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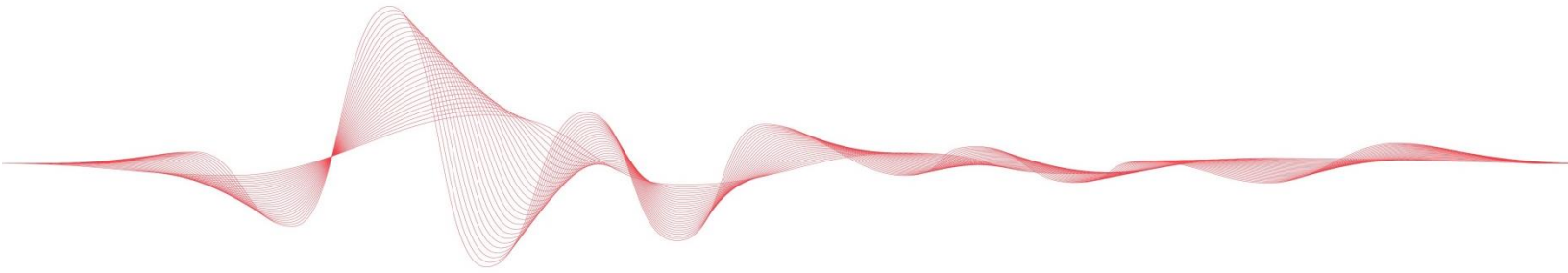
Primary versus Delayed voice prosthesis fitting

- Comparison of primary and delayed voice prosthesis fitting
- Evaluation of TE puncture with primary voice prosthesis fitting
- Tracheoesophageal puncture stability and resizing



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Preface

This document contains a bibliography and summaries of selected publications relating to primary voice prosthesis fitting (i.e. immediately after the tracheoesophageal puncture) versus delayed voice prosthesis fitting (i.e. delayed until several days or weeks after the tracheoesophageal puncture). The document is part of a growing, and regularly updated collection of documents, the *Atos Medical Clinical Evidence Series*, covering various clinical topics related to Atos Medical's areas of expertise. The topics are chosen based on questions that we receive from our customers.

Examples of available topics are:

- Laryngectomy and Reflux
- Primary versus Delayed TE puncture

If you would like to receive a list of all currently available topics, if you are interested in any of the topics listed above, or if you have a suggestion for additional topics, please contact your local Atos Medical representative. Due to International Copyright law, we cannot provide full-text publications of the references. If a publication is available online via 'Open Access' the link is provided in the document.

Table of content

Comparison of primary and delayed voice prosthesis fitting

When creating a tracheoesophageal puncture, the voice prosthesis can be placed either immediately, ie primary (fitting/intraoperative fitting) or placed several weeks after the procedure (delayed fitting). In the latter case the puncture is stented with a catheter for several days, until the voice prosthesis is fitted[3,5].

Several important patient benefits of primary fitting have been demonstrated when compared to delayed fitting. Early familiarity for the patient with the voice prosthesis and maintenance thereof, along with faster and more successful postoperative voicing with related social benefits have been shown [1,3,5].

From a clinical care perspective, there are several important benefits shown of primary fitting. The absence of catheter interference with the laryngectomy tube and the voice prosthesis flanges protect the puncture tract against reflux/saliva. Furthermore, postoperative application of an HME system is not complicated by the presence of a catheter, thus providing the patient with optimal pulmonary care[3,5].

In addition to the above, primary fitting have shown to result in fewer post discharge emergency room visits[3], diminished risk for TE wall separation (due to use of retrograde insertion technique), better stabilization of the TE wall by flanges of voice prosthesis, reduced irritation of stoma/fistula due to the absence of a catheter in puncture tract[4]. Combined with the benefits of fewer early voice prosthesis changes, longer durability of voice prosthesis and shorter onset of speech rehabilitation, this result in reduced hospital savings due to shorter hospital stay and fewer SLP visits for TEP adjustments[1,4].

Collectively, the benefits shown from primary fitting of voice prosthesis has resulted in the standard of care in most European countries and is increasingly becoming the preferred method in countries where delayed fitting was the method of choice.

The publications listed below concern the publications regarding comparison of primary and delayed voice prosthesis fitting that are referenced above. Clicking the link while holding the Ctrl key will take you directly to the summary you are interested in.

[1]Robinson et al. Total laryngectomy with tracheoesophageal puncture: Intraoperative versus delayed voice prosthesis placement. Head & Neck 2017 Jun(6) 1138-44.

[2]Lukinovic Overview of 100 patients with voice prosthesis after total laryngectomy--experience of single institution. Coll Antropol. 2012 Nov;36 Suppl 2:99-102.

[3]Cleveland Clinic. Primary vs. Secondary Tracheoesophageal Puncture (TEP) Fitting: A Comparison of Voice Restoration and Complications (N = 20). Cleveland Clinic, Head & Neck Institute, Outcomes 2011

[4]Sidell et al. Improved tracheoesophageal prosthesis sizing in office-based tracheoesophageal puncture. Ann Otol Rhinol Laryngol. 2010 Jan;119(1):37-41.

[5]Brown et al. Postlaryngectomy voice rehabilitation: state of the art at the millennium. World J Surg. 2003 Jul;27(7):824-31.

Robinson et al 2017

Title
Total laryngectomy with tracheoesophageal puncture: Intraoperative versus delayed voice prosthesis placement.

"…this evidence can be used to help drive practice change in centers continuing to use delayed voice prosthesis placement protocols ."

Authors
Robinson RA, Simms VA, Ward EC, Barnhart MK, Chandler SJ, Smee, RI.

Affiliation(s)
Department of Speech Pathology Prince of Wales Hospital Sydney, Australia

Journal and year of publication
Head & Neck 2017 Jun(6) 1138-44.

Type of publication
Retrospective study

Introduction
Studies support using intraoperative voice prosthesis insertion performed at the time of primary tracheoesophageal puncture (TEP) during laryngectomy. However, none have compared intraoperative voice prosthesis insertion with delayed voice prosthesis insertion. The purpose of this study was to prospectively examine patient, services, and cost benefits of intraoperative versus delayed voice prosthesis placement.

Subjects and Methods
Voice prosthesis use, duration to the first voice prosthesis change, early communication, and costs were compared between 14 patients who underwent a laryngectomy and who received intraoperative voice prosthesis placement, and 10 patients who underwent initial catheter stenting and then delayed voice prosthesis insertion.

Results
Intraoperative voice prosthesis placement was associated with significantly fewer early device changes (1.4 vs 2), voice prosthesis changes because of resizing (8% vs 80%), longer durations to initial voice prosthesis change (159.7 vs 24.5 days), earlier commencement of voice rehabilitation (13.2 vs 17.6 days), reduced length of hospital stay (17.2 vs 24.5 days), and cost savings of $559.83/person.

Conclusions
The authors conclude observed superior clinical and patient benefits with intraoperative voice prosthesis placement during primary TEP.

Lukinovic et al, 2012

Title
Overview of 100 patients with voice prosthesis after total laryngectomy--experience of single institution.

"Tracheoesophageal puncture with the insertion of voice prosthesis remains the most successful rehabilitation method following the total laryngectomy."

Authors
Lukinović J[1], Bilić M, Raguz I, Zivković T, Kovac-Bilić L, Prgomet D.

Affiliation(s)
University of Zagreb, Zagreb University Hospital Center, Department of Otorhinolaryngology, Head & Neck Surgery, Zagreb, Croatia.

