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Device and Technique for Placement of Tracheoesophageal Prosthesis Using a Flexible Esophagoscope

Summary

Following a laryngectomy, lung-powered voicing is achieved through placement of a one-way valve voice prosthesis using a rigid esophagoscope. This technique confers poor visualization and can be difficult or impossible in patients with stenosis of the pharynx or esophagus, a small pharynx, or with reduced neck extension. The rigidity of the esophagoscope itself can often induce scarring and cervical spine mobility issues. A device was developed that allows for the safe and quick placement of a voice prosthesis using a flexible esophagoscope. The device assists with performance of a tracheo-esophageal puncture by stenting open the esophagus and delivering radial force to prevent the esophagus from collapsing, preventing posterior esophageal wall injury. This device allows for a safer, faster placement of the prosthesis. It may also allow the placement to occur in an ambulatory outpatient clinic. The device can be used in patients previously precluded from the procedure due to scarring, cervical spine disease, and narrowing of the esophagus.

Key Investigator
Jeffrey S. Wolf

Field
Internal Medicine
Laryngectomy

Technology
Medical device

Advantages
Superior visualization and increased safety

Ability to dilate the esophagus and place a voice prosthesis without replacing or changing scopes

May be used in patients excluded from using a rigid esophagoscope

Status
Available for licensing

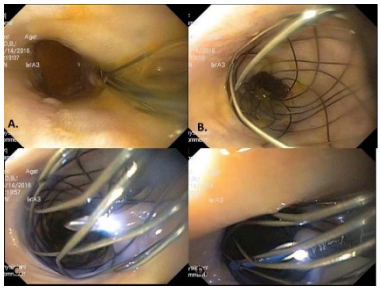
Patent Status
PCT/US2016/063495
EP 16 800 635.1
US Application 15/359,884

UMB Docket Reference
JW-2015-097
JW-2017-004

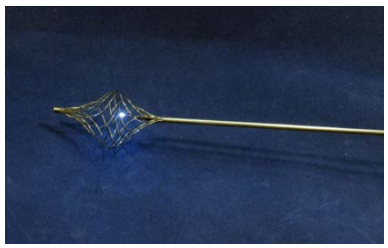
Market

Approximately 100,000 laryngectomies are performed worldwide each year, most as part of the management of advanced laryngeal cancer. However, many patients are unable to undergo this procedure due to the use of a rigid esophagoscope, which is contraindicated in patients with radiation fibrosis, stenosis, and cervical mobility issues. The use of a flexible scope during this procedure would expand the number of patients eligible to undergo it. There are currently no devices on the market allowing the placement of a prosthesis via a flexible esophagoscope and no other patents related to this, making this a first-in-class device. This device would allow the placement of the prosthesis to be performed in an outpatient setting instead of an operating room, greatly decreasing health care costs associated with the procedure. Furthermore, this device could be used to perform transoral or transnasal esophagoscopy.

Technology



Made of expandable braid at the distal end, the device is inserted in the trachea using the working channel of a flexible endoscope. Upon being exposed in the esophagus, the device expands, preventing the lumen wall from collapsing. This distended position reduces the risk of puncturing the posterior wall of the esophagus while inserting and withdrawing a needle and introducing, trapping, and withdrawing a voicebox wire (see figure). The use of a flexible esophagoscope offers superior visualization and allows the procedure to be performed on patients precluded from undergoing a procedure with a rigid esophagoscope. Additional, related iterations of devices and methods for expanding the esophagus, as well as supplementary channels, have been fashioned.



Technology Status

First generation prototypes of this technology manufactured and its performance tested during secondary tracheoesophageal punctures on more than five fresh cadavers. The prototype device and technique using a flexible esophagoscope allowed for visualization of the puncture, protection of the esophagus, and trapping and withdrawal of the wire, suggesting it is a safe, alternative method for fistula creation. Second generation prototypes have been built and are currently being tested.

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