At Atos Medical, we are committed to giving a voice to people who breathe through a stoma, with design solutions and technologies built on decades of experience and a deep understanding of our users.

www.atosmedical.com
Speaker Disclosure

• Todd Coleman is employed as a clinical specialist for Atos Medical, Inc, a fabricator and distributor of medical devices used in the rehabilitation of patients status-post total laryngectomy.
Terminology

• Total Laryngectomy – title of the surgical procedure

• Laryngectomee – label used by some individuals to identify a person that has undergone a total laryngectomy
Total Laryngectomy - What is it?

• Removal of the entire larynx, permanently separating the trachea from the mouth

• The oral cavity maintains communication with the esophagus for nutrition

• The trachea is secured to the outer neck and the laryngectomee breathes through the opening, referred to as the stoma
Why is a Total Laryngectomy Performed?

- Majority of procedures are to treat advanced head and neck cancer
- Chronic aspiration
- Severe neck trauma
- Congenital defects or cancer
Frequency of Total Laryngectomy

• Approximately 3,200 surgeries performed in 2013 in the United States

• 44% of the procedures occurred in the South, followed by 24% in the Midwest and 18% in the Northeast

• 81% of patients are males

* Healthcare Cost and Utilization Project (H-CUP), 2015
Frequency of Total Laryngectomy

- 83% of surgeries were being performed in teaching hospitals by 2008

- Hospital length of stay averages 14 days

The Total Laryngectomy Procedure

• Surgical time is typically 4-9 hours, dependent on:
  - Tumor involvement
  - Extent of neck dissection
  - Prior history of XRT affecting tissue integrity
  - Type of reconstruction
Total Laryngectomy: Pre-Operative
Total Laryngectomy: Post-Surgery
The Total Laryngectomy Procedure

• Primary Steps:
  - Incision and flap elevation above anterior and external jugular veins. Typically carried superiorly just past the hyoid and inferiorly to the clavicles
The Total Laryngectomy Procedure

• Primary Steps:
  - Strap muscles transected
The Total Laryngectomy Procedure

• Primary Steps:
  - ETT repositioned for incision of the trachea between the second and third rings and for maturation of the stoma
The Total Laryngectomy Procedure

• Primary Steps:
  - Radical or modified neck dissection may be performed
  - Constrictor muscles detached from the thyroid and the suprathyroid muscles are dissected. Esophagus separated from posterior wall of cricoid cartilage
The Total Laryngectomy Procedure

• Primary Steps:
  - Larynx entered from above, tumor assessed visually and through biopsies, and final separation of the larynx performed
The Total Laryngectomy Procedure

• Reconstruction Options
  - Primary – local tissue repositioned and sutured
  - Pectoralis Major Flap
  - Radial Forearm Free Flap
  - Lateral Thigh Free Flap
  - Rectus Free Flap
  - Scapula Free Flap
The Total Laryngectomy Procedure

• Primary Steps:
  - Pharynx is closed and tracheostoma formed with meticulous suturing
The Total Laryngectomy Procedure

• Primary Steps:
  - 3-4 suction drains placed and platysma and skin closed
The Total Laryngectomy Procedure

• Post-operative outcome
The Total Laryngectomy Procedure

- Fully healed tracheostoma
Discharge & Readmission Following Surgery

- Majority of patients are discharged home

- Fistula development – primary cause for readmission*
  - PCF accounted for 27% of unplanned readmissions
  - ED visit within 30 days of discharge associated with a 5-fold increased risk of readmission
  - Majority of ED visits were related to stoma or TEP complications

*Patients Undergoing Total Laryngectomy An At-Risk Population for 30-Day Unplanned Readmission, Graboyes et al., JAMA Otolaryngology–Head & Neck Surgery, 2014
Pulmonary Rehabilitation Following Total Laryngectomy

• Highly important for the patient!
Immediate Post Operative Pulmonary Goals

• Replace some of the lost function of upper airway
• Less use of moist air and suction
• Engage patient in their postoperative stomal care
• Help nursing distinguish between laryngectomy patient and tracheostomy patient
• Working towards autonomy of the patient in the management of their stoma
Long Term Goals for Pulmonary Rehabilitation

• Decrease hyper-secretion of mucus associated quality of life issues
• Improve overall stoma cleanliness
• Improve social acceptance
• Improve patient’s overall self acceptance
• Patient independence in carrying out stoma and pulmonary care
Normal Respiratory Physiology

• Trachea, bronchi, nose
  - Lined with goblet cells which produce protectant mucus to trap bacteria and smaller debris
  - Cilia that transport mucus and large debris away from lungs

• Mucus – NOT abnormal, it’s protective

• Mucus Viscosity
  - dependent on hydration, humidification, warming, infection, obstruction, environmental exposure

