 60	392	7	201	65

The Kaplan-Meier plot with a log-rank test was performed for each clinical feature. The lifetime of the VP on a patient during radiotherapy is statistically longer compared to VP on non-irradiated patients and on patients after radiotherapy ($p = 0.001$). The other log rank tests show no statistical significance.

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possible. The age of the patient did not influence the lifetime of the prosthesis (Table I). Radiotherapy however, influenced the lifetime of the device in our study. There were three groups of VP. Group 1 included the devices received by patients who had never been irradiated, group 2: devices received by patients during radiotherapy (the VP is then irradiated) and group 3: devices received by patients after their radiotherapy (Table I). The lifetime of the Provox®2 VP was similar in group 1 and 3 (254 and 207 days) but is significantly longer in group 2 (551 days, $p = 0.001$).

Discussion

Tracheoesphageal VP is the treatment of choice for speech rehabilitation after total laryngectomy. The Provox® VP have been used in our centre since 1993. The survival time of these VPs in our series ranged from 25 to 1065 days with a median lifetime of 303 days for the first generation Provox® and ranged from nine to 735 days with a median lifetime of 144 days for the second generation Provox®2. The survival lifetime of these VPs is extremely variable from one patient to another one and for the same patient from one valve to another one. This variability of lifetime is found in the literature with a median lifetime of VPs ranging from 94 to 241 days for the Provox® VP and from 69 to 104 days for the Provox®2 VP. In our study, the survival lifetime of the Provox®2 VP is statistically shorter than the Provox® ($p = 0.017$) (Figure 1).

Only four studies in the literature have compared the lifetime of the Provox® and Provox®2 VP. Three of them showed a shorter lifetime for the Provox®2 that was not statistically significant.[10,12,13] Op de Coul *et al*. showed that this difference was statistically significant and they attributed it to the fact that as the new generation Provox®2 could be replaced with less discomfort, the patient came to the outpatient clinic sooner and does not wait several days with a leaking prosthesis before consulting as he did with the first generation Provox®.[14] If this was true, the two survival curves would be parallel with a shift of several days, but Figure 1 shows that there is an excess of failures within the first six months with the Provox® VP. There is a larger number of early failures with the second generation Provox®2 compared to the first generation ($p<0.05$). This observation suggests a weaker Provox®2 VP rather than the explanation from Op de Coul *et al.*[14]

The difference in survival lifetime between these two Provox valves may be due to the valve itself or to extrinsic factors such as anti-fungal treatment, the gender or age of the patient, the radiotherapy, the medical history of the patient or the number of previous VPs the patient had received. Anti-*Candida* medication can affect the survival time of the device.[3,15,16] Three studies[5,8,14] show that previous radiotherapy can lead to a shorter survival lifetime of the VP, but other authors[9,12,14,17] show that this difference is not significant. In our study, the lifetime of the Provox®2 is shorter in the group of patients with a history of radiotherapy, but this difference is not statistically significant. On the other hand, it could be shown that the lifetime of the Provox®2 that is exposed to radiation is statistically longer ($p = 0.001$, Table I). For the Provox®2, the median lifetime of the first valve is longer than the next ones. This difference is not statistically significant ($p = 0.08$). This difference is probably due to the high number of patients undergoing radiotherapy with their first valve. An explanation of these results is that the Provox®2 VP that is irradiated could undergo structural changes that make it more resistant to destruction by micro-organisms.

- **The aim of the study is to compare the survival lifetime of first and second generation Provox® voice prostheses**
- **Retrospective comparison of survival time of 152 devices placed in 38 patients**
- **Media survival time Provox®1 was 303 days and Provox® 2 144 days**
- **Conclusion that the shorter survival time of Provox®2 could be due to the difference in elasticity of the valves which could lead to a different level of colonization and invasion of the valves by micro-organisms**

De Carpentier *et al*.[8] showed that the first Provox® VP has a significantly shorter lifetime than the next ones in a group of patients undergoing radiotherapy. In our series, the device lifetime of the first valve compared with the next ones is also shorter for the first generation Provox® (246 *versus* 358 days) but is paradoxically longer for the Provox®2 VP (222 *versus* 141). It is possible that the Provox®2 is particularly affected by micro-organisms with a shorter lifetime than the first generation Provox® VP and that the irradiation of the Provox®2 make this valve more resistant to destruction by micro-organisms. Other clinical features may affect the lifetime of the device, Op de Coul *et al*. showed that ages more than 70 years were associated with an increased lifetime. We also found that the lifetime of the device was surprisingly longer with older patients (for the Provox® VP and not the Provox®2 VP), but it was not statistically significant (Table I). The gender or the clinical past of the patient do not seem to affect the survival time of the device neither in our study nor in the literature. The various clinical features are equivalently distributed between the two groups. Therefore, the difference in lifetime between the two Provox® VP seems to be due to the valve itself and not to extrinsic factors.

The main cause of the replacement of these VPs is due to the deterioration of the silicon valve by micro-organisms.[3] Microscopic studies revealed that *Candida*[15] and other upper respiratory tract commensals (e.g. *Staphylococcus aureus*[3]) grow on the surface of the prosthesis and also in the silicon material itself. The elasticity of the two Provox® is different. The

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Provox®2 is more flexible in order to facilitate the replacement by an anterograde technique. This difference of elasticity could lead to a difference in colonization and destruction of the silicone material, which could explain the difference of survival lifetime between the first and second generation Provox®. The irradiation of the Provox®2 in patients undergoing radiotherapy with their valve could also change the elasticity of the device and make it more resistant to destruction by micro-organisms.

Conclusion

The survival lifetime of the Provox®2 is statistically shorter than the original Provox®. One possible reason for this shorter lifetime is the difference of elasticity of the two voice prostheses that can lead to a difference in colonization and destruction of the silicone material. To confirm this retrospective study other studies are required such as a prospective study comparing the prostheses, or a microbiological study to compare the colonization and the destruction of the valves by the micro-organisms.

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