A New Self-Administered Questionnaire to Determine
Patient Experience with Voice Prostheses
(Blom-Singer Valves)


ABSTRACT

Aim: To obtain information about valved speech and related issues in patients who have undergone total laryngectomy with the help of a new structured questionnaire on voice prosthesis.

Settings and Design: A questionnaire-based pilot study set at a tertiary referral head and neck cancer unit.

Materials and Methods: Twenty-five patients using voice prostheses, who showed no signs of recurrence after having undergone total laryngectomy were interviewed with the help of a questionnaire that assessed issues such as voice quality, valve maintenance, leakage, quality of life, humidification and hands-free system over the preceding seven days. The data was analyzed using non-parametric tests (Mann-Whitney and Spearman rank).

Results: Twenty-five patients (16 males) with a median age of 65 years (IQ range: 59–70 years) had been using the prosthesis for a median of 6 years (IQ range: 5–10 years). The majority of the patients (n=20) were fully informed about their valve size and diameter and most were able to remove and replace their own prosthesis. Fourteen patients (60%) had leakage-related issues. Women were less satisfied with their voice quality as compared to men. Overall, there appeared to be an improvement in quality of life with the use of the voice prosthesis.

Conclusions: The subjects were fairly well informed about their valve and experienced a high level of satisfaction with their voice. This questionnaire serves as a valuable tool for monitoring voice rehabilitation in patients who have undergone laryngectomy.

KEY WORDS: Humidification, insertion, leakage, quality of life, valve change, voice prosthesis

Vocal rehabilitation after total laryngectomy has been a major concern to head and neck surgeons since the time of first total laryngectomy operation by Billroth in 1837.[1] Rehabilitation using voice prostheses has been considered as the gold standard in this regard[2] and several voice prostheses have been developed, each with their special characteristics and qualities.[3] Newer prostheses have been developed with the intention of reducing complications, increasing valve life and improving quality of life.[4–6] Problems related to the life of prosthesis, valve function and the tracheoesophageal fistula continue to challenge multidisciplinary health care professionals providing follow-up care to these patients.[7,8,10]

However, the assessment of voice rehabilitation outcome by means of a questionnaire has so far been limited. This pilot study describes the development and analysis of a new self-administered structured-questionnaire that assures collection of relevant, factual data about the voice valve and its related issues that can be analysed quantitatively and systematically.

Materials and Methods

This prospective study was initiated after obtaining clearance from the institutional Review Board. Speech and language therapy database was used to identify twenty-nine patients without recurrence, who were using voice prostheses after having undergone total laryngectomy.

A self-administered questionnaire was mailed to these subjects along with a personalised covering letter providing information about purpose of the survey, the importance of participation, investigators associated with the study along with a statement guaranteeing confidentiality along with a prepaid return envelope.

The questionnaire (attached as an appendix) comprising of clear instructions on how to complete it had 12 subdivisions (Table 1) and 64 mostly close-ended multiple choice ques-
and was used during consultation by the head and neck surgeons and the speech and language therapists. The questionnaire content was pre-validated during an inter-departmental multidisciplinary meeting attended by experienced head and neck surgeons, speech and language therapists, nursing and other ancillary staff. During this process, each question was discussed and debated at length. The questionnaire consisted of the following sub-divisions: general, device-related, speech-related, leakage-related, prosthesis replacement-related, valve change and removal related, device loss-related, valve maintenance-related, stoma-related, quality of life-related, humidification system-related and finally hands free system-related. The questions were short, simple, precise and asking for only one piece of information at a time. We used closed format of questions because we believed that this would be easy and quick to complete and minimise discrimination. The questionnaire was sent by mail in a self-administered fashion as we thought that it would be easy to administer in a standard manner, preserve confidentiality, allow patients to complete it at their own convenience and be cost-effective.

Chart abstraction was performed to identify the socio-demographic data. The data was then entered into a worksheet (Excel’03, Microsoft Corp, Washington).

Statistical analysis was performed using the Statistical Package for Social Sciences, version 10.0 (SPSS Inc, Chicago, III). A p-value below 0.05 was considered significant. Results were compared using non-parametric tests (Mann-Whitney and Spearman-Rank).

