University of Groningen

Does Prophylactic Replacement of Voice Prosthesis Make Sense? A Study to Predict Prosthesis Lifetime

Heirman, Anne N.; van der Noort, Vincent; van Son, Rob; Petersen, Japke F.; van der Molen, Lisette; Halmos, Gyorgy B.; Dirven, Richard; van den Brekel, Michiel W. M.

IMPORTANT NOTE: You are advised to consult the publisher's version (publisher's PDF) if you wish to cite from it. Please check the document version below.

Document Version
Publisher's PDF, also known as Version of record

Link to publication in University of Groningen/UMCG research database

Citation for published version (APA):
Heirman, A. N., van der Noort, V., van Son, R., Petersen, J. F., van der Molen, L., Halmos, G. B., Dirven, R., & van den Brekel, M. W. M. (2023). Does Prophylactic Replacement of Voice Prosthesis Make Sense? A Study to Predict Prosthesis Lifetime. *Otolaryngology - Head and Neck Surgery*, *168*(3), 429-434. https://doi.org/10.1177/01945998221116815

Original Research

Does Prophylactic Replacement of Voice Prosthesis Make Sense? A Study to Predict Prosthesis Lifetime

Anne N. Heirman, MD[1], Vincent van der Noort, PhD[2],
Rob van Son, PhD[1,3], Japke F. Petersen, MD, PhD[1],
Lisette van der Molen, PhD[1], Gyorgy B. Halmos, MD, PhD[4],
Richard Dirven, MD, PhD[1], and
Michiel W.M. van den Brekel, MD, PhD[1,3,5]

Abstract

Objective. Voice prosthesis leakage significantly affects the quality of life of patients undergoing laryngectomy, causing insecurity and frequent unplanned hospital visits and costs. In this study, the concept of prophylactic voice prosthesis replacement was explored to prevent leakages.

Study Design. Retrospective cohort study.

Setting. Tertiary hospital.

Methods. This study included all patients who underwent laryngectomy between 2000 and 2012 in the Netherlands Cancer Institute. Device lifetimes and voice prosthesis replacements of a retrospective cohort were used to calculate the number of needed voice prostheses per patient per year to prevent 70% of the leakages by prophylactic replacement. Various strategies for the timing of prophylactic replacement were considered: adaptive strategies based on the individual patient's history of replacement and fixed strategies based on the results of patients with similar voice prosthesis or treatment characteristics.

Results. Patients used a median 3.4 voice prostheses per year (range, 0.1-48.1). We found high inter- and intrapatient variability in device lifetime. When prophylactic replacement is applied, this would become a median 9.4 voice prostheses per year, which means replacement every 38 days, implying >6 additional voice prostheses per patient per year. The individual adaptive model showed that preventing 70% of the leakages was impossible for most patients and only a median 25% can be prevented. Monte-Carlo simulations showed that prophylactic replacement is not feasible due to the high coefficient of variation (SD/mean) in device lifetime.

Conclusion. Based on our simulations, prophylactic replacement of voice prostheses is not feasible due to high inter- and intrapatient variation in device lifetime.

Keywords

voice prosthesis, voice rehabilitation, total laryngectomy, prosthetic leakage, device lifetime

In most Western countries, the most successful technique for voice restoration after total laryngectomy (TL) is tracheoesophageal prosthetic speech.[1] The most commonly used voice prostheses (VPs) are indwelling VPs, which can be categorized as regular and problem-solving VPs. Regular VPs are the most commonly used for patients with laryngectomy. In case of frequent short device lifetimes, the so-called problem-solving VPs are indicated. Regular VPs are expected to have a median lifetime ranging from 2 to 6 months.[2,3] Soolsma et al showed that problem-solving VPs have a 16-fold longer device lifetime than regular VPs (median device lifetime, 337 days).[4]

The main reason for VP replacements is transprosthetic leakage (55%-80%), followed by periprosthetic leakage (5%-30%).[5-8] The frequent replacements significantly affect the patient's quality of life, causing insecurity and unplanned hospital visits and costs.[9] The standard policy for replacements is "wait to leak," but possibly the replacements can be planned to prevent leakage (prophylactic replacement). The principle of prophylactic replacement has been used in pacemaker users for years. This has given pacemaker users the security of a continuously working device.[10,11] The device lifetime of

