Postlaryngectomy Rehabilitation in this Era of Increasing Organ Preservation Treatment

At the last WCLC in 1994

- TL was still the preferred treatment option for advanced larynx cancer, although the first organ preservation studies (VA and EORTC) started a paradigm shift.

- Tracheoesophageal voice rehabilitation was well on its way to become the gold standard for restoring oral communication after TL, 21 and 14 years after the publication of functioning voice prostheses by Mozolewski in Poland (1973) and Singer and Blom (1979).

Disclosure Statement

- The Netherlands Cancer Institute receives a Research Grant (RG) from Atos Medical Sweden, which contributes to the existing infrastructure for health-related quality of life research of the department of Head and Neck Oncology and Surgery.

- All reported research, including studies carried out in relation to this RG, has been approved by the institutional Medical Ethical Review Board.

Start of present prosthetic voice rehabilitation history*

Mozolewski 1973*, presented at Boston meeting, 1978

Singer-Blom 1980**


VP development in the first decade/eighties

- Difference in preference of type of VP:
  - non-indwelling Bl-S/Panje devices (USA/UK/Australia)
  - indwelling devices (Groningen/Trassac/Nijdam/Provox) in Europe
- Difference in TEP approach
  - primary TEP + direct VP fit (Groningen/Provox)
  - primary TEP + stenting + delayed VP insertion (Bl-S)
- Focus on perceptual, acoustic and clinical research showing better voice quality and easier acquisition of TE than of E speech
- Identification of hypertonicity pathophysiology as main reason for failing to acquire fluent TE (and probably also E) speech (Singer-Blom, 1981)
- First identification of complex biofilm formation (bacteria + yeast) as major culprit of decreased VP device life (Mahieu et al. 1986)

Rationale for preference of indwelling voice prostheses in Europe (e.g. Groningen, Provox) instead of non-indwelling devices in USA/UK/Australia (e.g. Blom-Singer, Panje)

Advantages
- Designed to be inserted immediately at TEP, allowing primary placement
- No replacement required by patient
- Shorter learning curve and little dexterity needed for daily care
- More robust design: longer device life
- With increasing age (loss of dexterity/visual acuity) still applicable

Disadvantage
- Patients stays dependent of clinician, but non-indwelling device patients also regularly require clinician’s help and device aspirations are more frequent than with indwelling devices

Postlaryngectomy surgical and prosthetic vocal rehabilitation in the Netherlands Cancer Institute

- Staffiers’ procedure1 1979-80
- Non-indwelling prostheses: to be handled by the patient
  - Blom-Singer2 1980
  - Panje3 1980
- Indwelling prostheses: to be handled by the clinician
  - Groningen4 1980-88
  - Provox5 1988-

1 Staffier et al. Laryngol Rhinol Otol (Stuttg). 1978
5 Hilgers & Schouwenburg. Laryngoscope 1990

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- Since 1994, focus on organ preservation. RTOG 91-11: adding CT to RT in stage III-IV larynx cancer preserves more larynges than RT alone, but does not improve survival and increases toxicity and complications rates in salvage surgery
- Somewhat neglected: the preceding VA study* had shown significant better survival for T4N0 with TL, reason to exclude this patient category from RTOG 91-11
- Moreover, it became all too obvious that organ preservation is not synonymous with function preservation


E.g.; Machtay et al. J Clin Oncol 2008. RTOG 91-11, 97-03, and 99-14 (43% severe complications); Theunissen et al. Otolaryngol Head Neck Surg 2012 (11% of TLs in 10-years for dysfunctional larynx)
And is larynx preservation the relevant outcome/success parameter of that study for the organ preservation discussion? 