### Results

Twenty-five patients responded (89% response rate) to the questionnaire, of whom, 16 patients were male and 9 were female, with a median age of 65 yrs (IQ range: 59–70 years). The patients in our study had been using a voice prosthesis (Blom-Singer) for a median of 6 years (IQ range: 5–10 years). A primary tracheo-oesophageal puncture had been done in seventeen patients and eight patients had a secondary puncture. In the secondary puncture group, a range of different methods was being used such as writing, mouthing, electrolarynx and oesophageal speech.

The Blom-Singer voice prosthesis was the valve-make in all 25 patients of this study. In particular, the Blom-Singer low pressure valve was reportedly being used by 14 patients, the duckbill and the indwelling in 2 patients each. Seven patients could not offer any details about their valve other than the make (Blom-Singer). Eighty percent of the patients (n=20) were fully aware of the dimensions of their valve. The valve length ranged from 6 to 14 mm having similar numbers in each group (6 mm: 4 pts, 8 mm: 3 pts, 10 mm: 4 pts, 12 mm: 3 pts, and 14 mm: 4 pts, 5 pts did not respond) with both 16 and 20 Fr being used (Figure 1).

Twenty patients in our study reported as being satisfied with their voice restoration (11 = “a lot,” 9 = “quite a bit,” 2 = “a little,” 3 = “no”). Further analysis suggested higher levels of satisfaction in males and patients who had undergone primary puncture. However, these differences did not reach statistical significance. Interestingly some of the reasons reported by the patients in our study for dissatisfaction for their restored voices included a deep male voice (as reported by the female patients), unpredictable voice, inability to sing, voice fatigability and unrealistic expectations about the voice valve (Table 2). Only two patients felt their voice was poor in terms of clarity over the telephone. Thirteen patients in the study rated the tone of their voice as too low.

Fourteen patients reported leakage around or through the prosthesis while drinking during the last 7 days. Over half of the patients said that they have been using an anti-fungal treat-

### Table 1: Summary of the subdivisions used in the questionnaire

<table>
<thead>
<tr>
<th>Subdivisions of the Questionnaire</th>
<th>Prosthesis replacement</th>
<th>Stoma-related</th>
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<tr>
<td>Device-related</td>
<td>Change and removal</td>
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<td>Device loss</td>
<td>Humidification</td>
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<td>Leakage</td>
<td>Maintenance</td>
<td>Hands free</td>
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### Table 2: Summary of statistical correlation analysis

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<th>Parameter</th>
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<th>P-value</th>
<th>Comments</th>
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<tr>
<td>Age vs satisf</td>
<td>No Spearman-Rank</td>
<td>ns</td>
<td></td>
</tr>
<tr>
<td>Leakage vs diam.</td>
<td>No Mann-Whitney</td>
<td>ns</td>
<td></td>
</tr>
<tr>
<td>Leakage vs age</td>
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</tr>
<tr>
<td>QOL vs valve</td>
<td>Yes Mann-Whitney</td>
<td>P&lt;0.04</td>
<td>Median difference, BS/LP = rest, (95% CI:10.1)</td>
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<tr>
<td>QOL vs satisf.</td>
<td>Yes Spearman Rank</td>
<td>P&lt;0.001</td>
<td>0.72 (95%: 0.44–0.87)</td>
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<tr>
<td>Valve vs satisf.</td>
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<td></td>
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<tr>
<td>F vs QOL</td>
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<tr>
<td>F vs make</td>
<td>No Mann-Whitney</td>
<td>ns</td>
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<tr>
<td>Leakage vs make</td>
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<tr>
<td>QOL vs leakage</td>
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<tr>
<td>Sex vs tone</td>
<td>No Fischers’ exact</td>
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<td>Tone vs QOL</td>
<td>No Mann-Whitney</td>
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<tr>
<td>Sex vs QOL</td>
<td>Yes Mann-Whitney</td>
<td>P&lt;0.05</td>
<td>Females lower Median Difference, Males – Females, (95% CI:10.1)</td>
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</tbody>
</table>

F=frequency of valve changes, QOL = quality of life, diam.= gauge of valve (16/20Fr), Satisf. = satisfaction with surgical voice restoration.
ment, usually nystatin oral suspension but less frequently nystatin pastilles, fluconazole and yoghurt.

