Improving Short In-situ Lifespan of TE Voice Prosthesis

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Tracheoesophageal Voice Prosthesis
TEP Voice Viewed Radiographically
Background

• Since its introduction in the 1970’s the TEP has proven to be an extremely successful method of voice rehabilitation after laryngectomy.
• To deal with the issues surrounding changing the prosthesis the indwelling voice prosthesis was introduced in mid 90’s.
Common Reasons for Prosthesis Replacement

Complaint
Leaking through
Fungal Colonization/Biofilm
Fungal Colonization

- Nystatin therapy significantly prolongs prosthesis lifespan (Leder, et al., 1997).

- Nystatin tablet significantly increased the prosthesis lifespan compared to brushing (Ameye, et al., 2005).

- Use of the Advantage TE voice prosthesis improved lifespan by 11 weeks (Leder, et al., 2005).
Common Reasons for Prosthesis Replacement

Complaint
Leaking around
Leaking around or Periprosthetic leakage

Most often a sizing issue
When it isn’t a prosthesis sizing problem

• Kress, et al., (2006) Peritract leaking is a significant problem and detected 13-27% of the replacements. Of those leaking around, 57% were dilated-atrophic and 43% infected-necrotic type. Custom-fit prosthesis with enlarged phlanges were able to fix leaking around.

• Injection of biplastique, fat or collagen successful (Lorincz, et al., 2005; Seshamani, et al., 2006).

• Purse-string suture successful (Op Coul, et al., 2000)
Common Reasons for Prosthesis Replacement

Complaint
Decline in voice quality
Hilgers, 2007

Oh, et al., 2002
Granulation Tissue

- Granulation tissue can cause accidental extrusion and potential loss of TE tract.
- Occurs in 15-20% of patients (Smith & Pfleiderer, 2003).
- Upsizing of voice prosthesis, silver nitrate, electocautery and CO2 laser successfully manage granulation tissue.
Extrusion of TEP

- Band of scar tissue holding TEP from falling into airway
- Esophageal Flange of TEP
- Trachea
- Tracheal Flange of TEP
Endoscopic Confirmation of TEP Placement
Opening Pressure
Low Pressure voice prosthesis

Illustration 6: Survey of the opening pressures of low-pressure prostheses

P. Kress, P. Schäfer, F.-P. Schwerdtfeger, Klinikum Mutterhaus der Borromäerinnen Trier S. Roesler, University of Applied Science Esslingen. 2007 Poster Presentation
Opening Pressure
Increased Resistance voice prosthesis

Illustration 7: Survey of the opening pressures of increased-resistance prostheses

P. Kress, P. Schäfer, F.-P. Schwerdtfeger, Klinikum Mutterhaus der Borromäerinnen Trier
S. Roesler, University of Applied Science Esslingen
Effect of Total Laryngectomy on Esophageal Motility

- Kirchner et al. (1963) reported an area of reduced contractility in the upper 3-5cm of the esophagus (result of denervation?)

- Hanks et al. (1981) studied patients who had not had prior radiation treatment or esophageal surgery before & after laryngectomy:
  - Laryngectomy caused a consistently weaker UES.
  - There were no changes in the proximal or distal esophagus at any time.
  - Speculated that radiation treatment may alter esophageal motility & function more than surgery in order to cause dysphagia.

- Seeman et al. (1992) describe 3 case studies in which patients presented with dysphagia which was ultimately found to be due to radiation-induced esophageal motor dysfunction. This occurred from 4 - 30 years after radiation treatment.
What’s Gastroesophageal Reflux got to do with it?
Gastroesophageal Reflux (GERD) in Head and Neck Cancer

- 58-67% of head and neck cancer patients have pathological GERD (Copper, et al., 2000; Koufman, 1991)
- 82% of total laryngectomized patients have pathological GERD (Smit, 1998)
TEP and GERD

• Gerwin, et al., (1997)
  – case study
  – TEP complications from GERD
  – necessitated permanent prosthesis removal.

  – 9 TEP patients after fundoplication
  – 7/9 had resolution of GERD symptoms
    • TEP complications and frequent changes were eliminated.
    • High patient satisfaction
Does Nissen Fundoplication affect TEP device lifespan?

The OHSU Experience
Materials and Methods

• Eleven TEP subjects who have had either a complete (360 degree) or partial (270 degree) posterior laparoscopic fundoplication.

• Frequency and indications for voice prosthesis change were compared for an equal period before and after fundoplication (mean 10.8 months: range 3-24 months).
GERD Workup

- 9/11 had dual sensor 24-hour pH probe
- 2/11 had EGD
- 7/11 had manometry
- The majority had 2 or more of above diagnostic procedures to establish GERD
Results

• Average device lifetime increase
  – 3.09 months preoperatively (range 1 to 8 months) to 4.58 months postoperatively (range 3 to 8 months). ($p = 0.002$)

• Frequent changers (7/11)
  – Most dramatic improvement ($p = 0.001$), increasing device lifespan an average of 2.5 months (10.4 weeks)
Average Device Life
Pre- & Post-Fundoplication by Group

Prosthesis Life Before and After Fundoplication

All Patients
(n = 11)

Frequent Changers
(n = 7)

Pre (mo.s) | Post (mo.s) | Pre (mo.s) | Post (mo.s)
-----------|------------|------------|------------
3.09       | 4.58       | 2.17       | 4.59       

p = .002  
p = .001
Conclusion

• Perhaps there is a connection between GERD and device lifespan?
• In those laryngectomized patients with well-documented, severe GERD, fundoplication may be beneficial.
But what if a Nissen is not appropriate?