TALK Score: Development and Validation of a Prognostic Model for Predicting Larynx Preservation Outcome. Sherman et al. Laryngoscope 2012

TALK = T4 (1) – Albumen (<4mg/dL=1) – alcohol/Liquor (≥6 units=1) – Karnofsky (<80=1)

Larynx preserving probability: TALK score 0 = Good Risk; 1-2 = Intermediate Risk; 3-4 = Poor Risk

3-year larynx preservation rates by TALK score: 65% (0), 41% (1-2) and 6% (3-4), P < .0001

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- In the mean time more and more evidence is collected that T4 disease has a significant better prognosis/overall survival with TL + postoperative RT ……

- Veterans Affairs Laryngeal Cancer Group study. N Engl J Med. 1991; 324: 1685-90. TLE vs CRT: survival 68% vs. 60% (P = .0098)
- Carvalho AL et al. Int J Cancer 2005; 114: 806-816: downward trend for survival of larynx cancer contrary to trends in other HN sites
- Chen, Halpern. Arch Otolaryngol Head Neck Surg 2007; 133: 1270-76. HR for Death TLE 1, RT 1.6, CRT 1.3 (P < .001) (SEERS database; N=7000)

For postlaryngectomy rehabilitation in this era of increasing organ preservation treatment:

- Moreover, patients still might prioritize survival over organ preservation (i.e. time-trade off studies*)

Conclusion: % of HCPs who believed patients would trade survival for ‘voice box’ time substantially higher than patients would. Only a minority of patients would trade survival for ‘voice box’ time (despite their poor rehabilitation level in the mid nineties)

*Hamilton et al. Head Neck. 2015. Quality compared to quantity of life in laryngeal cancer: A time trade-off study. “In many individuals, larynx conservation may not be the primary consideration in treatment preference.”

This means that TL is here to stay, also while T4 CT+RT still has to be considered experimental treatment, which after proper counseling should be offered only on patient’s specific request, or in the course of a clinical trial
But this also means that during counseling the patient should be offered a comprehensive postlaryngectomy rehabilitation program.

- The larynx is more than just a ‘voice box’: due to its central position in the respiratory tract, its removal requires rehabilitation of all three ‘systems’ depending on an intact airway/respiratory airflow, i.e.
  - vocal rehabilitation
  - pulmonary rehabilitation
  - olfactory rehabilitation

- Rehabilitation of laryngectomized patients requires a dedicated multidisciplinary team effort (HN surgeon, SLP, oncology nurse, patient counselor) for achieving optimal results and quality of life.

Medical device research is increasingly time consuming:
from start research project to publication

  - Hilgers & Schouwenburg. Laryngoscope 1990


  - Soolsma, vd Brekel, Ackerstaff, Balm, Tan, Hilgers. Laryngoscope 2008

- Provox Vega/Smart Inserter: 2006 – 2010
  - Hilgers, Ackerstaff, van Rossum, Jacobi, Balm, Tan, van den Brekel. Acta Otolaryngol. 2010
  - Hilgers, Ackerstaff, Jacobi, Balm, Tan, van den Brekel. Laryngoscope 2010

- Provox Vega Puncture Set: 2008 – 2013
  - Hilgers, Lorenz, Maier, Meeuwis, Karnebijn, Vander Poorten, Vink, Quer, van den Brekel. Eur Arch Otolaryngol. 2013
  - Lorenz, Hilgers, Maier. HNO. 2013


Provox Puncture Set (PVPS), a novel, fully disposable set for primary and secondary TEP and immediate implantation of a Provox Vega voice prosthesis.

Pro’s and con’s of primary tracheoesophageal puncture (TEP) with direct fit of an indwelling voice prosthesis, in stead of stenting with feeding tube and delayed fitting

- Direct fit of VP:
  - Less traumatizing for TEP
  - First VP length mostly 8 mm, sometimes 10 mm
  - First VP length mostly 14-18 mm
  - Supports/stabilizes party wall
  - Protects optimally against leakage (saliva, reflux)
  - Does not interfere with cannula or heat and moisture exchanger (HME)
  - Familiarizes patients rapidly with voice prosthesis and its daily maintenance (brush cleaning) through nurses

- No need for early postoperative prosthesis sizing and fitting, but immediate focus on voicing
- First replacement/fitting mostly months later, when most patients are in much better mental/physical shape