The reported median valve life was three months (IQ range: 3–5 months). Specifically, patients were using between 1 and 14 new prostheses per year. Analysing this alarmingly wide range, we found no relationship to the type of valve used or to the usage of antifungal treatments (Figure 2). The main reasons for replacement were leakage through the prosthesis ($n=14$), leakage around the prosthesis ($n=5$), no production of voice ($n=2$) and excess effort for voice production ($n=1$).

Fourteen of the twenty-five patients in our study reported needing help with the change of their prosthesis. Reasons stated for this included awkward entry, poor lighting and angulations of the stoma. However, we were unable to configure who exactly provided the help required. Furthermore, valve removal was reported as being more often easy ($n=20$) than insertion which was more difficult ($n=6$). Sixteen patients reported bleeding during valve change although this was never severe. There were three reported cases of the valve being accidentally pulled out during the tape removal and in one instance the valve was pulled out by a child.

All patients in our study mentioned that the prosthesis was easy to clean. A variety of methods were used to clean the prosthesis including pipette ($n=16$), brush ($n=4$), pipe cleaner ($n=3$). It was reported as cleaned median once a day (IQ range: 1–3). Twenty-one patients were satisfied with their stoma size and shape (three patients did not respond). One patient reported a large and irregular stoma. Further investigations revealed that he had undergone multiple flap reconstructions which had altered the geometry of the stoma.

Twenty-four patients (a little: 3 pts, quite a bit: 5 pts, a lot: 16 pts, and no response: 1 pt) reported that their quality of life had improved to varying extent with the use of a voice prosthesis (Figure 3). On closer scrutiny, no difference was found between the primary and secondary puncture groups but more males than females reported that they had a lot of improvement in the quality of their life. Issues that negatively affected their perception included mucous plugs, tired thumb and poor fixation of the base plate.

Fifty per cent ($n=12$, no response in 1) of the group were using a humidification system such as the Provox or a combination of the Provox with the Blom-Singer, Blom-Singer alone, or the Laryngofoam. Most patients changed the filter at a median of 24 hours (range 4–24 hours). Half of the group reported a lot of satisfaction with their voice whilst using a humidification system. Most patients rated the clarity, loudness and fluency as reasonable to good; four patients rated the loudness on the telephone as poor. Fifty percent ($n=12$) of the patients found the tone of their voice to be too low (Figure 4). Three patients scored poorly (no: 3 pts, a little: 3 pts, quite a bit: 2 pts, a lot: 2 pts) on improvement of the quality of life with the humidification system. No difference was found on further comparison with the primary and secondary puncture patients. Common complaints reported by the patients against the humidification system were getting breathless on exertion and inability to get a good seal.

We had a small number of patients ($n=4$, males=3, females=1) regularly using a hands-free system. The common complaints reported by these patients for the hands-free system were the high cost, poor seal and reduced air entry.

Discussion

Developing a new questionnaire, which covers the broad subject of voice valves and its related issues is challenging. Again, although it sounds simple, we found that phrasing the questions correctly, concisely and obtaining consensus amongst the members of the team was difficult. This questionnaire does not attempt to project itself as an alternative to existing questionnaires on quality of life and voice assessment nor does it have a scoring system. It is a tool that will help elicit interest.
ing and useful information about the valve and its related issues that would have been hitherto unknown or difficult to obtain. In particular, this article is about the institution’s experience with the Blom-Singer valve.

It is important to note that the secondary puncture patients had in most cases, experienced a period of little or no voicing and therefore were likely to have a different perspective on voice restoration and quality of life as compared to patients who had undergone a primary puncture.[6]

Most patients knew the make, length and diameter of their valve. This is perhaps a combination of patient interest coupled with continued input from speech and language therapists. We found that all sizes of voice prosthesis were being used (see Figure 1), indicating the variability of the partitioning wall (tracheo-oesophageal partition).