Journal and year of publication
Coll Antropol. 2012 Nov;36 Suppl 2:99-102.

Type of publication
Retrospective study

Introduction
Tracheoesophageal (TE) voice has become the preferred choice of speech rehabilitation. Voice rehabilitation is possible as early as few days after the surgery, which contributes to the patients's psychological recovery. Despite the simplicity of the method of TE puncture, it is very important to provide a thorough assessment of the patient to determine whether he is a candidate and the timing of placement.

The aim of this study was to determine and compare the success of the voice prosthesis rehabilitation in patients belonging to different groups formed according to age, irradiation status and timing of prosthesis insertion.

Subjects and Methods
Voice prostheses were inserted in 100 patients in the ENT Department, University Hospital Center Zagreb, from January 2004 until February 2011, and 91 of these patients were included in this study. Seventy-one had a secondary insertion, 20 had a primary insertion. Voice rehabilitation was initiated the 10th day after primary insertion and the 1st-3rd day after secondary insertion. The postoperative voice quality was compared using five degree scales.

Results
Rehabilitation was successful in 75.8% of the patients, 90% with primary insertion and 71% with secondary insertion. Early complication rate was 4.4%, and 10.9% of patients had late complications. Out of 14 patients that had some complication during the postoperative period, 11 were finally successfully rehabilitated. Statistical analysis did not show significant differences regarding the complications rate and success rate of rehabilitation between groups of patients, formed according to age, irradiation status and timing of prosthesis insertion.

Conclusions
Tracheoesophageal puncture with the insertion of a voice prosthesis remains the most successful rehabilitation method following total laryngectomy. Successful rehabilitation was higher with primary insertion, although there was no significant difference with secondary insertion. The results are similar to the results of another retrospective study (Brown et al. 2003, discussed in this document).

Cleveland Clinic, 2011

Title
Primary vs. Secondary Tracheoesophageal Puncture (TEP) Fitting: A Comparison of Voice Restoration and Complications (N = 20).

"...the elimination of the TEP catheter stenting has significantly reduced complications, restored speech by the first speech pathology visit, and virtually eliminated post-operative ER visits."

Authors
Dept of Speech Language Pathology

Affiliation(s)
Cleveland Clinic, Head and Neck Institute, Cleveland, Ohio, USA.

Journal and year of publication
Cleveland Clinic, Head and Neck Institute, Outcomes 2011.

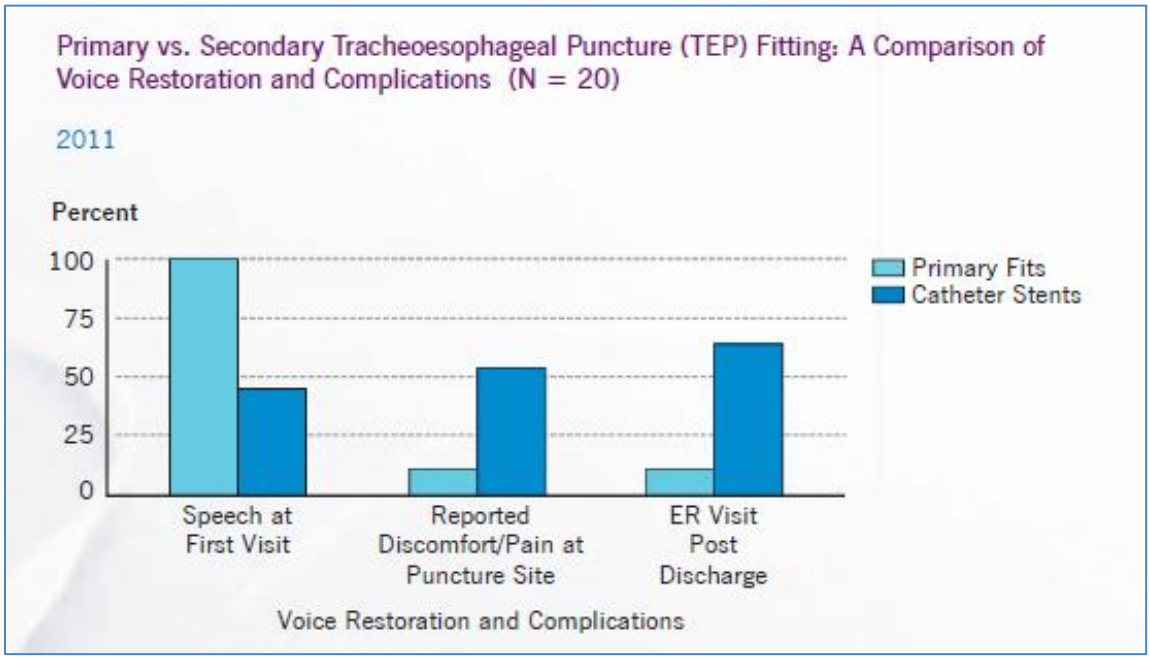
Type of publication
Online publication

Link (see p 28)
http://my.clevelandclinic.org/Documents/outcomes/2011/outcomes-hni-2011.pdf

Introduction
Primary tracheoesophageal puncture (TEP) voice restoration has been a highly successful and cost-effective approach to re-establishing voice and speech in laryngectomized patients at Cleveland Clinic since the early 1990s. In 2011, as an effort to improve patient comfort and early speech outcomes, the Head & Neck Institute modified the traditional approach of using a red rubber catheter to stent the newly created TEP and to facilitate tube feeding during the early post-operative phase. Instead, they began by placing the initial voice prosthesis during the TEP surgery.

Subjects and methods
Twenty laryngectomized patients, 9 with immediate placement during TEP surgery and 11 using the red rubber catheter.

Results
Preliminary findings for this different approach suggest that the elimination of the TEP catheter stenting has significantly reduced complications, restored speech by the first speech pathology visit, and virtually eliminated post-operative ER visits.



Conclusion

Primary voice prosthesis fitting increases the possibility to speak at first visit, decreases reports of discomfort/pain at puncture site, and decreases ER visits after discharge.

Sidell et al, 2010

Title
Improved tracheoesophageal prosthesis sizing in office-based tracheoesophageal puncture.

"Voice prosthesis sizing was better in patients who had office-based TEP [with primary VP fitting] than in patients who had operating room-based TEP [with catheter placement and delayed VP fitting].

Authors
Sidell D, Shamouelian D, Erman A, Gerratt BR, Chhetri D.

Affiliation(s)
Division of Head and Neck Surgery, David Geffen School of Medicine, University of California, Los Angeles, Los Angeles, California 90095-1624, USA.

Journal and year of publication
Ann Otol Rhinol Laryngol. 2010 Jan;119(1):37-41.

Type of publication
Retrospective chart review

Introduction
Tracheoesophageal puncture (TEP) for postlaryngectomy speech is increasingly being performed as an office-based procedure. The authors review their experience with office-based TEP and compare outcomes with those of operating room-based TEP. The hypothesis was that office-based TEP results in improved prosthesis sizing, reducing the number of visits dedicated to prosthesis resizing.

Methods
A retrospective chart review was performed of all patients who underwent secondary TEP at the institution from 2001 to 2008, office-based or operating room-based. The primary dependent measure was the change in the length of the voice prosthesis. Also the number of visits made to the speech-language pathologist for resizing before a stable prosthesis length was achieved was evaluated, and the number of days between voice prosthesis placement and the date a stable prosthesis length was observed.