- Does not have GERD
- Not a surgical candidate due to medical reasons
  - Medically fragile
  - Esophageal dysmotility
  - Patient preference
- Trial of different prosthesis types not effective
- PPI intervention not effective or appropriate
- Anti-fungal protocol not effective
New Technology

The ActiValve magnetic prosthetic significantly increased (14-16x) the time in-situ, (Hilgers, et al. 2003; Soolsma, et al. 2008)
New Technology

The InHealth DualValve Indwelling in development for short in situ lifespan.
Does the Provox ActiValve result in increased device-life in patients with below average device-life without change in voice-related QOL?
Acknowledgements

Thank you to Atos Medical for facilitating this project by providing the ActiValve devices at a reduced cost
Materials and Methods

Placement of ActiValve only after the following:

- Change in prosthesis type not effective
  - Advantage (1st generation)
  - High Resistance
  - Provox2
- Anti-fungal protocol not effective
- Behavioral changes not effective
- PPI protocol not effective
- Prosthesis size stable over the last 3 changes
- Medically stable and not undergoing cancer treatment
- s/p successful voice restoration at least one year
Subjects

- 13 TEP (12 M, 1 F) users who averaged a less than 2 month in-situ lifespan (range .8 - 3.2 months).
- Medical/surgical history:
  - All were radiated either before (46.2%) or after (53.8%) TL
  - 4 had also had chemotherapy (30.8%)
  - 8 TL w/primary closure (61.5%)
  - 3 TL w/ partial pharyngectomy RFFTT (23%)
  - 1 TL w/partial pharyngectomy w/ rectus flap (7.7%)
  - 1 Total laryngopharyngectomy w/ jejunal interposition (7.7%)
Follow-Up Data

- 8 subjects wore the ActiValve for at least 6 months.
- These individuals wore an average of 2.6 ActiValves (range 1-5) for an average of 22.9 months (range 13-28).
- 5 subjects discontinued use. Reasons for discontinuation:
  - Granulation tissue (n=2)
  - Accidental extrusion (twice) (n=1)
  - Did not survive to complete follow-up (n=2)
Results

- For the 8 subjects still wearing the ActiValve at follow-up, we calculated:
  - The average life of their last 6 Indwelling TEP changes and compared it to the life of the ActiValve. The average life of the Indwelling was 1.85 months (range .8-3.2 months)
  - Lifespan with the ActiValve averaged 10.93 months (range 6-24 months)
  - Using a paired-samples t-test, the ActivValve was found to have significantly longer in situ life ($p < .01$)
• Most subjects experience an increase in device life of over 5x
• Our most frequent changer with >1 month in-situ lifespan increased by 28x !
What did they like about the ActiValve?

- Over 75% found it the same or easier to get voice started and speaking rate was the same
- Nearly 90% found
  - effort with speaking the same or easier
  - say about the same amount or more on one breath
  - they had the same or better intelligibility
  - Hands-free speaking was the same or easier
- All found they had the same or better loudness

And...

When asked what do you like most about the new prosthesis........’it doesn’t leak’
Voice-Related Quality of Life

- Mean scores prior to placement of the ActiValve on the V-RQOL were 50.96
- At 2-4 week follow-up the V-RQOL 72.22
- At 6 months to 1 year 65.07

Why?
May be due to coughing less
Fewer visits to the clinic
Did not have to plan their lives around their TEP
Anecdotal reports of breathing better
What they did not like.....

- Valve sticking
- Need to use brush more frequently
- Need to lube device
Cost

Not factoring in travel and time costs:

• ActiValve is cost effective and provides a savings when in-situ lifespan of indwelling prosthesis is at <2 months and ActiValve in-situ lifespan is 6 months or more. In our study patients would have saved $590-$6458.

• Break even at when traditional indwelling lifespan at 2-3 months.

• ActiValve cost effectiveness decreases with longer traditional indwelling prosthesis lifespan.
ActiValve

- Tolerated well by the majority of patients
- Improved in-situ lifespan
- Improved quality of life
- Cost effective in the frequent replacement patient
Clinically what we do....

• Expect frequent changes in the first few months post fitting

Once stable:
• Watch the prosthesis when swallowing saliva/breathing
  – Incidental opening noted
• Watch the prosthesis when drinking fluids
  – Leaking around or through
• Dysphagia complaints – Modified Barium Swallow
  – Stasis
  – Backflow/regurgitation
  – Diet modification/avoidance
• GERD complaints
  – Work up
  – Behavioral protocol
  – PPI protocol
Clinically what we do....

- What does the prosthesis look like when removed?
  - Nystatin protocol
  - Anti-fungal prosthesis

- Trials with other prosthesis
  - Fungal problem – anti-fungal prosthesis
  - Pressure problem – high resistance prosthesis

- When all else fails
  - ActiValve trial
  - GI work-up for Nissen
## Relative Costs of TE Voice Prosthesis

<table>
<thead>
<tr>
<th>InHealth Technologies</th>
<th>Atos Medical</th>
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<tbody>
<tr>
<td>Low Pressure VP 75.00</td>
<td>NID 85.00</td>
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<td>DualValve VP ????</td>
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TEP Voice Viewed Radiographically:
Laryngectomy with Jejunal Interposition & Stricture
Thank You