• Mucus Production - 14ml/day (Widdecombe & Widdecombe, 1995) to 100ml/day (Pride, 1997)
Membranes Lining the Respiratory Tract: Defense Mechanisms

- Pseudo stratified Ciliated Columnar Epithelial Cells
- Goblet Cells
- Mucous Glands

http://virtual.yosemite.cc.ca.us/rdroual/Course%20Materials/Elementary%20Anatomy%20and%20Physiology%20%2050/Lecture%20outlines/respiratory%20system.htm
Most Defense Mechanisms Exist in Upper Respiratory Tract

• Goblet cells hyper-secrete in response to irritants (i.e. dust particles; smoke; bacteria)

• Cilia
  - trap large pieces of debris
  - push them out of the airways

• Goblet Cells
  - produce mucus
  - attract and trap smaller microorganisms and debris
  - keep tract moist

• Coughing & Sneezing
  - expel particles from the respiratory system

Image from http://www.studyblue.com/hello/
Factors that Increase Mucus Production and Impact Ciliary Function

- Inhaled Irritants
  - Bacteria
  - Viruses
  - Volatiles
  - Dust
  - Pollens
  - Smoke
- Infections
- Dehydration
- Temperature
- Excessive caffeine or alcohol Intake

Pulmonary Changes Due to Loss of Function in Upper Respiratory Tract:

- Changes in Mucus
  - Color
  - Quantity
  - Consistency
  - Blood Streaks
  - Odor
  - Casts, Crusts, Casings
- Excessive Coughing
- Dry/Dehydrated Tracheal Mucosa
Important Definitions:

• **Mucus**: a viscid, slippery secretion that is usually rich in mucins and is produced by mucous membranes, which it moistens and protects (normal)

• **Sputum**: expectorated matter especially from the air passages in diseases of the lungs, bronchi, or upper respiratory tract in the infection of lungs, bronchi or upper respiratory tract (not normal)

Definitions from Merriam-Webster.com
Normal Physiology of the Respiratory System

• Lined with Cilia and Goblet Cells
  - transports mucus and debris/sputum
  - Activity dependent on RH & Temp

• At The Nose
  - Lined with cilia
  - Air Temp = 72°F
  - RH = 45%
  - Ambient Dirty

• At the Trachea
  - Air Temp = 98.6
  - RH = 99%
  - Filtered Pristine
Physiology of the Post-Laryngectomy Respiratory System

• At The Trachea
  - Air Temp = 72°F
  - RH=45%
  - Ambient Dirty

• Remember:
  - Ciliary activity impaired when RH drops below 70%
  - Ciliary activity ceases when RH <50%
Mucus Plugs & Laryngectomee

- Loss of filtering, heating and humidifying results in:
  - Hypersecretion of mucus
  - Cessation or reduction of ciliary activity
  - Bronchial secretions accumulate to the point that they obstruct the airway
Post Laryngectomy Effects on Breathing

• Lost functions of the upper airway
  - Heating
  - Filtering
  - Humidity
  - Pulmonary resistance

• The loss of nasal functions lead to a wide range of pulmonary complaints such as coughing, excessive mucus production, crusting, and shortness of breath.

References:
• Ackerstaff, Souren, van Zandwijk, Balm, Hilgers. Laryngoscope 1993;103;1391-4
Multi-Institutional Study: Assessing Effects of Heat & Moisture Exchanger Use on Respiratory Symptoms & Voice Quality of Laryngectomized Individuals

N= 81 TL
• 62 men, 19 women
• Mean age 66
• Assessed 3 month usage of HME’s

Results:
n=59 used HME on regular basis

<table>
<thead>
<tr>
<th></th>
<th>Increase</th>
<th>No difference</th>
<th>Decrease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cough</td>
<td>4 (7%)</td>
<td>15 (25%)</td>
<td>40 (68%)</td>
</tr>
<tr>
<td>Mucus</td>
<td>3 (5%)</td>
<td>13 (22%)</td>
<td>43 (73%)</td>
</tr>
<tr>
<td>Airway clearing</td>
<td>5 (9%)</td>
<td>18 (31%)</td>
<td>36 (60%)</td>
</tr>
<tr>
<td>Stoma cleaning</td>
<td>3 (5%)</td>
<td>25 (43%)</td>
<td>21 (52%)</td>
</tr>
</tbody>
</table>
Long-Term HME Use & Pulmonary Issues

• Vaporizer use
  - 37% in non-HME users
  - 40% in non-compliant HME group
  - 9% in compliant HME users

• External humidifier use
  - 73% in non-HME users
  - 53% in non-compliant HME group
  - 36% in compliant HME users

How does the Provox HME work?