Results
Thirty-one patients were included in this study. Eighteen patients underwent secondary OR-based TEP with secondary fitting 3-5 days later, and 13 patients underwent office-based secondary puncture with primary fitting. There was a significant difference in prosthesis length change between patients who had office-based TEP and patients who had operating room-based TEP ($p < 0.001$). In addition, the office-based cohort required fewer visits to the speech-language pathologist for TEP adjustments before a stable TEP length was achieved ($p < 0.001$).

Conclusions
Voice prosthesis sizing was better in patients who had office-based TEP with primary fitting than in patients who had operating room-based TEP with secondary fitting 3-5 days later. This outcome is likely due to the lesser degree of swelling of the tracheoesophageal party wall in the office-based procedure.

Brown et al., 2003

Title
Postlaryngectomy voice rehabilitation: state of the art at the millennium.

"[The immediate retrograde insertion of the voice prosthesis] saves a lot of time, as there is no longer any need to send the patient home for some days with a feeding tube, allowing rehabilitation to start on the day of surgery."

Authors
Brown DH[1], Hilgers FJ[2], Irish JC[1], Balm AJ[1].

Affiliation(s)
[1]The Wharton Head and Neck Center, Princess Margaret Hospital, University of Toronto, Canada; [2]The Netherlands Cancer Institute, Amsterdam, The Netherlands

Journal and year of publication
World J Surg. 2003 Jul;27(7):824-31.

Type of publication
Review

Summary
This article reviews postlaryngectomy voice rehabilitation with a historical background as well as the present state-of-the-art. With respect to primary versus secondary fitting of the voice prosthesis, the authors state that the advantages of primary puncture followed by primary fitting of the voice prosthesis are numerous, provided a device of sufficient length is used. The following pros and cons of primary fitting are listed:

Pros:
- The retrograde insertion technique diminishes the risk of separation of the tracheoesophageal wall.
- The tracheoesophageal wall is to some extent also stabilized by the voice prosthesis.
- The flanges of the voice prosthesis give protection against leakage of saliva and gastric reflux.
- The prosthesis causes less irritation of the stoma and the puncture than a feeding tube taped to the skin around the stomal area.
- No postoperative interference with a cannula or a heat and moisture exchanger.
- Patients can become familiar with maintenance of the voice prosthesis soon after operation.
- There is no need for early postoperative prosthesis fitting.
- At around the tenth postoperative day, there can be immediate focus on voicing itself, which can give a tremendous psychological boost to the patient.
- Postoperative radiotherapy is not contraindicated, and most patients have developed a useful voice before this treatment starts.
- The first replacement is usually months down the road, when wound healing is completed, surgical edema has subsided, and the patient is generally in much better physical and mental shape.
- Still allows a leading role of the speech therapist on the multidisciplinary rehabilitation team.

Cons:
- The presence of a feeding tube in the nose and throat for 10 days
- Temporary deterioration of the voice during postoperative radiotherapy.

Evaluation of TE puncture with primary voice prosthesis fitting

Evaluations show a low complication rate for primary TE puncture with primary voice prosthesis fitting[8,9]. Results are similar for secondary TE puncture with primary fitting: high success rates, no significant immediate complications, no reported postoperative dislodgements, early voice acquisition, and no necessity for a subsequent fitting procedure[2,7].

As a result of the change toward primary voice prosthesis fitting in countries that traditionally used the delayed fitting technique (utilizing a catheter to stent the puncture until the voice prosthesis is fitted several days or weeks later), several publications have come out that have evaluated the technique of fitting a voice prosthesis immediately after creating the TE puncture[3,6-9]. Initial and long-term success rates are reported to be high[8,9], speech is acquired early[8] and the procedure is described as safe and effective[3,9]. Intraoperative placement of the voice prosthesis after primary puncture in cases with free tissue reconstruction and salivary bypass tube has also found to be effective[5].

To allow easier and faster primary and delayed puncturing, the Provox Vega Puncture Set (PVPS) was developed. This PVPS, based on the Seldinger technique, is a fully disposable, sterile set of instruments for primary and secondary TE puncture and immediate voice prosthesis insertion. The PVPS proved itself to be a reliable aid in the insertion of voice prostheses, allowing quick and easy insertion of the voice prosthesis with minimal tissue trauma, in the vast majority of cases without requiring additional instruments[4,5].

The publications listed below all concern publications regarding the evaluation of TE puncture with primary voice prosthesis fitting that are referenced above. Clicking the link while holding the Ctrl key will take you directly to the summary you are interested in.

[1]Gitomer et al. Influence of timing, radiation, and reconstruction on complications and speech outcomes with tracheoesophageal puncture. Head Neck. 2016 Dec; 38(12):1765-1771.

[2]Bergeron et al. Office-based tracheoesophageal puncture: updates in techniques and outcomes. Am J Otolaryngol. 2014 Sep-Oct;35(5):549-53.

[3]Damrose et al. The hybrid tracheoesophageal puncture procedure: indications and outcomes. Ann Otol Rhinol Laryngol. 2014 Aug;123(8):584-90.

[4]Hilgers et al. Development and (pre-) clinical assessment of a novel surgical tool for primary and secondary tracheoesophageal puncture with immediate voice prosthesis insertion, the Provox Vega Puncture Set. Eur Arch Otorhinolaryngol. 2013 Jan;270(1):255-62.

[5]Lorenz et al. [A novel puncture instrument: the Provox-Vega® puncture set : Its use in voice prosthesis insertion following laryngectomy.]. HNO. 2013 Jan;61(1):30-7.

[6]Divi et al. Primary TEP placement in patients with laryngopharyngeal free tissue reconstruction and salivary bypass tube placement. Otolaryngol.Head Neck Surg. 2011 144[3], 474-476.

[7]Deschler et al. Simplified technique of tracheoesophageal prosthesis placement at the time of secondary tracheoesophageal puncture (TEP). Laryngoscope. 2011 Sep;121(9):1855-9.

[8]Gultekin et al. Effects of neck dissection and radiotherapy on short-term speech success in voice prosthesis restoration patients. J Voice. 2011 Mar;25(2):245-8. Epub 2010 Feb 26.

[9]Deschler et al. Evaluation of voice prosthesis placement at the time of primary tracheoesophageal puncture with total laryngectomy. Laryngoscope. 2009 Jul;119(7):1353-7.

Gitomer et al, 2016

Title
Influence of timing, radiation, and reconstruction on complications and speech outcomes with tracheoesophageal puncture.

Authors
Gitomer SA[1,2], Hutcheson KA[1], Christianson BL[1], Samuelson MB[1], Barringer DA[1], Roberts DB[1], Hessel AC[1], Weber RS[1], Lewin JS[1], Zafereo ME[1,2].

Affiliation(s)
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[2]Bobby R. Alford Department of Otolaryngology - Head and Neck Surgery, Baylor College of Medicine, Houston, Texas, US

Journal and year of publication
Head Neck. 2016 Dec;38(12):1765-1771.

Type of publication
Retrospective

Objective
To determine the impact of radiation, reconstruction, and timing of tracheoesophageal puncture (TEP) on complications and speech outcomes.

Methods
Retrospective review identified 145 patients who underwent TEP between 2003 and 2007.