[1]Department of Head and Neck Oncology and Surgery, The Netherlands Cancer Institute, Amsterdam, the Netherlands
[2]Department of Biometrics and Statistics, The Netherlands Cancer Institute, Amsterdam, the Netherlands
[3]Amsterdam Center of Language and Communication, University of Amsterdam, Amsterdam, the Netherlands
[4]Department of Otorhinolaryngology–Head and Neck Surgery, University of Groningen, University Medical Center Groningen, Groningen, the Netherlands
[5]Department of Maxillofacial Surgery, Amsterdam University Medical Center, Amsterdam, the Netherlands

Corresponding Author:
Anne N. Heirman, MD, Department of Head and Neck Oncology and Surgery, The Netherlands Cancer Institute, Plesmanlaan 121, Amsterdam, North Holland 1066 CX, the Netherlands.
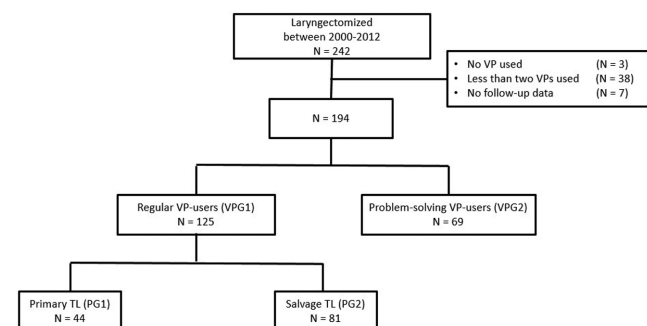Email: a.heirman@nki.nl

Figure 1. Flowchart of included patients and subgroups. TL, total laryngectomy; VP, voice prosthesis.

pacemakers depends on the battery. The device lifetime of VPs depends on many more aspects, such as the ability of a patient to clean the VP properly, the type of VP, biofilm formation, shrinking tracheo-oesophageal puncture, hypertrophy, and infection. Distance to the hospital, voice problems, diet, having a partner, and country of origin have also been found to be related to device lifetime.[3,12-18]

The aim of the present study was to explore the possibility of prophylactic VP replacement (PVPR) by predicting VP lifetime and by calculating the needed number of VPs when applying PVPR through these predictions.

Materials and Methods

In this study, a retrospective database was used.[3] All included patients (N = 242) were laryngectomized between January 2000 and December 2012 and in regular follow-up in the Netherlands Cancer Institute. The last date of follow-up was January 5, 2017.

After the initial inclusion of 242 patients, patients with <2 VP replacements or no follow-up data were excluded. This resulted in 194 patients (**Figure 1**). Patients were analyzed by the type of VP used and the indication for TL. All VPs analyzed in this article were manufactured by Atos Medical AB. Analyses were done for the total group and 2 subgroups. The following data were collected for each VP replacement: date of insertion, replacement or removal, type and size, and reason for replacement or removal. VPG1 was composed of patients using only regular VPs (Provox2 or Provox Vega). VPG2 consisted of patients alternating between regular and problem-solving VPs (ActiValve Light, Strong or Xtra Strong). There were no patients using only problem-solving VPs.

Patient group 1 (PG1) underwent primary laryngectomy with or without additional treatment. Patient group 2 (PG2) had a salvage laryngectomy for recurrence or second primary tumor or a laryngectomy for a functional reason.

All VP replacements were performed by qualified and trained speech-language pathologists, residents, or head and neck surgeons.

Statistical Analysis

Descriptive analysis was used to summarize patient and device characteristics. The VP lifetime was measured in days,

calculated from the insertion date to the date of removal or last follow-up. Kaplan-Meier analyses were used to assess device lifetimes and a moment for prophylactic replacement. Device lifetime of VPs ongoing at the end of the observation period were right-censored, as well as device lifetimes of VPs still in situ when the patient was lost to follow-up or died. Standard deviations were used to describe variability in device lifetime, and Mann-Whitney U was used to test for differences in device lifetime and variability. Statistical analyses were performed in R version 4.1.0 and SPSS version 27.0 (IBM).

