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## ORIGINAL ARTICLE

# Management of voice prosthesis leakage with Blom-Singer large esophageal and tracheal flange voice prostheses

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**KEYWORDS**

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Leakage;  
Complications

**Summary**

*Introduction:* Voice rehabilitation after total laryngectomy is a major socio-economic challenge. Voice rehabilitation can be achieved by voice prostheses, which provide rapid patient satisfaction. Enlarged tracheo-oesophageal puncture is a frequent complication and can be difficult to manage.

*Material and method:* A prospective study was conducted from November 2010 to October 2011 on 28 Blom-Singer large oesophageal and tracheal flange voice prostheses placed in 18 patients with enlarged tracheo-oesophageal puncture causing leakage around the voice prosthesis.

*Result:* Leakage around the voice prosthesis resolved in all patients with a mean prosthesis lifespan of 95 days. The patients considered voice quality to be similar to that obtained with the initial voice prosthesis.

*Conclusion:* The Blom-Singer large oesophageal and tracheal flange voice prosthesis is a useful solution for the management of periprosthetic leakage ensuring similar voice quality and an identical lifespan to that of other voice prostheses.

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**Introduction**

Voice rehabilitation has been a major challenge since the first laryngectomy performed by Billroth in 1873. Loss of speech is responsible for major economic, social and psychological consequences [1]. Voice rehabilitation techniques include oesophageal speech, electronic larynx, phonatory shunt and voice prosthesis [2]. The voice prosthesis was described for the first time in the 1980s by Blom and Singer

[2]. The very good results (80–90% success) that are rapidly obtained with this technique contributed to the popularity of this technique [2–4]. However, it is associated with certain complications, including periprosthetic leakage, which can be difficult to treat [4–6]. The most frequent complication is enlarged tracheo-oesophageal puncture [4–6]. Leakage can be responsible for sometimes severe pneumonia [7], requiring rapid management. Other rarer complications have been reported: intrusion, extrusion, abscess of the tracheo-oesophageal wall, allergic reaction and granulation [4–6]. We report our experience of the management of this complication using the Blom-Singer large esophageal and tracheal flange voice prosthesis, recently released on the French market.

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## Material and method

This prospective study was performed between 17 November 2010 and 05 October 2011 on a series of 28 Blom-Singer prostheses placed in 18 patients (17 males and one female) with periprosthetic leakage.

All patients had undergone total laryngectomy or total pharyngolaryngectomy followed by radiotherapy. The primary prosthesis was placed during the first surgical procedure as laryngectomy or pharyngolaryngectomy except for one patient, in whom prosthesis placement was performed after her second neck surgery (oesophagectomy with gastric reconstruction).

The mean interval between laryngectomy and Blom-Singer prosthesis placement was 3204 days (107 months) for a median of 2573 days (range: 398–11,879 days) (86 months).

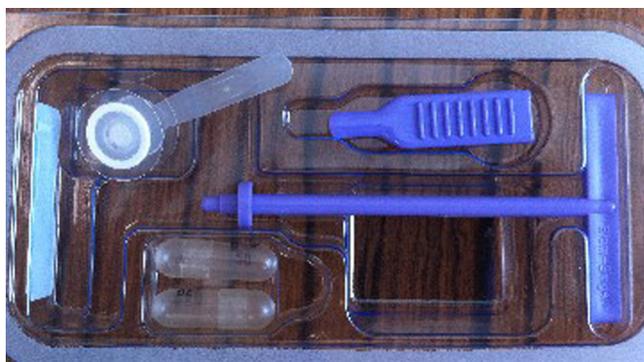
Analysis of comorbidities revealed two patients with diabetes and eight patients with peripheral artery disease. Five patients developed a second cancer (four gastrointestinal cancers and one lung cancer). One patient underwent renal transplantation. All patients were smokers and drinkers prior to total (pharyngo)laryngectomy. None of these patients continued to smoke after laryngectomy, but eight continued their alcohol intake.

The Blom-Singer prosthesis was always placed during an outpatient visit after local anaesthesia with lidocaine spray, after healing of the tracheo-oesophageal puncture.

The indication for Blom-Singer voice prosthesis was periprosthetic leakage due to enlargement of the tracheo-oesophageal puncture in 16 patients and prosthesis dislodgement in two patients. Replacement by the same type of voice prosthesis was performed in cases of leakage through the voice prosthesis.

All voice prostheses were Blom-Singer® large esophageal and tracheal flange, 20 Fr (6.65 mm). The length of the prosthesis was adapted to the thickness of the tracheo-oesophageal wall.