Results
Ninety-nine patients (68%) had primary and 46 (32%) had secondary TEP, with complications occurring in 65% and 61%, respectively (p = .96). Twenty-nine patients (20%) had major complications (18 primary and 11 secondary; p = .42). Ninety-four patients (65%) had pre-TEP radiation, 39 (27%) post-TEP radiation, and 12 (8%) no radiation. With patients grouped by TEP timing and radiation history, there was no difference in complications, fluency, or TEP use. With mean 4.7-year follow-up, 82% primary and 85% secondary used TEP for primary communication (p = .66). Free-flap patients used TEP more commonly for primary communication after secondary versus primary TEP (90% vs 50%; p = .02).

Conclusion
Careful selection of patients' candidacy for TEP provided similar TE speech outcomes and complication rates regardless of timing of TEP or radiation. For more complex patients who require extended surgical resection and reconstruction, secondary TEP may be a better option to achieve successful voice restoration because of the opportunity for enhanced pre-TEP testing, education, and selection.

Bergeron et al, 2014

Title
Office-based tracheoesophageal puncture: updates in techniques and outcomes.

"TEP in an office-based setting with immediate voice prosthesis placement continues to be a safe method of voice rehabilitation for postlaryngectomy patients….".

Authors
Bergeron JL[1], Jamal N[2], Erman A[3], Chhetri DK[4].

Affiliation(s)
[1]Department of Otolaryngology-Head & Neck Surgery, Stanford University School of Medicine, Stanford, CA, USA.
[2]Department of Otolaryngology-Head & Neck Surgery, Temple University School of Medicine, Philadelphia, PA, USA.
[3]Department of Audiology and Speech, David Geffen School of Medicine, University of California, Los Angeles, Los Angeles, CA, USA.
[4]Department of Head and Neck Surgery, David Geffen School of Medicine, University of California, Los Angeles, Los Angeles, CA, USA.

Journal and year of publication
Am J Otolaryngol. 2014 Sep-Oct;35(5):549-53.

Type of publication
Retrospective chart review

Introduction
Tracheoesophageal puncture (TEP) is an effective rehabilitation method for post-laryngectomy speech and has already been described as a procedure that is safely performed in the office. This study reviews long-term experience with office-based TEP with primary fitting over the past 7 years in the largest cohort published to date.

Subjects and Methods
A retrospective chart review was performed of all patients who underwent TEP by a single surgeon from 2005 through 2012, including office-based TEP with primary fitting and operating room TEP procedures with secondary fitting 3-5 days post-operative. Indications for the chosen technique (office versus operating room) and surgical outcomes were evaluated.

Results
Fifty-nine patients underwent 72 TEP procedures, with 55 performed in the outpatient setting and 17 performed in the operating room. There were no major complications in any of the office or operating room TEP procedures. The indications for performing TEPs in the operating room included 2 primary TEPs, 14 due to concomitant procedures requiring general anesthesia, and 1 due to failed attempt at office-based TEP. Nineteen patients with prior rotational or free flap reconstruction successfully underwent office-based TEP.

Conclusions
Primary TEP is at times preferred over secondary TEP, but it is not always feasible. Secondary TEP may be necessary, even in situations where primary TEP placement is performed. Secondary TEP in an office-based setting with immediate voice prosthesis placement continues to be a safe method of voice rehabilitation for post-laryngectomy patients, including those who have previously undergone free flap or rotational flap reconstruction.

Link to open access article

Damrose et al, 2014

Title
The hybrid tracheoesophageal puncture procedure: indications and outcomes.

"Concurrent tracheoesophageal puncture and voice prosthesis placement is a simple and efficient method of voice restoration in the laryngectomized patient, …."

Authors
Damrose EJ[1], Cho DY[1], Goode RL[1].

Affiliation(s)
[1]Division of Laryngology, Department of Otolaryngology–Head and Neck Surgery, Stanford University School of Medicine, Stanford, California, USA

Journal and year of publication
Ann Otol Rhinol Laryngol. 2014 Aug;123(8):584-90

Type of publication
Retrospective chart review

Introduction
The aim of this report was to describe a novel and efficient method of tracheoesophageal puncture using a hybrid device assembled from 2 commercially available puncture kits: Atos Medical guidewire combined with InHealth Technologies dilator[1]. The authors aim to demonstrate the utility of this technique in the performance of primary and secondary TEP procedures, under general and local anesthesia, with and without flap reconstruction, and to evaluate the efficacy of concurrent puncture and valve placement. The procedure, including assembly of the hybrid device and concurrent puncture and valve placement, will be referred to as the Hybrid Tracheoesophageal Puncture Procedure (HTEPP).

Subjects and Methods
Thirty-four patients who underwent either primary or secondary tracheoesophageal puncture for voice restoration were included. Charts were reviewed retrospectively for complications, time to first valve change, operative time, and blood loss.

Results
Using this novel hybrid device, simultaneous puncture and valve placement was achieved in 34 consecutive patients. Three patients required multiple procedures. Therefore, a total of 38 HTEPPs was performed, 8 cases primary and 30 secondary. In all cases voice prosthesis placement was successful. There was 1 major complication and blood loss was negligible. Surgical time to create the puncture and place the prosthesis was on average 5.5 minutes (± 1.5 minutes). All patients achieved tracheoesophageal voicing.

Conclusions
Concurrent tracheoesophageal puncture and voice prosthesis placement is a simple and efficient method of voice restoration in the laryngectomized patient and can be more easily accomplished with a hybrid device assembled from the components of 2 commercially available puncture kits (according to authors). It can be performed under local as well as general anesthesia. The procedure is adaptable to a variety of clinical situations.

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[1] This procedure is not recommended by Atos Medical.

Hilgers et al., 2013

Title
Development and (pre-) clinical assessment of a novel surgical tool for primary and secondary tracheoesophageal puncture with immediate voice prosthesis insertion, the Provox Vega Puncture Set.

"Participating surgeons rated appreciation, ease of use, time consumption and estimated surgical risks as better. The new PVPS appeared to be the preferred device by all participating surgeons."

Authors
Hilgers FJ[1,2], Lorenz KJ[3], Maier H[3], Meeuwis CA[4], Kerrebijn JD[4], van der Poorten V[5], Vinck AS[5], Quer M[6], van den Brekel MW[1,2].

Affiliation(s)
[1]The Netherlands Cancer Institute, Amsterdam, The Netherlands;
[2]Institute for Phonetic Sciences, and Academic Medical Center, University of Amsterdam, The Netherlands;
[3]German Armed Forces Hospital, Ulm, Germany;
[4]Eramsus University Medical Center, Rotterdam, The Netherlands;
[5]University Hospital Leuven, Leuven, Belgium;
[6]Hospital de la Santa Creu i Sant Pau, Universitat Autònoma de Barcelona, Barcelona, Spain

Journal and year of publication
Eur Arch Otorhinolaryngol. 2013 Jan;270(1):255-62.

Type of publication
Prospective study

Introduction
Development and (pre-) clinical assessment were performed of a novel surgical tool for primary and secondary tracheoesophageal puncture (TEP) with immediate voice prosthesis (VP) insertion in laryngectomized patients, the Provox Vega Puncture Set (PVPS). After preclinical assessment in fresh frozen cadavers, a multicenter prospective clinical feasibility study in two stages was performed.

Subjects and Methods
Stage-1 included 20 patients, and stage-2 27. Based on observations in stage-1, the PVPS was re-designed (decrease in diameter of the dilator from 23.5 to 18 Fr.) and further used in stage-2. Primary outcome measure was immediate VP insertion without requiring additional instruments. Secondary outcome measures for comparison of the new with the traditional TEP procedure were: appreciation, ease of use, time consumption, estimated surgical risks and overall preference. A mini-max two-stage study design was used to establish the required sample size.