PVPR Prediction Model

In this study, PVPR was considered feasible if at least 70% of VPs were replaced before leaking, allowing a 30% leakage fraction as acceptable. This cutoff point was chosen by consensus of the research team and called DeviceLife70 (DL70; expressed in days). The current standard policy (wait to leak) has a 100% leakage fraction. To train the prediction model, the DL70 was chosen as the number of days at which the Kaplan-Meier curve for device lifetime in the different groups of patients crossed the 70% boundary. Several models were considered: 1 DL70 for all patients, separate DL70s for type of VPs used (VPG1 and VPG2), and separate DL70s for indication TL (PG1 and PG2). All models assumed that problem-solving VPs would never be prophylactically replaced.

For evaluation of the prediction models, we counted how many VPs received by the patients would be prophylactically replaced and how many would still have been replaced because of leakage if the various prediction models had been used at the time. VPs with a device lifetime shorter than DL70 were considered "replaced because of leakage." VPs with a device lifetime at DL70 or higher were considered "prophylactically replaced." Time in situ of additional VPs (that would be used in case of PVPR) was estimated from known history of VP use per year. Thus, for each patient, the number of needed VPs per year under the various prediction models was calculated. In the evaluation of the model that used different DL70s for VPG1 and VPG2, we assumed that all patients started in VPG1 and switched to VPG2 as soon as they had their first problem-solving VP. The data are displayed in medians and ranges.

Individual Adaptive Simulations

As there is a high device lifetime variability, an individual adaptive model per patient was made. This model used the device lifetime of the first 3 used VPs to calculate the replacement moment for the coming VP, as the DL70 based on these 3 VPs. After each replacement because of leakage, the moment of replacement for the next VP would be calculated as the DL70 on the last 3 VPs. When the current VP reached this moment and hence would be replaced prophylactically, the next moment of replacement would be the DL70 based on the last 3 VPs, increased with 17% to correct for the fact that the actual lifetime of the last VP was longer than its in situ time. The 17% value of this correction factor was found by trial and error. Problem-solving VPs are not prophylactically replaced because of their longevity.

Monte Carlo Simulations

Since VP replacement data are sparse, the possibilities for leakage reduction by simulating device lifetimes through Monte Carlo simulations were investigated. The main unknown factor in formulating an optimal device change policy is the probability distribution of the in vivo device lifetimes. These Monte Carlo simulations were used to investigate the relationship between variability in device lifetime (inter- and intrapatients) and the limits of PVPR. The relevant parameter of this unknown probability distribution is the coefficient of variation (CV = SD/mean). The Monte Carlo simulations model the average time between leakage events, relative to the default policy and the associated number of device replacements as a function of the simulated CV. The simulations are repeated for 4 probability distributions. For details, see Supplemental Material (available online).

Ethical Considerations

This study does not fall under the scope of the Medical Research Involving Human Subjects Act and was approved by the review board of the Netherlands Cancer Institute (IRBd21-092).

Results

Patient Characteristics

The patient, tumor, and treatment characteristics of the 194 patients are shown in **Table 1**. The majority of the patients were male (79%), and the mean age was 63 years (SD, 10.8). Most patients had laryngeal carcinoma (72%), and the majority were treated with (chemo)radiotherapy (67%) before TL. Half of the patients underwent a bilateral neck dissection during TL.

The median overall survival was 60.8 months (95% CI, 38.7-82.9). The mean follow-up time was 66.4 months (95% CI, 58.5-74.3).

Voice Prostheses

The 194 patients used 3265 VPs in total during this study period. VPs with in situ times <1 day (n = 92), VPs of an unknown type (n = 25), and VPs replaced for developmental study purposes (n = 86) were excluded, leaving 3062 VPs for analysis.

Device Lifetime

The median device lifetime of all VPs (N = 3062) was 69 days. The median number of used VPs per patient per year was 3.4 (range, 0.2-48.1).

Of the 194 patients, 125 used only regular VPs (VPG1), and 69 used regular and problem-solving VPs (VPG2). The median device lifetime of regular VPs was 67 days in VPG1 and 57 days in VPG2. This difference was significant (Mann-Whitney U, $P < .05$). The longevity of problem-solving VPs was 2.5 times longer than regular VPs, namely 168 days.