- Antimicrobial, hygroscopic properties
- Hygroscopic core increases moisture retention
- Water vapor condenses during exhalation & re-humidifies during inspiration
- Pulmonary heat & moisture (humidity) are retained
- Logical barrier to gross airborne matter
- Increase airflow resistance
- Temperature regulation
Provox Micron HME with Electrostatic Filter

- Electrostatic Filter (the only true filter on the market for the total laryngectomee)
- ≥99.8 BFE and VFE (bacterial and viral filtration efficacy)
- Finger Depression for TE speech
- Good for 24hrs once exposed to air
- Designed to wear in special circumstances (i.e. travel, flu/virus seasons, public exposure, etc.)
Influence of HME on the Tracheal Environment in Hot & Cold Environments

• Min (end-inspiratory) and max (end-expiratory) tracheal temperature significantly increased under cold-room conditions (40 F)

• End inspiratory temperature significantly decreased (about 7 F) in the warm and dry environment (89.6 – 100 F)

Scheenstra R, Muller S, Hilgers F, Head & Neck 2011 Sep 27;33(9):1285-93
HME Use Guidelines

• Patient should be sufficiently alert
• Ideally should be worn around the clock
• Once placed over the stoma, discard after 24 hours
• Discard if HME becomes heavily soiled
• Remove for administration of aerosolized/nebulized medication
• DO NOT RINSE
Patient Education Video
Means of Attaching a HME

• Adhesive Baseplates
  - Several shapes and sizes available to match patients’ anatomy
  - Different materials available to address varying skin properties
Means of Attaching a HME

• Adhesive baseplate placed over the stoma
• Can last for several days after application
Means of Attaching a HME

• Provox LaryTube
  - Constructed of soft, flexible medical grade silicone
  - Available in 3 different lengths and 4 diameters
Provox LaryTube

- Three types available: Standard, Fenestrated, With Ring
- Can be used immediately following surgery
- Addresses both proximal and distal stenosis
- Durable; typical lifespan over one year
- Can be fenestrated for tracheoesophageal prosthesis (TEP) speech
Provox LaryTube

- General cleaning: soak for 15 minutes in 8.5 fl oz water + 2-3 drops of dish soap solution

- Disinfection recommended once daily with one of the following:
  - 70% ethanol: 10 minutes
  - 70% isopropyl alcohol: 10 minutes
  - 3% hydrogen peroxide: 60 minutes
Means of Attaching a HME

• Provox LaryButton
  - Made of soft, flexible medical grade silicone
  - Available in 2 different lengths and 4 diameters
Provox LaryButton

• Addresses stomal stenosis
• Stoma must be fully healed prior to use
• Selection criteria: shape of stoma and presence of circumferential tissue fold in stoma (aka – “stoma lip”)
Provox LaryButton

• Sizing Kit available to assess suitability
• LaryButton also very durable
• Cleaning and disinfection identical to the Provox LaryTube
InHealth® Blom-Singer™ HME System

- HumidiFilter® System
  - Reusable holder
  - Disposable filters, change daily
  - Treated with lithium chloride (moisture retention) & chlorhexadine (antifungal)
  - Cover with finger to speak

- InHealth EasyTouch™
  - Disposable system to be changed daily
  - Mucus Shield helps protect mucus from entering filter
  - Depress to speak
  - Recommended to wear w/ TruSeal™ baseplate
Kapitex® HME System

• Trachi-Naze®
  - 3 types of filters (day, night & exercise)
  - Used only with TrachiNaze baseplates
  - Use 24hrs/day
  - Activated charcoal to block volatile fumes
  - Change daily

• Trachi-Naze Plus®
  - 3 types of filters (day, night & exercise)
  - Used only with TrachiNaze buttons
  - Use 24hrs/day
  - Activated charcoal to block volatile fumes
  - Change daily
Cyranose HME System

- **Adhesive:**
  - Double sided, hypoallergenic adhesive
  - 2 shapes

- **Secretion Trap:**
  - Double grid with tight medical grade stainless steel mesh
  - Clean with warm water and soap

- **HME:**
  - Made up of polyurethane foam

- **Casing:**
  - Medical stainless steel, closed by a spring operated obstruction valve

- Hands free valve available
Comparison of HME Performance

Nebulizers and Inhalers

• Aerosol/gas forms typically not an issue
  - A more circular conduit can be helpful in facilitating improved contact with the stoma

• Powder form of medication can be challenging to direct down the stoma

• Remove HME prior to administration
When to Introduce a HME?

- In the past, most laryngectomees were not fitted for a HME system until 3-6 + weeks following surgery

- Issues with:
  - Excessive mucus
  - Mucus plugs, especially after discharge
  - Poor compliance with external humidity after discharge
  - Habituating to very low airflow resistance
  - Frequent suctioning
Example of Common Post-Operative External Humidity Complaints...