Most patients in our study reported being satisfied with their voice restoration (80%). Reported voice satisfaction rates in the literature vary from 40% to 90%, depending on the rating scale used, extent of surgery and patient related comorbidities.[7,8] Although not statistically significant, both males and patients who have had a primary puncture were more satisfied with their voice restoration. One possible reason could be that males more readily accept the low tone of the prosthetic speech as compared to women. We would have expected secondary puncture patients to be more satisfied but this was not reflected in our study, possibly because the group was experienced having utilised prosthetic speech for many years.

A few patients judged the clarity of the voice on the telephone as poor. The absence of visual cues during a telephonic conversation may make it harder to follow valued speech. The majority of women felt that the tone of their prosthetic voice was too low. This raises an important issue as the current available techniques of voice restoration are unable to provide a voice appropriate to the gender of the user. The voice-valve itself plays no role in this since it is simply a one way valve to allow air entry into the PE segment while preventing aspiration with the voice being produced by the vibrations of the neoglottis.

As most of the patients had suffered leakage through or around the valve over the last seven days prior to completing the questionnaire, these data may have been influenced by the timing and the wording of the questionnaire. Also, it was noticed that many of our patients did not clarify further as to whether the leakage was through or around. For future research, more specific information is needed in this respect. However, the patients were not able to provide this information in retrospect, despite the specific phrasing in the questionnaire.

Most of our patients were on regular antifungal medication. Interestingly, two of our patients were using yogart as a treatment for leakage highlighting the role of home remedies.[9]

The median life of the valves in this study was three months which was consistent with other studies reported in the literature.[4,5,8] No correlation was found with leakage and antifungal usage or type of valve. Indwelling valves are designed to last longer,[8,9,10] but this was not the case in our study. We expected to find less frequent changes in patients using regular antifungal. This did not appear to be the case (see Figure 2) and the reasons remain unclear possibly indicating the lack of effectiveness of the existing antifungal agents in use. Clearly, further work is required to ascertain why there is such variability in the valve life especially as in the case of the patient using more than fourteen valves in a calendar year. The main reasons for replacement were leakage through or around the prosthesis which was as expected and is consistent to previous publications.[6,11]

As most of our patients were using a non-indwelling valve, we would have expected them to change their own valve unlike the indwelling that is changed by the clinician; however we did not find this in our study due to the reasons already mentioned.[5,11–13] In all probability, the necessary help to change the valve is being provided either by the clinician/speech and language therapist or a close associate of the patient.

Quality of life is difficult to define due to the many variables involved. Overall there was a tendency to satisfaction with their quality of life which is in keeping with other studies.[6,8,10] However, it must be kept in mind that a majority of our patients were primary puncture patients and would not have had the possibility to compare the situation without a valve and one with it. Women scored significantly lower on their quality of life (Mann-Whitney, P<0.05, median difference, males – females, (95%CI)1(0,1)) as compared to men. This could be a reflection of their dissatisfaction with the tone of their prosthetic voice.

Due to the small numbers and different makes in use as reported by the patients in our study, no further inferences can be drawn in this group and those using the hands-free system.

Finally to sum up, the advantages of this questionnaire are: it is simple, easy to complete, assessing general and specific issues about the device and its accessories as well as encouraging suggestions/complaints from the patients using the voice prosthesis. It could be useful as a tool for audit and research. Although this questionnaire appears to be long, 89% percent participation reflects the relevance and the interesting nature of the subject.

Conclusions

Patients in our study were fairly well-informed about their valve with a high level of satisfaction with their voice quality. Although surgical voice restoration seems to have improved our patient’s quality of life, this is a difficult area to assess as there are many variables influencing this.

This questionnaire is an effective method of gathering a wealth of useful information on patients using voice prosthesis. It serves as a tool in the monitoring and audit of laryngectomies. It can also help in decision-making based on a patient feed-
back of voice and valve related issues.

References


Appendix

Voice prosthesis questionnaire

This questionnaire asks about your voice prosthesis and related issues over the past seven days. Please answer all of the questions by circling the correct response.