VPG1 (regular VP users) was divided into 2 groups: PG1, primary laryngectomy with or without additional treatments; PG2, salvage laryngectomy for recurrence or second primary

Table 1. Patient, Tumor, and Treatment Details of All Patients (N = 194).

	No. (%)
Sex	
Male	153 (79)
Female	41 (21)
Age, y, mean ± SD	62.8 ± 10.8
Tumor stage	
I	3 (2)
II	18 (9)
III	96 (50)
IV	77 (39)
Primary tumor site	
Larynx	140 (72)
Hypopharynx	26 (13)
Oropharynx	17 (9)
Miscellaneous	11 (6)
Indication TL	
Primary TL	7 (3)
Primary TL+ additional treatment	56 (29)
Salvage TL[a]	108 (56)
TL for second primary	23 (12)
Pharyngectomy	
No (standard laryngectomy)	137 (71)
Near total	37 (19)
Circumferential	17 (9)
Unknown	3 (2)
Neck dissection during TL	
No	49 (25)
Unilateral during TL	48 (25)
Bilateral during TL	95 (49)
Unknown	2 (1)
Reconstruction	
No (primary closure)	124 (64)
Yes[b]	67 (34)
Unknown	3 (2)

Abbreviation: TL, total laryngectomy.
[a]18 patients underwent salvage TL for a dysfunctional larynx.
[b]Varying reconstruction methods were used: pectoralis major muscle (n = 49), free radial forearm flap (n = 8), gastric pull-up (n = 7), anterolateral thigh flap (n = 2), and latissimus dorsi flap (n = 1).

tumor or a laryngectomy for a functional reason (**Figure 1**). The median device lifetime was 81 days in PG1 and 65 days in PG2. The Mann-Whitney U test showed a significant difference in device lifetime ($P < .01$).

Device Lifetime Cutoff Points

For all groups, the 70% cutoff point (DL70) was calculated, which was used for the calculations in the prophylactic replacement model (**Table 2**).
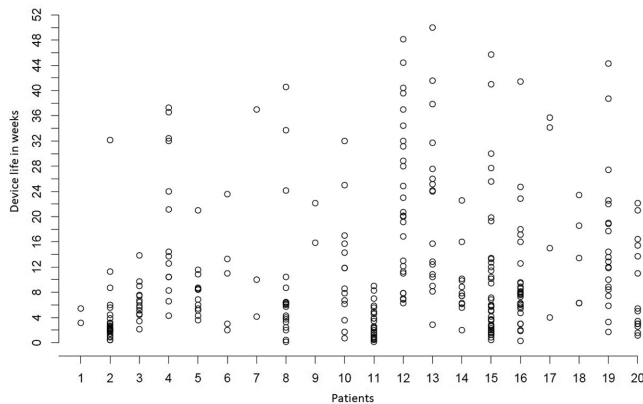
Variability in Device Lifetime

Device lifetimes showed great variability, within and between patients. The median within-patient SD of device lifetime in

Table 2. DeviceLife70 Cutoff Points for the Prophylactic VP Replacement Model.

Patient group	Cutoff, days
All patients	40
VPG1	41
VPG2	90
PG1	45
PG2	39

Abbreviations: PG1, primary laryngectomy; PG2, salvage, second primary, and dysfunctional larynx laryngectomy; VP, voice prosthesis; VPG1, regular VP users; VPG2, problem-solving VP users.

Figure 2. Overview of inter- and intrapatient variability of device lifetime of regular voice prostheses in weeks. This is a representative sample of 20 regular voice prosthesis users (VPG1).

all patients was 64.5 days (range, 1.4-909.3). For VPG1, the median within-patient SD was 85.3 days (range, 11.2-909.3), whereas for VPG2 the median within-patient SD was 53.6 days (range, 1.4-667.4). This difference in SD of the device lifetime was significant (Mann-Whitney U, $P < .05$). Note that in all 3 cases the median within-patient SDs are of the same order of magnitude as the overall median device lifetime, indicating a high CV (**Figure 2**).

Prophylactic Voice Prosthesis Replacement

When PVPR was applied to all patients per the DL70 of 40 days, the calculated median number of used VPs per year was 9.7 (range, 9.1-48.1), implying >6 (6.2; range, 0.0-9.0) additional VPs per patient per year to prevent 70% of the leakage events. PVPR after 40 days in case of no leakage would lead to a net mean in situ time of 38 days in the set of all patients.