- Uncomfortable collar
- Difficulty sleeping (noise)
- Damp hospital gown
- Excessive mucus and coughing
- Confined to bed
- Frequent suctioning
- Risk of mucus plugs
- Poor compliance
- Frequent need for one-on-one nursing care
- Differentiating tracheostomy patients from total laryngectomee patients
Randomized controlled trial on postoperative pulmonary humidification after total laryngectomy: External Humidifier versus Heat and Moisture Exchanger (Provox)


<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Compliance#</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Used daily*</td>
<td>11 (42%)</td>
<td>23 (100%)</td>
</tr>
<tr>
<td>Used 24/7</td>
<td>3 (12%)</td>
<td>20 (87%)</td>
</tr>
<tr>
<td>Coughing#</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 – 5x/day</td>
<td>14 (58%)</td>
<td>21 (90%)</td>
</tr>
<tr>
<td>6 – 10x/day</td>
<td>6 (21%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>&gt;10x/day</td>
<td>6 (21%)</td>
<td>2 (10%)</td>
</tr>
<tr>
<td>Mucus expectoration#</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean daily frequency</td>
<td>5.5</td>
<td>2.5</td>
</tr>
<tr>
<td>Range</td>
<td>0 - 15</td>
<td>0 – 5.5</td>
</tr>
<tr>
<td>Sleeping problems#</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not favorable</td>
<td>21 (81%)</td>
<td></td>
</tr>
<tr>
<td>A little favorable</td>
<td>2 (8%)</td>
<td></td>
</tr>
<tr>
<td>Favorable</td>
<td>3 (11%)</td>
<td>23 (100%)</td>
</tr>
<tr>
<td>Nursing time involved in patient care# ***</td>
<td>30 minutes/day</td>
<td>20 minutes/day</td>
</tr>
</tbody>
</table>

*** All nurses had a preference for the HME System.
Heat and Moisture Exchange Devices for Patients Undergoing Total Laryngectomy


- HME patient education is easy
- Secretions are easier to manage with the use of HME
- Stoma hygiene is better with the use of HME devices
- The HME system is easy to implement and use
- HME use decreases the frequency of stoma suctioning

Strongly disagree | Strongly agree
---|---
0 | 5
Advantages of Immediate Postoperative HME Use

- Easy adaptation & compliance
- ↓ suctioning & nursing care
- Cost-effective
- Eliminate noisy moist air
- Immediate HME benefits
- Avoid mucus plugging
- Early familiarization with stoma care
- Preparation for ambulatory care
- Easier to differentiate trach vs. laryngectomee
- Easier discharge planning
Introduction of an HME Immediately Post-Operatively
Select an HME based on...

- Pt. tolerance of airflow resistance
- Humidification requirements
- Environmental considerations
  - Public exposure
  - Climate
  - Air travel
  - Allergies
  - Environment
  - Physical activity
- Manual dexterity
Considerations when Starting an HME

• How long has patient been a total laryngectomee?

• Need to adapt to resistance from HME (low resistance device initially)

• Amount of mucus / coughing increases during the first days of use (thinning effect)

• Improvement of pulmonary function takes time (several weeks to months)

• Easier and more hygienic stomal occlusion

• The sooner the HME is introduced, the easier the transition
Additional Strategies Post-Operatively

- 3-5ml of sterile saline via the stoma 2-3 times daily

- Moisten crusted mucus with saline or saline/hydrogen peroxide mixture before removing with tweezers

- Use deep suction sparingly

- Reminders to remove HME before coughing
Patients’ Experiences with HMEs and Attachments After Total Laryngectomy

- 30 new HME users followed over the course of 12 weeks

- Findings:
  - Average of 6.8 days required to become accustomed to the HME
  - All participants used an HME for > 20 hours per day
  - 43.3% initially reported that breathing was more difficult with HME, while 56.6% of people found either no difference or breathing to be easier
  - After 12 weeks, only one person reported breathing difficulty with HME
Patients’ Experiences with HMEs and Attachments After Total Laryngectomy

• Findings continued:
  - After 12 weeks of HME use over 70% of the patients reported that breathing with an HME is easier than breathing through an open stoma
  - At 2 weeks 60% of people reported less tracheal dryness/irritation; this increased to 82.8% at 12 weeks of HME use
  - 63.3% reported less coughing after 2 weeks – no change at 12 weeks
  - All participants wished to continue use of the HME at close of the study
Remember

• These are NOT HMEs…
HME Benefits

• Decreased mucus production

• Reduced coughing

• Improved hygiene

• Quality of life!

Atos Medical
Your voice