Name: _____________________________ NHS no: _____________________________ Date: _____________________________
Age: _____________________________ Sex: male/female

1. How long have you been using a voice prosthesis? number of years / months ______

2. How did you communicate before the voice prosthesis was inserted? regular speech / oesophageal speech / electrolarynx / whisper / no voice / sign language / writing mouthing / other ______

3. Which voice prosthesis do you currently use? Blom-Singer /Provox / Other ______
Duckbill / Low pressure / Indwelling /Provox1/Provox2/Other ______
3a. Do you know the length (mm) & diameter (fr) of the current prosthesis? ______ mm ______ fr

4. Are you satisfied with your voice restoration following the removal of the voice box?
1 = no, 2 = a little, 3 = quite a bit, 4 = a lot
4a. If not, what is the main reason? ______
4b. How would rate the clarity of your voice? 1 = poor, 2 = moderate, 3 = reasonable, 4 = good
4c. How would you rate the loudness of your voice? 1 = poor, 2 = moderate, 3 = reasonable, 4 = good
4d. How would you rate the tone of your voice? 1 = too low, 2 = too low, 3 = reasonable
4e. How would you rate the fluency of your voice? 1 = poor, 2 = moderate, 3 = reasonable, 4 = good
4f. How would you rate the clarity of your voice on the telephone? 1 = bad, 2 = moderate, 3 = reasonable, 4 = good

5. Has there been any leakage of the voice box while drinking during the last 7 days? 1 = yes, 2 = no
5a. If yes, how often? 1 = sometimes, 2 = often, 3 = always
5b. How annoying is this leakage? 1 = not at all, 2 = a little, 3 = quite a bit, 4 = very much
5c. Do you use a plug in case of leakage? (indwelling users only) 1 = yes, 2 = no
5d. If not, why not? ______
5e. Do you use any anti-candida (fungal) treatment? 1 = yes, 2 = no
5f. If yes, please specify i.e. name of medication, frequency, duration, method of use. ______

6. Has the voice prosthesis ever been replaced? 1 = yes, 2 = no
6a. On an average, how often? Every ______ months/year
6b. How many new voice prostheses have you had in the last 12 months? Number ______
6c. Reason(s) for replacement:
1 = leakage through prosthesis, 3 = no voicing, 6 = bloating/burping/increased wind
2 = leakage around prosthesis, 4 = voicing was too effortful, 5 = others ______
Laryngectomy leads to several structural and functional limitations such as hyposmia, swallowing problems and coughing and mucus production due to breathing through a tracheostoma. In addition, laryngectomy means loss of voice and therefore considerable restriction of communication. Voice restoration and protection of the airways nowadays are an integral part of therapy. There are different methods of voice restoration. Tracheo-esophageal substitute voice has been shown to be the most similar to normal voice and is therefore preferred. Patients using tracheo-esophageal voice are mostly

### Expert’s Comments

**Patients’ Experience with Voice Prostheses**

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7. Do you change your own prosthesis? 1 = yes, 2 = no
   7a. How would you describe the removal? 1 = very easy, 2 = rather easy, 3 = rather difficult, 4 = very difficult
   7b. If difficult, please explain why?
   7c. How would you describe the insertion? 1 = very easy, 2 = rather easy, 3 = rather difficult, 4 = very difficult.
   7d. If difficult, please explain why?
   7e. Is there any bleeding during insertion or removal? 1 = no, 2 = a little, 3 = quite a bit, 4 = a lot

8. Please indicate whether your voice prosthesis has ever been: 1 = coughed out, 2 = swallowed
   8a. How often has this happened in the last 12 months? Number __
   8b. If you have experienced an accidental loss of the voice prosthesis, what caused it?

9. Is the prosthesis easy to clean? 1 = yes, 2 = no
   9a. If not, why?
   9b. Do you use a brush or a pipette for cleaning the voice prosthesis?
   9c. If yes, how many times per day?
   9d. If not, why not?