For regular VP users (VPG1), the PVPR showed that patients would need 6 additional VP replacements per year: the median number of VPs used was 3.4 (range, 0.1-48.1) but was 9.4 (range, 8.9-48.1) when applying PVPR. For the indication TL subgroups, in PVPR the median number of VPs was 8.6 (range, 8.1-48.1) for PG1 and 9.7 (range, 9.4-21.9) for PG2, but the additional number of VPs per year was 6.1 in both subgroups.

PVPR in an Individual Adaptive Model

As described in the methods, the timing of prophylactic replacement was chosen to prevent 70% of leakages under the assumption that the lifetime of the next VP would be similar to that of the previous 3 VPs in the same patients. In our data, we found a high intrapatient variability. We calculated the CV and found a median 0.8 (range, 0.02-3.01). Due to this high intrapatient variability and the fact that the first 3 VPs would not be prophylactically replaced, in practice the prevention of 70% of leakage events was not reached in most study patients. Of 194 patients, just 9 (4.6%) reached 70% prevented leakages. The median percentage leakage prevented by this method was 36% (range, 0%-81%). In the subgroup of patients with only regular VPs (VPG1), the numbers were even worse: a median 25% of leakages prevented (range, 81%-100%). The patients in whom 70% of the leakage events could be prevented were patients with a high number of used VPs (range, 21-57) during the study period.

PVPR in Monte Carlo Simulations

Monte Carlo simulations were run for the DL70 case varying the CV between 0 and 1 (Supplemental Material, available online). The results showed that for a CV >0.5 the benefits in terms of decreased number of leakage events per year (<50%) decreased considerably while the costs in terms of additional VPs increased significantly (>163%). For a median CV of 0.8 as found in our patient base, there were around 20% fewer leakages per year requiring some 170% more devices. In this simulation, increasing the DL70 to a higher value can marginally decrease the number of leakage events but with a mounting increase in the number of devices needed.

Discussion

With this study, we found that PVPR in patients with laryngectomy is not feasible. PVPR would optimally reduce unexpected VP leakages and consequent aspiration and improve the quality of life of patients. To prevent at least 70% of all leakages in regular VP users, on average an additional 6 VPs per patient per year are needed, which is not desirable given the costs and additional hospital visits.

Device lifetime differed significantly between primary TL (PG1) and salvage TL (PG2), but the number of additional VPs in PVPR was similar. The device lifetime of regular VPs in patients using only regular VPs (VPG1) was significantly longer than in patients alternating between regular and problem-solving VPs (VPG2), as explained by the indication for problem-solving VPs (a short device lifetime with regular VPs).[3]

The high inter- and intrapatient variability in device lifetime (**Figure 2**) makes it impossible to apply the concept of PVPR in daily practice. The device lifetimes are widely spread, and there is no clear trend visible. This is supported by the high standard deviation in device lifetime (median, 64.5 days), which is around the median device lifetime, causing the high CV (median, 0.8). The individual adaptive simulations

showed that just 25% to 36% of the leakages could be prevented. The Monte Carlo simulations showed that PVPR would be valuable only if the CV were <0.5, again stating that PVPR is not possible in real life.

As mentioned, prophylactic replacement has been successful for pacemaker users. The main reason why pacemakers are suitable for prophylactic replacement is the low variability in the device lifetime of batteries. The device life of VPs depends on many more aspects causing unpredictable, early VP leakage and a high variability in device lifetime. With problem-solving VPs, device life did become longer, but because of the high costs, they are not available worldwide for patients and, when available, are mostly used in patients with a short device lifetime.[19,20] Variability in device life is a problem found in all types and brands of VPs and different countries,[16] making the results of this study generalizable for all patients using a VP worldwide.

The ultimate goal in PVPR would be to replace VPs at a set moment just before leakage, predicted by previous device lifetime and known patient or treatment variables. With such a policy, one could reduce the number of unexpected VP replacements and potentially prevent aspirations. This would likely provide patients more security and peace of mind and possibly increase quality of life. Planned replacements are also more convenient for the treating physician or speech-language pathologist. However, replacing VPs too early implies that patients would need extra VPs and would thus visit the clinics more often, which would increase costs. The total costs of VPs and their replacements are variable and depend on, for example, the type of VP used, hospital costs, number and type of health care professionals involved, travel expenses, and health care system. Therefore, a cost analysis was not made.