Results
In stage-1, dilatation forces were considered too high in patients with a fibrotic TE wall. With the final thinner version of the PVPS, Provox Vega voice prostheses were successfully inserted into the TE puncture in 'one-go' in 24/27 (89%) of the procedures: 20 primary and 7 secondary. Participating surgeons rated appreciation, ease of use, time consumption and estimated surgical risks as better. Related adverse events were few and minor. The new PVPS appeared to be the preferred device by all participating surgeons.

Conclusion

This study shows that the novel, disposable PVPS is a useful TE puncture instrument allowing quick and easy insertion of the voice prosthesis in the vast majority of cases. It allows for immediate insertion of the VP in almost 90% of the cases without requiring additional instruments. There was a high degree of satisfaction with the PVPS and a substantial preference over the traditional Provox trocar and cannula method by the participating surgeons. The PVPS can lower the threshold for those surgeons, who still delay the VP insertion after stenting the TEP tract with a catheter.

Link to open access article

Lorenz et al, 2013

Title
[A novel puncture instrument: the Provox-Vega® puncture set: Its use in voice prosthesis insertion following laryngectomy.] [Article in German]

"The Provox Vega Puncture Set proved itself to be a safe aid in the insertion of voice prostheses. It is significantly easier to use than other systems and tissue trauma is minimal"

Authors
Lorenz KJ[1], Hilgers FM[2], Maier H[1].

Affiliation(s)
[1]German Armed Forces Hospital, Ulm, Germany; [2]The Netherlands Cancer Institute, Amsterdam, The Netherlands; [3]Institute for Phonetic Sciences, and Academic Medical Center, University of Amsterdam, The Netherlands

Journal and year of publication
HNO. 2013 Jan;61(1):30-7.

Type of publication
Prospective study

Introduction
The use of voice prostheses has been considered the gold standard in voice rehabilitation following laryngectomy for the last 20 years. Insertion is generally performed as a primary procedure during laryngectomy or as a secondary procedure with a re-usable trocar or rigid esophagoscope, a guidewire and anatomic hemostatic forceps. The use of these instruments requires a certain level of experience on the one hand, while on the other use of a trocar and subsequent manipulation with the hemostatic forceps can lead to tissue trauma around the membranous wall or damage to the voice prosthesis. This publication presents the results of a phase I/II study using a novel atraumatic puncture set for primary and secondary tracheoesophageal puncture with immediate insertion of voice prostheses.

Subjects and Methods
Once patients had been fully informed and given their consent, the Provox-Vega® puncture set was used in 21 patients in either a primary (16) or a secondary (5) procedure. All procedures were documented on video, while approach, complications and surgical success were recorded using a questionnaire.

Results
The average surgical time was 83.5 (±19.12) seconds for primary puncture with voice prosthesis insertion and 212.57 (±93.03) seconds in secondary procedures. The prosthesis could be inserted without complication in 19 patients, while a longer prosthesis needed to be selected intraoperatively in two patients due to a thick membranous wall. No serious complications were observed. One patient incurred a discrete injury to the mucosa of the esophageal posterior wall.

Conclusion
The Provox-Vega® Puncture Set proved itself to be a safe aid in the insertion of voice prostheses. It is significantly easier to use than other systems and tissue trauma is minimal. This new puncture system is easy to learn and, in most cases, no further instruments were required. Compared to the conventional method, it was preferred by all surgeons. The Provox-Vega Puncture Set could increase the acceptance of prosthetic voice rehabilitation after laryngectomy and make this procedure of voice rehabilitation available to more patients.

Divi et al, 2011

Title
Primary TEP placement in patients with laryngopharyngeal free tissue reconstruction and salivary bypass tube placement.

"No complications were noted with intra-operative prosthesis placement."

Authors
Divi V, Lin D T, Emerick K, Rocco J, and Deschler DG.

Affiliation(s)
Department of Otology and Laryngology, Massachusetts Eye and Ear Infirmary, Harvard Medical School, Boston, MA 02114, USA.

Journal and year of publication
Otolaryngol.Head Neck Surg. 2011 144[3], 474-476.

Type of publication
Prospective study

Introduction
The authors examined the feasibility and advantages of primary tracheoesophageal puncture (TEP) with intraoperative placement of the voice prosthesis for patients undergoing laryngopharyngectomy requiring free tissue reconstruction and salivary bypass tube placement.

Subjects and Methods
Six patients were identified; 4 underwent total laryngopharyngectomy, and 2 underwent total laryngectomy with partial pharyngectomy. All 6 required free tissue reconstruction, and a salivary bypass tube was placed in all cases. All patients had a 20F Indwelling Blom-Singer prosthesis placed.

Results
No complications were noted with intraoperative prosthesis placement. No prostheses were dislodged in the postoperative period. Three of 6 patients had initial success with tracheoesophageal voice production. One patient required removal of the TEP postoperatively for feeding tube placement. The prosthesis was replaced 1 month later with good voice restoration. Two patients died from disease prior to voice acquisition. At 6 months, 4 patients available for evaluation had successful voice outcomes, and 3 were disease free.

Conclusion
Primary TEP is favorable to secondary puncture, even with pharyngeal reconstruction. It also allows for earlier voice restoration, with overall an excellent success rate for good voice production. There were no adverse outcomes related to early placement of the prosthesis. Although the patient cohort is small, this study demonstrates that primary placement of a TEP prosthesis is feasible in patients undergoing laryngopharyngectomy with free flap reconstruction with salivary bypass tube placement and affords distinct advantages to traditional catheter placement.

Deschler et al, 2011

Title
Simplified technique of tracheoesophageal prosthesis placement at the time of secondary tracheoesophageal puncture (TEP).

"Primary prosthesis placement at the time of secondary TE puncture is a successful option for surgical voice restoration with […] and minimal complications."

Authors
Deschler DG, Emerick KS, Lin DT, Bunting GW.

Affiliation(s)
Massachusetts Eye and Ear Infirmary, Division of Head and Neck Surgery, Department of Otology and Laryngology, Harvard Medical School, Boston, Massachusetts, USA.

Journal and year of publication
Laryngoscope. 2011 Sep;121(9):1855-9.

Type of publication
Retrospective chart review

Introduction
In the author's institution, secondary tracheoesophageal (TE) puncture standardly involves placement of a catheter at time of TE puncture creation. They explore the feasibility of placement of the prosthesis at the time of TE puncture (TEP) obviating the need for a subsequent procedure to place the prosthesis. The technique is described and the success and potential advantages are evaluated.

Subjects and Methods
Retrospective chart review of consecutive patients who underwent TE prosthesis placement at the time of secondary TEP from March 2009 to January 2011.
Fourteen patients underwent the primary TE prosthesis placement at the time of secondary puncture and were evaluated. Assessed outcomes included patient demographics, success of prosthesis placement, need for repeat procedure, early or late prosthesis dislodgement, complications, and specific voice outcomes.

Results
Patient cohort included nine males, five females, with average age of 64 years. All TE prosthesis placements were successful. The 12-mm 20 F Blom-Singer Indwelling prosthesis was used in all cases. No complications occurred during prosthesis placement. Two perioperative complications occurred: one case of transient pulmonary edema from general anesthesia, one case of posterior tracheal wall swelling. The second was addressed with placement of a larger prosthesis. All patients successfully achieved good voice at an average of 4 days after the procedure (range: 1-9 days).