The insertion kit delivered with the voice prosthesis was systematically used for placement according to the following technique (Fig. 1): the oesophageal flange is introduced into the small portion of the gel cap (Fig. 2) and the prosthesis is then fixed onto the inserter (Fig. 3). The gel cap is introduced into the tracheo-oesophageal puncture and maintained in place for 3 min to allow the gel cap to dissolve,



**Figure 1** Insertion kit (Blom-Singer large esophageal flange voice prosthesis, distributor in France Ceredas®).



**Figure 2** Prepared prosthesis.



**Figure 3** Prosthesis on its inserter.

allowing deployment of the oesophageal flange within the oesophagus (Fig. 4).

This study population presented several specificities: two patients died (one from myocardial infarction, and the other from massive stroke), 40 days and 183 days after insertion, respectively, with no abnormality of the voice prosthesis, and one prosthesis was placed between the trachea and a gastric pull-up oesophagoplasty.



**Figure 4** Prosthesis in place (before cutting the tag).

## Results

All periprosthetic leakages resolved. Voice prostheses replaced after dislodgement remained inside the tracheo-oesophageal puncture without periprosthetic leakage.

Prosthesis placement was simple except for one patient with a narrow tracheostomy preventing visual control of the tracheo-oesophageal puncture. The flexible inserter + prosthesis assembly did not always provide effective tactile feedback. No placement failure was observed in this series.

Voice quality was assessed subjectively by the patients. To the question: "How would you assess your voice: better, identical, less good?", all patients replied "identical" to the voice obtained with the previous prosthesis.

The mean lifespan obtained for the 12 changed prostheses was 95 days for a median of 70 days (range: 24–219 days). The mean follow-up, corresponding to the period between placement of the last prosthesis and 5 October 2011, the end of the study, was 72 days for a median of 94 days (range: 5–272 days).

Several difficulties were encountered: insertion of the oesophageal flange into the gel cap can be fairly difficult, but this technique is rapidly acquired with experience; insertion into the tracheo-oesophageal puncture can be difficult due to the flexibility of the insertion system when the tracheo-oesophageal puncture is situated too inferiorly or in the case of a narrow tracheostomy. This flexibility limits the tactile feedback perceived by the operator, which can make blind insertion fairly difficult.

Placement of this new prosthesis was considered to be less traumatic than placement of the previous prosthesis by patients from our centre as well as patients referred by other centres. One patient had been previously fitted with a Provox Vega® (Atos Medical) prosthesis, while all of the other patients had been previously fitted with a Provox 2® prosthesis.

Several failures were observed: one case of prosthesis dislodgement, which was successfully replaced by a new prosthesis, which remains in place and functional; and one case presented early signs of exclusion with a wound of the posterior tracheal wall. The prosthesis had to be removed and replaced by a cuffed cannula and a nasogastric tube. Healing was obtained 3 weeks later, allowing placement of another prosthesis.

## Discussion

A recent meta-analysis [5] reviewed enlargement of the tracheo-oesophageal puncture after voice prosthesis placement. The authors reported a mean risk of 7.2% of enlargement of the tracheo-oesophageal puncture. This incidence varies from series to series from 1 to 29% [2,3,7–12]. Risk factors for enlargement of the tracheo-oesophageal puncture have not been clearly identified [4]. Loss of tissue elasticity appears to be involved and could be related to wound healing or radiotherapy. Radiotherapy [1,3,5,13,14] could play a role in enlargement of the tracheo-oesophageal puncture although this role has not been formally demonstrated. Other factors appear to predispose to enlargement of the tracheo-oesophageal puncture

[3–5,7,11]: postoperative stenosis, presence of very large lymph nodes (N2, N3), extensive initial tumour resection, malnutrition and recurrences (local, regional or distant).

The diameter of the initial prosthesis does not appear to be a decisive factor, although divergent results have been reported in the literature. According to Issing et al. [15], tracheo-oesophageal fistulas are only observed with large diameter prostheses, while Acton et al. [7] reported leakages only with small diameter prostheses.

Few studies have reported the time to onset of enlargement of the tracheo-oesophageal puncture after the initial surgery, but it appears to vary between 1 and 115 months with a mean of between 20 and 40 months [4,11,16]. This complication occurred much later in the present series.