Data on complications of leakage, such as aspiration pneumonia, were not available in our database, though they are important for decision making in VP replacements. The review of Hutcheson et al gives a nice overview of pneumonia rates in patients with laryngectomy. The authors stated that aspiration pneumonia due to leakage is relatively rare but could have serious (fatal) consequences.[21] In Poland, there is an ongoing randomized controlled trial comparing the effect of replacing VPs every 3 months against a wait-to-leak policy, investigating complications, fistula colonization, and patient satisfaction.[22] Results are not yet available. If results show fewer leakages in the replacement arm and comparable or fewer complications and high patient satisfaction, this might be a step in prophylactic replacement of VPs.

Limitations

The concept of PVPR in this article is hypothetical. Our results are based on analysis in a retrospective data set and Monte Carlo simulations, mainly investigating regular Provox VPs. It is well known that other brands of VPs suffer from an inconsistent device lifetime,[16] so it is unlikely that prophylactic replacement is an option for other brands. We investigated a cutoff point of 70% because of reached consensus on the profitability for patients.

Conclusion

This is the first study exploring multiple policies to prevent VP leakage using hypothetical prophylactic VP changes in patients with laryngectomy. To prevent 70% of all occurred leakages during the study period, on average >6 additional VPs would be necessary annually per patient. The variability in device lifetime between, but most of all within, patients makes it impossible to predict device lifetime and set the interval for VP replacements. There are significant differences in device lifetime in subgroups for the used type of VP and indication for TL. These differences do not contribute to a better predictability of leakage. Based on the presented results, prophylactic replacement of VPs is not a feasible policy.

References

1. van Sluis KE, van der Molen L, van Son RJJH, Hilgers FJM, Bhairosing PA, van den Brekel MWM. Objective and subjective voice outcomes after total laryngectomy: a systematic review. *Eur Arch Otorhinolaryngol*. 2018;275(1):11-26. doi:10.1007/s00405-017-4790-6
2. Lewin JS, Baumgart LM, Barrow MP, Hutcheson KA. Device life of the tracheoesophageal voice prosthesis revisited. *JAMA Otolaryngol Head Neck Surg*. 2017;143(1):65-71. doi:10.1001/jamaoto.2016.2771
3. Petersen JF, Lansaat L, Timmermans AJ, van der Noort V, Hilgers FJM, van den Brekel MWM. Postlaryngectomy prosthetic voice rehabilitation outcomes in a consecutive cohort of 232 patients over a 13-year period. *Head Neck*. 2019;41(3):623-631. doi:10.1002/hed.25364
4. Soolsma J, van den Brekel MW, Ackerstaff AH, Balm AJ, Tan B, Hilgers FJ. Long-term results of Provox ActiValve, solving the problem of frequent *Candida*- and "underpressure"-related

voice prosthesis replacements. *Laryngoscope*. 2008;118(2):252-257. doi:10.1097/MLG.0b013e318159ebde

5. Starmer HM, Agrawal N, Koch W, Richmon J, Webster K, Gourin CG. Does prosthesis diameter matter? The relationship between voice prosthesis diameter and complications. *Otolaryngol Head Neck Surg*. 2011;144(5):740-746. doi:10.1177/0194599810395362

6. Brook I, Goodman JF. Tracheoesophageal voice prosthesis use and maintenance in laryngectomees. *Int Arch Otorhinolaryngol*. 2020;24(4):e535-e538. doi:10.1055/s-0039-3402497

7. Acton LM, Ross DA, Sasaki CT, Leder SB. Investigation of tracheoesophageal voice prosthesis leakage patterns: patient's self-report versus clinician's confirmation. *Head Neck*. 2008;30(5):618-621. doi:10.1002/hed.20764

8. Parrilla C, Longobardi Y, Galli J, et al. Periprosthetic leakage in tracheoesophageal prosthesis: proposal of a standardized therapeutic algorithm. *Otolaryngol Head Neck Surg*. Published online January 5, 2021. doi:10.1177/0194599820983343