Comparison of primary (N=45) vs secondary VP fit (N=38) in primary TEP (N=83)

- No significant differences for
  - Stomal breakdown (SB) (primary 13.3%, secondary 13.5%, $p = 1.00$)
  - Pharyngocutaneous fistula rate (PCF) (primary 11.1%, secondary 16.2%, $p = 0.53$)
  - Voice outcomes in any studied variable. Specifically, ability to voice at the first post-operative visit (V1V) was statistically similar between primary and secondary fitting (88% vs 77%, $p = 0.23$)

- Significant difference for
  - Post-operative emergency department (ED) utilization significantly higher in secondary fit group (17.8% vs 42.1%, $p = 0.03$)

Conclusions

- While primary TEP with voice prosthesis placement is not commonly accepted in the United States, it has been adopted with good success at our institution since 2011
- This study provides clear evidence that it is a safe alternative to either secondary TEP or primary TEP with secondary prosthesis fitting
- While this study does not identify any voice-related benefits to primary TEP and fit, the decreased rate of post-operative ED visitation is quite robust
- While this study has obvious limitations and a controlled, prospective study would provide superior evidence, we offer compelling evidence that primary TEP and prosthesis fitting is a safe, efficacious strategy for voice rehabilitation following total laryngectomy.
The case for immediate pulmonary protection and rehabilitation


N=53; HME use shows significant
- Improved patient compliance (100% vs 42%)
- Reduced coughing (>5x daily 10% vs 42%)
- Reduced mucus expectoration/need for suctioning (2.5 vs 5.5)
- Less sleeping problems (17% vs 77%)
- Higher patient satisfaction (100% vs 11%)
- Reduced nursing time (20 min. vs 30 min.)
- Reduced daily costs ($6 vs 15-60)

Easy oxygen application if needed

Valve and Valve seat made of fluoroplastic (Teflon-like) material
Spontaneous opening of valve during breathing, potentially counteracted by magnets
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Spontaneous opening of valve during breathing, potentially counteracted by magnets

The main TEP problems (widening – atrophy – hypertrophy) are comorbidity issues: reflux and PE segment stenosis:

- There has been an unfortunate non-scientific discussion on the imaginary correlation between VP diameter and TEP widening, which has distracted for long from looking for the real culprits
- TEP widening is a co-morbidity issue: aside from possible causes like prolonged pistoning, previous (chemo-)radiotherapy, recurrent disease, poor thyroid function, poor nutrition, suboptimal TEP technique, most prominently that is gastro-esophageal reflux** and/or neoglottis stricture***; and not prosthesis diameter*

*** A stenosis will result in an increased velocity of fluids, which increases the pressure and the risk of periprosthetic leakage; dilatation of the stenosis will very likely solve this!
Thus, think “co-morbidity” in case of periprosthetic leakage, and when simple prosthesis-downsizing fails

1. Short-term: application of thin (0.5 mm) silicon washer behind tracheal flange, or VP with enlarged esophageal flange, or both; in case of 17 or 20Fr VP, consider upsizing to next larger diameter
2. Submucosal purse string suture (3x0 vicryl)
3. Tissue augmentation with collagen or Bioplastique
4. In case of failure: surgical closure of the TEP

Long-term: PPI treatment and/or PE segment dilatation

Postlaryngectomy Rehabilitation in this Era of Increasing Organ Preservation Treatment - Conclusions

- TL remains the best chance for cure for T4 larynx cancer
- The advantages of tracheoesophageal voice in fluency and speed of acquisition, obvious from the start in the early eighties, are still outweighing possible disadvantages, despite the somewhat higher RT-related complication rates, in which comorbidity (reflux and pharyngeal stenosis) play an important role
- Recent material/technical developments and improvements are promising and contributing to the continued success of voice prostheses as the gold standard for restoring post-laryngectomy oral communication and more

Example of progress in 30+ years of prosthetic voice rehabilitation


Thank you for your attention