10. Are you able to achieve a tight stoma-seal when using your voice? 1 = yes, 2 = no
    10a. Which finger do you use to occlude the stoma?
    10b. Are you happy with the stoma size and shape?

11. Do you think the voice prosthesis has improved your quality of life? 1 = no, 2 = a little, 3 = quite a bit, 4 = a lot

12. Do you any complaints about the voice prosthesis?

13. Do you a humidification system? - 1 = yes, 2 = no
    13a. Which humidification system do you currently use?
    13b. How often do you change your filter/protector? Every__ hours
    13c. Are you satisfied with your voice with the humidification system? 1 = no, 2 = a little, 3 = quite a bit, 4 = a lot
    13d. How would you rate the clarity of your voice since using a humidification system? 1 = poor, 2 = moderate, 3 = reasonable, 4 = good
    13e. How would you rate the loudness of your voice since using a humidification system? 1 = too low, 2 = too low, 3 = reasonable
    13f. How would you rate the fluency of your voice since using a humidification system? 1 = poor, 2 = moderate, 3 = reasonable, 4 = good
    13g. How would you rate the clarity of your voice on the telephone since using a humidification system? 1 = bad, 2 = moderate, 3 = reasonable, 4 = good
    13h. Have you noticed an improvement since using a humidification system? 1 = no, 2 = a little, 3 = quite a bit, 4 = a lot
    13i. Do you any complaints about the humidification system?

14. Do you use an hands-free system for voicing? 1 = yes, 2 = no
    14a. If yes, which system do you use? Blom-Singer ATV / ATV11 / Provox Free-hands / Others
    14b. Are you satisfied with your hands free voice? 1 = no, 2 = a little, 3 = quite a bit, 4 = a lot
    14c. How would you rate the clarity of your hands free voice? 1 = poor, 2 = moderate, 3 = reasonable, 4 = good
    14d. How would you rate the loudness of your hands free voice? 1 = poor, 2 = moderate, 3 = reasonable, 4 = good
    14e. How would you rate the tone of your hands free voice? 1 = too low, 2 = too low, 3 = reasonable
    14f. How would you rate the fluency of your hands free voice? 1 = poor, 2 = moderate, 3 = reasonable, 4 = good
    14g. How would you rate the clarity of your voice on the telephone? 1 = bad, 2 = moderate, 3 = reasonable, 4 = good
    14h. Do you think the hands free voice prosthesis has improved your quality of life? 1 = no, 2 = a little, 3 = quite a bit, 4 = a lot
    14i. Do you any complaints about the hands-free?
equipped with a voice prosthesis preventing aspiration but leading exhaled air into the esophagus by a one-way valve system. Patients who use voice prosthesis or other devices need to have special knowledge or abilities to maintain their functioning.

The article presents a questionnaire that has been designed to acquire more information about laryngectomies’ knowledge and experience. The authors report the results of the questionnaire: patients’ handling and satisfaction with voice prostheses, heat and moisture systems and free-hands devices for the tracheostoma, substitute voice quality and quality-of-life. They divide the questionnaire’s issues into device-related, substitute voice-related, stoma-related divisions and ask for functional and subjective limitations. Considering every day’s experience with laryngectomies a lot of questions seem to be too abstract to be well understood by patients. Comparing this new questionnaire to established questionnaires it lacks descriptive questions that prevent from ambiguity. This could explain some results that vary considerably from other publications. It seems fairly exceptional that leakage while drinking occurred in more than half of all patients during the last 7 days before they answered the questionnaire. The authors should consider possible distorsional effects of the approach and data collection. Statistical results are therefore questionable.

Some issues that are part of the presented questionnaire have already been published and also validated. For example quality-of-life evaluations of laryngectomies, objective voice outcome and subjective voice outcome using standardized questionnaires such as the EORTC, the SF-36, VHI, or VRQOL.

The presented questionnaire lacks precision and validation. However, parts of it could be used for clinical and scientific purposes to complete information about specific issues concerning laryngectomies using voice prosthesis and other devices. Functional and subjective limitations of the patients should rather be evaluated by existing standardized questionnaires. The questionnaire presented in this paper is not yet useful and needs revision.

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