9. Summers L. Social and quality of life impact using a voice prosthesis after laryngectomy. *Curr Opin Otolaryngol Head Neck Surg*. 2017;25(3):188-194. doi:10.1097/MOO.0000000000000361

10. Boriani G, Bertini M, Saporito D, et al. Impact of pacemaker longevity on expected device replacement rates: results from computer simulations based on a multicenter registry (ESSENTIAL). *Clin Cardiol*. 2018;41(9):1185-1191. doi:10.1002/clc.23003

11. Deharo JC, Djiane P. Longévité des stimulateurs cardiaques: Remplacement du boîtier de stimulateur. *Annales de Cardiologie et d'Angéiologie*. 2005;54(1):26-31. doi:10.1016/j.ancard.2004.11.003

12. Op de Coul BM, Hilgers FJ, Balm AJ, Tan IB, van den Hoogen FJ, van Tinteren H. A decade of postlaryngectomy vocal rehabilitation in 318 patients: a single institution's experience with consistent application of provox indwelling voice prostheses. *Arch Otolaryngol Head Neck Surg*. 2000;126(11):1320-1328. doi:10.1001/archotol.126.11.1320

13. Kress P, Schäfer P, Schwerdtfeger FP. Clinical use of a voice prosthesis with a flap valve containing silver oxide (Blom-Singer Advantage), biofilm formation, in-situ lifetime and indication. *Laryngorhinootologie*. 2007;85:893-896. doi:10.1055/s-2006-925292

14. Hilgers FJM, Ackerstaff AH, Balm AJM, Van den Brekel MWM, Bing Tan I, Persson JO. A new problem-solving indwelling voice prosthesis, eliminating the need for frequent *Candida*- and ''underpressure''-related replacements: Provox ActiValve. *Acta Otolaryngol*. 2003;123(8):972-979. doi:10.1080/00016480310015371

15. Krishnamurthy A, Khwajamohiuddin S. Analysis of factors affecting the longevity of voice prosthesis following total laryngectomy with a review of literature. *Indian J Surg Oncol*. 2018;9(1):39-45. doi:10.1007/s13193-017-0700-z

16. Kress P, Schäfer P, Schwerdtfeger FP, Rösler S. Are modern voice prostheses better? A lifetime comparison of 749 voice prostheses. *Eur Arch Otorhinolaryngol*. 2014;271(1):133-40. doi:10.1007/s00405-013-2611-0

17. Lewin JS, Baumgart LM, Barrow MP, Hutcheson KA. Device life of the tracheoesophageal voice prosthesis revisited. *JAMA Otolaryngol Head Neck Surg*. 2017;143(1):65-71. doi:10.1001/jamaoto.2016.2771

18. Yenigun A, Eren SB, Ozkul MH, Tugrul S, Meric A. Factors influencing the longevity and replacement frequency of Provox voice prostheses. *Singapore Med J*. 2015;56(11):632-636. doi:10.11622/smedj.2015173

19. Galli J, Calo L, Meucci D, et al. Biofilm in voice prosthesis: a prospective cohort study and laboratory tests using sonication and SEM analysis. *Clin Otolaryngol*. 2018;43(5):1260-1265. doi:10.1111/coa.13141

20. Timmermans AJ, Harmsen HJM, Bus-Spoor C, et al. Biofilm formation on the Provox ActiValve: composition and ingrowth analyzed by Illumina paired-end RNA sequencing, fluorescence in situ hybridization, and confocal laser scanning microscopy. *Head Neck*. 2016;38(suppl 1):E432-E440. doi:10.1002/hed.24014

21. Hutcheson KA, Lewin JS, Sturgis EM, Kapadia A, Risser J. Enlarged tracheoesophageal puncture after total laryngectomy: a systematic review and meta-analysis. *Head Neck*. 2011;33(1):20-30. doi:10.1002/hed.21399

22. Rzepakowska A. Estimation of benefit from regular versus leakage-related exchange of voice prosthesis in patients post laryngectomy considering complications rate, fistula colonization by *Candida* species and patients satisfaction feedback. Clinical Trials.gov. 2020. Accessed November 22, 2021. https://clinicaltrials.gov/ct2/show/NCT04268459