Two prosthesis placement techniques have been proposed. The primary (or delayed primary) technique consists of creating the tracheo-oesophageal puncture at the time of the laryngectomy or pharyngolaryngectomy procedure and constitutes our preferred technique. The second technique consists of secondary placement after healing of the laryngectomy. This sequence (primary or secondary) does not appear to have any impact on the complication rate [1]. The time to onset of enlargement of the tracheo-oesophageal puncture varies, but a mean interval of 20 to 40 months after creation of the tracheo-oesophageal puncture is generally observed [3]. periprosthetic leakage induces pulmonary contamination by saliva or food that can be responsible for pneumonia. The management of periprosthetic leakage is based on various conservative techniques with variable efficacy.

Reduction of the length of the prosthesis [3,17,18] appears to be the simplest and most effective technique, allowing control of the periprosthetic leakage in the majority of cases [3]. The efficacy of this technique can be explained by leakage between the flange of the prosthesis and the posterior surface of the trachea. This leakage is controlled by restoring close contact between these two structures. A larger diameter voice prosthesis [9] can also be proposed, but can raise subsequent problems when larger diameter prostheses are no longer available.

Placement of a hand-made and, more recently, a commercially available anterior flange [12] has been proposed. This technique is effective and consists of using a sheet of soft silicone moulded to the shape of the posterior tracheal wall, but it requires a very rigorous surgical technique and the presence of a cough reflex.

Various injections [3,8,9,12,16–23] of exogenous material or autologous fat have been reported with variable results. Creation of a periprosthetic purse-string suture [3,11,17,18] allows temporary control of the problem, but the periprosthetic leakage frequently recurs [24]. Cauterization of the tracheo-oesophageal puncture [2] has been proposed by some authors.

Temporary removal of the prosthesis (with or without calibration) [3,5,8,10,17,18] is one of the least invasive and most effective techniques. The duration of prosthesis removal ranges from several days to several weeks and requires nasogastric tube feeding and cuffed tracheotomy cannula placement.

Regardless of the technique used, the duration of efficacy between two episodes of periprosthetic leakage ranges between several days and fourteen months [17,18,22] and

30 to 67% of patients require several treatments for their periprosthetic leakage [2–4,8–12,21,23].

The prosthesis lifespan of 95 days in our study was identical to that published in the literature for other implants (101–125 days) [3,25].

Like all new techniques, implant placement requires a learning curve. Introduction of the oesophageal flange can be initially difficult, but rapidly becomes easier with experience. Introduction into the tracheo-oesophageal puncture over the inserter may be difficult in two particular situations: when the tracheo-oesophageal puncture is low or when the tracheostomy is narrow. The prosthesis-inserter unit is flexible and the low tactile feedback can make insertion fairly difficult when visual control is impossible. However, we encountered this difficulty in only one case.

One episode of dislodgement of the prosthesis was observed and could be due to several factors: enlargement of the tracheo-oesophageal puncture responsible for the periprosthetic leakage, this case occurred early in our experience; the inserter was removed too early and the oesophageal flange was not completely deployed. Prosthesis dislodgement has not been observed since.

Following repeated failures of conservative treatment for enlarged tracheo-oesophageal puncture, definitive treatment is usually proposed, consisting of surgical closure of the tracheo-oesophageal puncture, often a difficult procedure requiring muscle interposition. Permanent closure of the tracheo-oesophageal puncture is required in 14 to 50% of cases of periprosthetic leakage [2,3,9–11,16]. Simple suture of the puncture generally results in failure. Interposition of pectoralis major muscle is the solution most frequently proposed in patients with a history of neck radiotherapy, while local flaps can be proposed in non-irradiated cases.

To our knowledge, the use of this type of prosthesis has not been previously proposed or published. All of the above techniques have been used in our department. The most appropriate technique appears to be placement of a fine sheet of silicone between the tracheal wall and the tracheal flange of the voice prosthesis. This new voice prosthesis is based on the same idea with the addition of a large oesophageal flange without enlargement of the body of the prosthesis.

## Conclusion

This voice prosthesis provides a valuable contribution to the management of periprosthetic leakage. The prosthesis lifespan appears to be identical to that of other voice prostheses. Vocal quality appears to be maintained, but needs to be confirmed by objective data. The ease of use and the identical cost to that of other prostheses make this prosthesis a very valuable tool for the treatment of enlarged tracheo-oesophageal puncture. Many conservative techniques have been described, but none of them appears to be effective in the long-term. We report a technique with a completely different mode of functioning to the techniques used up until now. This technique will probably allow long-

term management of enlarged tracheo-oesophageal puncture.

## Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

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