Conclusion
This initial series of 14 consecutive patients demonstrates that primary placement of the tracheoesophageal voice prosthesis at the time of secondary TE puncture is safe, effective and reproducible. Functional voice was achieved in all patients with no significant immediate complications. No dislodgements occurred and no repeat procedures were required. Voice acquisition was achieved at an earlier time (4 days on average) than with traditional techniques and without the necessity of a subsequent procedure. Primary prosthesis placement at the time of secondary TE puncture is a successful option for surgical voice restoration with distinct advantages and minimal complications.

Gultekin et al, 2010

Title
Effects of neck dissection and radiotherapy on short-term speech success in voice prosthesis restoration patients.

"No complications were noted with intraoperative prosthesis placement. No prostheses were dislodged in the postoperative period."

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Journal and year of publication
J Voice. 2011 Mar;25(2):245-8.

Type of publication
Prospective study

Introduction
This study aimed to compare the short-term speech success of voice prosthesis (VP) among patients who underwent total laryngectomy or total laryngectomy in combination with neck dissection and those who received postoperative radiotherapy.

Subjects and Methods
Thirty-two male were included. Nine underwent total laryngectomy and 23 underwent total laryngectomy combined with neck dissection, and 17 of the 23 with neck dissection received postoperative radiotherapy. All patients had intraoperative placement of a Provox voice prosthesis completed in conjunction with the total laryngectomy. Patients' speech success was perceptually evaluated 3-4 weeks after the surgery and 3-4 weeks after the cessation of radiotherapy, using a 1-3 scale (1=failure to develop speech (aphonia); 2=communicate with short phrases only; and 3=communicate with fluency and long sentences).

Results
No complications were noted with intraoperative prosthesis placement. No prostheses were dislodged in the postoperative period. Eighteen of 32 patients (56%) demonstrated successful speech. Nine patients (28%) demonstrated less successful speech. Five patients (16%) were found to be aphonic.

Conclusion
Neck dissection and postoperative radiotherapy have no significant influence on short-term speech success in voice prosthesis restoration patients. Primary TEP with intraoperative placement of a voice prosthesis should be preferred in patients who have a laryngectomy in combination with neck dissection and/or will have postoperative radiation therapy. It provides early and successful voice restoration in the majority of the patients without interfering with radiation treatment and avoids a second surgical intervention.

Deschler et al, 2009

Title
Evaluation of voice prosthesis placement at the time of primary tracheoesophageal puncture with total laryngectomy.

"[A] voice prosthesis can be safely and effectively placed intraoperatively at the time of primary TEP and laryngectomy. Initial voice acquisition rates were high and long-term success was well within the acceptable range."

Authors
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Journal and year of publication
Laryngoscope. 2009 Jul;119(7):1353-7.

Type of publication
Retrospective chart review

Introduction
Primary tracheoesophageal puncture (TEP) is a well-described and accepted method of surgical voice restoration and is in the author's institution standardly completed with a catheter placement intraoperatively, which is replaced with a prosthesis at a later date. This study evaluates the intraoperative placement of the voice prosthesis at the time of the primary TEP in an effort to understand the potential advantages and disadvantages of voice prosthesis placement at the time of primary TEP completed in conjunction with total laryngectomy.

Subjects and Method
After approval by the institutional review board of the Massachusetts Eye and Ear Infirmary, a retrospective chart review was completed of all cases of primary tracheoesophageal prosthesis placement completed in conjunction with primary tracheoesophageal puncture performed at the time of total laryngectomy.

Results
Thirty patients were identified, 29 of whom underwent laryngectomy for advanced laryngeal carcinoma. Twenty-eight of 29 patients received preoperative full-dose radiation therapy. Twenty-nine of 30 patients had a 20Fr Classic Indwelling Blom-Singer voice prosthesis. One had placement of 16F Indwelling Blom-Singer prosthesis. No complications were noted with intraoperative prosthesis placement. No prostheses were dislodged in the postoperative period. Twenty-nine of 30 subjects had initial success with tracheoesophageal voice production. At 1-year follow-up, 23/30 subjects (77%) had successful voice restoration. Five failed because of recurrent disease, one subject never achieved successful voice, and one subject wanted the prosthesis removed although successful voice was achieved. Twenty-three of 25 (92%) disease-free subjects had functional voice restoration at 1-year post-total laryngectomy and primary prosthesis placement.

Conclusion
This study demonstrates that the voice prosthesis can be safely and effectively placed intraoperatively at the time of primary TEP and laryngectomy. Initial voice acquisition rates were high and long-term success was well within the acceptable range.

Tracheoesophageal puncture stability and resizing

Several published studies, including one comparative study, indicate that primary fitting of the voice prosthesis, in comparison to delayed fitting, may be associated with a more stable tracheoesophageal puncture, requiring less frequent resizing of the voice prosthesis.

Data concerning device life and size changes of the first device placed fitted primarily show that the device life of the first device placed, is generally longer than that of subsequent 'routine' replacements (average 180 days vs 137 days)[5,6], and that reasons for replacement of the first device do not differ from those for subsequent devices[6].

In the long-term, the majority of devices fitted primarily are replaced due to leakage through the device[4,5,7], whereas size changes account for 11%-12% of the changes[4,7], in about 31% of the patients[7].

It was demonstrated that the puncture decreased over time in a patient group consisting of 24% primary and 76% secondary TEPs of which all had their VP primarily fitted[1]. Although that study did not report the respective outcomes of primary vs secondary TEP and the puncture size therof, data from another study carried out in patients that underwent delayed fitting demonstrated that frequent size changes occur in the first few postoperative months[1], and that also in the long-term multiple re-sizings are needed in about 90% of the routinely followed patients[2].

One study compared in-office TEP (with primary placement of the voice prosthesis) with operating room-based TEP (with placement of a catheter and delayed voice prosthesis fitting). The results showed that office-based TEP with primary fitting of the voice prosthesis was associated with significantly less change in length of the device, and significantly fewer SLP visit for adjustment of voice prosthesis length[3].

The publications listed below all concern publications regarding tracheoesophageal puncture stability and resizing that are referenced above. Clicking the link while holding the Ctrl key will take you directly to the summary you are interested in.

[1]Jian et al. Tracheoesophageal fistula length decreases over time. Eur Arch Otorhinolaryngol. 2016 Jul:271(7)1891-94.

[2]Lundy et al. Longitudinal Tracheoesophageal Puncture Size Stability. Otolaryngol Head Neck Surg. 2012 Nov;147(5):885-8.

[3]Sidell et al. Improved tracheoesophageal prosthesis sizing in office-based tracheoesophageal puncture. Ann Otol Rhinol Laryngol. 2010 Jan;119(1):37-41.

[4]Mäkitie et al. Postlaryngectomy voice restoration using a voice prosthesis: a single institution's ten-year experience Ann.Otol.Rhinol.Laryngol. 2003 112(12):1007-10.

[5]Elving et al. The influence of radiotherapy on the lifetime of silicone rubber voice prostheses in laryngectomized patients. Laryngoscope, 112[9], 1680-1683. 2002.

[6]Schafer et al. [Voice restoration with voice prosthesis after total laryngectomy. Assessment of survival time of 378 Provox-1, Provox-2 and Blom-Singer voice prosthesis]. Laryngorhinootologie. 2001 Nov;80(11):677-81.

[7]Op de Coul et al. 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., 126[11], 1320-1328. 2000

[8]Leder and Sasaki. Incidence, timing, and importance of tracheoesophageal prosthesis resizing for successful tracheoesophageal speech production. Laryngoscope 1995 105(8 pt1):827-832.

Jian et al, 2016

Title
Tracheoesophageal fistula length decreases over time.

Authors
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Journal and year of publication
Eur Arch Otorhinolaryngol. 2016 Jul;271(7):1891-94.

Type of publication
Retrospective study

Introduction
This study aimed at further understanding the unpredictability of the fistula region following TE puncture by measuring the length of the fistula tract. Such findings may play an important role in the patient and insurers expectations for duration of post-laryngectomal care and reimbursement policies.

Subjects and Methods
37 Patients who underwent either primary or secondary puncture with primary fitting of VP between 2006 and 2014 were evaluated.

Results
The length of fistula decreased over time median Kendall correlation coefficient =-0,60 mean=-0,44 and this correlation between length and time was significant (p=0,00085). No comparison of patients with primary and secondary was however done by the authors.

Conclusions
This study found a significant decrease of fistula length over time due to thinning of the tracheosophageal wall, which suggests a need for shorter voice prosthesis over time. A careful clinical follow up with re-sizing of voice prosthesis over time is required.

Lundy et al, 2012

Title
Longitudinal Tracheoesophageal Puncture Size Stability.

"All patients had a red rubber catheter placed at the time of puncture […]. Prosthesis size was stable in only 5 (10%) patients and unstable in 45 (90%)."

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Journal and year of publication
Otolaryngol Head Neck Surg. 2012 Nov;147(5):885-8.

Type of publication
Retrospective chart review

Introduction
The purpose of this study was to investigate prosthesis size stability over time and determine which factors influenced the need for changes in size.

Subjects and Methods
Retrospective chart review was performed on all individuals who had previously undergone total laryngectomy and tracheoesophageal puncture and had a minimum of 3 years of consistent and consecutive follow-up data after their prosthesis was initially placed. All prostheses were fitted secondarily. The data from the first 3 months after the puncture were omitted because of "natural evolution of the fistula tract with wound healing that would be expected to result in prosthesis length and/or diameter changes". Data reviewed included demographic variables of age at time of tracheoesophageal puncture, ethnicity, and sex.

Results
Fifty patients were included, with a mean age of 64.7 years (range, 43-86 years), 41 (82%) men and 9 (18%) women. Surgical management was equally divided between those who underwent total laryngectomy (n = 25) as primary treatment vs those who had salvage laryngectomy (n = 25) for persistent or recurrent disease. Prosthesis size was stable, with no change in diameter or length, in only 5 (10%) patients and unstable in 45 (90%), as they were changed at least once. Analysis of the number of changes over time revealed a range of 1-25, with an average of 5.5 changes required during the first 3 follow-up years. Group inspection of the 5 patients with a stable puncture revealed that all underwent secondary puncture, tended to be older and had their laryngectomy as a primary treatment. The only factor that demonstrated statistical significance was sex (Fisher exact test = 0.035), with women being more likely to have a stable prosthesis size over time.

Conclusions
The results of this show that 90% of patients who underwent total laryngectomy and tracheoesophageal puncture with secondary fitting of a voice prosthesis required a change in their prosthesis size beyond the first 3 months of expected healing. On average 5.5 changes were required during the first 3 years following the 3 months healing period. The authors conclude that these results support the need for continual reassessment of the TE puncture when changing the prosthesis to ensure appropriate fit.

Sidell et al, 2010

Title
Improved tracheoesophageal prosthesis sizing in office-based tracheoesophageal puncture.

"Voice prosthesis sizing was better in patients who had office-based TEP [with primary VP fitting] than in patients who had operating room-based TEP [with catheter placement and delayed VP fitting].

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Journal and year of publication
Ann Otol Rhinol Laryngol. 2010 Jan;119(1):37-41.

Type of publication
Retrospective chart review

Introduction
Tracheoesophageal puncture (TEP) for postlaryngectomy speech is increasingly being performed as an office-based procedure. The experience with office-based TEP was reviewed and outcomes were compared with those of operating room-based TEP. The hypothesis was that office-based TEP results in improved prosthesis sizing, reducing the number of visits dedicated to prosthesis resizing.

Methods
A retrospective chart review was performed of all patients who underwent secondary TEP from 2001 to 2008. The primary dependent measure was the change in the length of the voice prosthesis. The authors also evaluated the number of visits made to the speech-language pathologist for resizing before a stable prosthesis length was achieved, and the number of days between voice prosthesis placement and the date a stable prosthesis length was observed.

Results
Thirty-one patients were included in this study. Eighteen patients underwent secondary OR-based TEP, and 13 patients underwent office-based TEP. There was a significant difference in prosthesis length change between patients who had office-based TEP (5/13) and patients who had operating room-based TEP (16/18) ($p < 0.001$). In addition, the office-based cohort required fewer visits to the speech-language pathologist for TEP adjustments before a stable TEP length was achieved ($p < 0.001$).

Conclusions
Voice prosthesis sizing was better in patients who had office-based TEP with primary fitting of a voice prosthesis than in patients who had operating room-based TEP with secondary fitting. This outcome is likely due to the lesser degree of swelling of the tracheoesophageal party wall in the office-based procedure.

Mäkitie et al, 2003

Title
Postlaryngectomy voice restoration using a voice prosthesis: a single institution's ten-year experience.

"..the Provox prosthesis is an effective method of postlaryngectomy voice rehabilitation, and it continues to be the preferred method of voice restoration…"

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Journal and year of publication
Ann Otol Rhinol Laryngol. 2003 112(12), 1007-1010.

Type of publication
Retrospective chart review

Introduction
This article describes the speech rehabilitation outcome of patients treated with total laryngectomy or total laryngopharyngectomy, who underwent primary or secondary TE puncture with immediate placement of a Provox voice prosthesis.

Subjects and Methods
A retrospective chart review was performed of 95 patients (88 men and 7 women; mean age, 63.5 years) who underwent TE puncture in the period 1992 to 2002. Eighty-one percent (77/95) of the patients underwent a primary TE puncture and 19% (18/95) underwent secondary TE puncture. All prostheses were placed primarily, immediately after the TE puncture was created.

Results
Long-term TE speech was rated as good or average for 78% (74/95) of the patients. The main causes for replacement of the device were device related: obstruction in 14.2% and leakage through in 51.8%. A total of 12.4% of the replacements was carried out due to the need for a size change.

Conclusion
The authors conclude that use of the Provox prosthesis is an effective method of postlaryngectomy voice rehabilitation, and it continues to be their preferred method of voice restoration in the majority of cases.

Elving et al, 2002

Title
The influence of radiotherapy on the lifetime of silicone rubber voice prostheses in laryngectomized patients.

"The first [voice prosthesis], placed during surgery, lasted longer than subsequent devices."

Authors
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Journal and year of publication
Laryngoscope. 2002 112(9), 1680-1683.

Type of publication
Retrospective analysis

Introduction
The aim of the study was to investigate the relationship between voice prosthetic lifetime in laryngectomized patients and the irradiation dose applied to the neck node levels (field of the neck) in which the major salivary glands are partially included. Furthermore, a possible relationship between voice prosthetic lifetime and the irradiation dose applied to the primary tumor site was studied.

Subjects and Methods
The records of 101 patients who underwent total laryngectomy between January 1993 and November 1999 at the Department of Otorhinolaryngology, University Hospital Groningen, The Netherlands, were analyzed. Patients used either a Groningen, Provox, or Provox2 voice prosthesis that was placed at the time of surgery. Follow-up was 1 – 106 months, average 26 months. A total of 685 voice replacements took place, 377 Groningen voice prostheses, 296 Provox2, and 12 Provox1 (the latter left out of the analyses due to the small number). The following parameters were obtained: age, sex, radiotherapy, radiation fields, irradiation dose per field, tumor site, TNM classification, and valve insertion.

Results
Irradiation to extensive neck fields, including the submandibular glands, did not influence the voice prosthetic lifetime after laryngectomy. However, primary tumor doses exceeding 60 Gray significantly shortened the mean voice prosthetic lifetime per patient. Interestingly, the device life of the first Groningen device, placed during surgery, was significantly longer (average 180 days) than the average device life of subsequent Groningen devices (average 137 days). The average lifetime of the Provox 2 voice prosthesis was 90 days, which presents no statistically significant difference with the Groningen button voice prosthesis, provided that the first Groningen button voice prosthesis, as used by all patients, are excluded from the analysis.

Conclusion
This study identified an association between radiation on the primary tumor site with a dose equal to, or more than 60 Gray and limited lifetimes of voice prostheses. The first device, placed during surgery, lasted longer than subsequent devices.

Schäfer et al, 2001

Title
[Voice restoration with voice prosthesis after total laryngectomy. Assessment of survival time of 378 Provox-1, Provox-2 and Blom-Singer voice prosthesis].

"Die Erstprothese hält im Mittelwert 267 Tage, die späteren Prothesen im Mittelwert 197 Tage." [The first voice prosthesis stays on average 267 days in-situ, the following prostheses 197 days]

Authors
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Journal and year of publication
Laryngorhinootologie. 2001 Nov;80(11):677-81.

Type of publication
Retrospective study

Introduction
Indwelling voice prostheses are used in Trier for voice restoration after total laryngectomy since 1991.

Subjects and Methods
To assess the voice prosthesis survival times the patients of the years 1993-1999 are assessed retrospectively. 58 patients provided with indwelling voice prosthesis were seen regularly at follow-up. 378 prostheses were changed. Provox 1 (n=136), Provox 2 (n=78) and Blom-Singer-Prostheses (n=172) were used. 37 prostheses were primary inserted during surgery, 21 secondary. Until 1995 they were replaced by a Provox 1, since 1995 by a Blom-Singer, and since 1998 by a Provox 2-prosthesis.

Results
The average survival lifetime of the prosthesis was 224 days for Provox-1, 96 days for Provox-2 and 107 days for Blom-Singer respectively. There is no significant difference found between Provox-2 and Blom-Singer Prosthesis. The survival time of the Provox-1 Prosthesis is significant longer. Further analyses showed that the first voice prosthesis had an average survival lifetime of 267 days, the following prostheses 197 days (p=0.06).

Conclusion
Using indwelling voice prosthesis for voice restoration after total laryngectomy an average survival time of the prosthesis of three months can be expected. The first voice prosthesis placed had a significant longer device life than the following prostheses. There are relevant individual differences. Provox-1 Prostheses (mostly the first inserted device) have a significantly longer survival time, but as they are more difficult to handle they are not suitable for routine use. The indication for the choice between Blom-Singer or Provox-2 Prosthesis should be influenced by the surgeons' experience.

Op de Coul et al, 2000

Title
A decade of postlaryngectomy vocal rehabilitation in 318 patients: a single Institution's experience with consistent application of Provox indwelling voice prostheses.

"…the device life of the first device was longer than that of subsequently placed devices. […] Overall, 65% of the devices were replaced with a device of the same size."

Authors
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Journal and year of publication
Arch Otolaryngol Head Neck Surg. 2000 126(11):1320-28.

Type of publication
Retrospective chart review

Introduction
This study aimed to assess long-term results with consistent use of indwelling voice prostheses (Provox and Provox2) for vocal rehabilitation after total laryngectomy.

Subjects and Methods
Three hundred eighteen patients were included, covering the time period November 1988 - May 1999. Overall 2700 voice prosthesis replacements were reviewed. Outcome measures were device lifetime, indications for replacement, adverse events, and voice quality. All initial devices were fitted primarily.

Results
Median patient-device follow-up was 67 months. Mean actuarial device lifetime for all indications for replacement was 163 days (median, 89 days). Main indications for replacement were device-related (leakage through (73%) and obstruction (4%)) or fistula-related (leakage around (13%), and hypertrophy and/or infection of the fistula (7%)). Overall, 64% of the devices were replaced with a device of the same size. Downsizing for leakage around occurred in 10% of the replacements (24% of the patients), and resizing due to inaccurate size of the device in situ occurred in 1% of the replacements (7% of the patients). Clinical factors for increased device lifetime were no radiotherapy (P =.03), and older than 70 years (P<.02). Success rate with respect to voice quality was 88%, which was significantly influenced by the extent of surgery (P<.001). The reasons for replacement did not differ between the first device placed after surgery or subsequent devices.

Note: Additional analyses showed that the device life of the first device was longer than that of subsequently ones (median 135 days). Also, there was no evidence of early replacement due to reduced length of the puncture tract. (Hilgers et al. Prosthetic voice rehabilitation at the Netherlands Cancer Institute, Global Postlaryngectomy Rehabilitation Academy, Amsterdam, the Netherlands).

Conclusion

The consistent use of indwelling voice prostheses shows a high success rate of prosthetic vocal rehabilitation, in terms of the percentage of long-term users (95%), and of a fair-to-excellent voice quality (88% of patients). The most common reason for replacement was leakage through the device in 73% of the replacements, in 73% of the patients. Size changes only occurred in 31% of the patients.

Leder and Sasaki, 1995

Title
Incidence, timing, and importance of tracheoesophageal prosthesis resizing for successful tracheoesophageal speech production.

"In general, all patients [that underwent a secondary placement with stenting with a red rubber catheter] require a size change within the first month after fitting the voice prosthesis."

Authors
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Journal and year of publication
Laryngoscope 1995 105(8 Pt 1), 827-832.

Type of publication
Retrospective study

Introduction
This retrospective study was undertaken to determine the incidence and timing of TE prosthesis resizing, amount of change in prosthesis length, etiologies associated with resizing, and importance of long-term professional follow-up for maintenance of successful TE speech production.

Subjects and Methods
Participants were 26 individuals with total laryngectomy and secondary TE puncture with catheter placement and delayed fitting of the voice prosthesis.

Results
Results indicated that all 18 participants available for long-term follow-up required TE prosthesis resizing of the initial device, and multiple resizings were required in 87% of the routinely followed participants. In 14 participants the prostheses were resized shorter (mean = -0.7 cm); in 3, longer (mean = +0.5 cm); and in 1, from a duckbill to a low-pressure prosthesis of the same size. The mean number of days from initial measurement and fitting to first prosthesis resizing was 26.

Conclusion
In this group of patients undergoing secondary puncture with catheter placement and delayed fitting of the voice prosthesis, multiple resizings were required, starting on average 26 days after the first fitting. In general, all patients require a size change within the first month after fitting the voice prosthesis.