Manual Control of the Upper Esophageal Sphincter

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Objectives/Hypothesis: Oropharyngeal dysphagia (OPD) is common and costly. In order to improve quality of life for patients and costs to society, better treatments than currently available are needed. The author hypothesized that manual control of the upper esophageal sphincter (UES) is possible by pulling the larynx directly forward with anterior traction on the cricoid cartilage. The purpose of this investigation was to evaluate the effectiveness of manual control of the UES as a possible therapy for OPD.

Study Design: Retrospective chart review, medical device development, prospective cadaver trial, and prospective animal experiment.

Methods: Charts were reviewed of all persons with OPD who had a traction suture placed by the author around the anterior rim of the cricoid cartilage. The opening of the UES was assessed with and without traction on the suture. The ability of the cricoid suture to improve UES opening was evaluated under fluoroscopy. The Swallow Expansion Device (SED) was designed to manually control the UES. The ability of the SED to open the UES was evaluated in cadavers and sheep. Anterior traction of the SED opened the UES in cadavers a mean of 1.16 cm (±0.22 cm) (P < .001). Anterior traction on the SED opened the UES in sheep a mean of 1.27 cm (±0.36) (P < .001). Aspiration was eliminated in 100% of the animals. The implant became infected and had to be removed in one (12.5%) animal. Remodeling of the cricoid cartilage was evident, but there was no histologic evidence of cartilage damage.

Conclusions: Manual control of the upper esophageal sphincter is possible. Simple anterior traction on the suture placed around the cricoid cartilage improved UES opening by 0.36 cm (±0.19) in a cohort of dysphagic patients. The Swallow Expansion Device opened the UES of cadavers and living sheep to superphysiologic proportions (P < .001). There was no histologic evidence of cricoid damage from prolonged use of the implant.

Key Words: Upper esophageal sphincter, swallow expansion device, oropharyngeal dysphagia, cricopharyngeus muscle, dysphagia, esophagus.

INTRODUCTION

In order of phylogenetic importance, the three primary functions of the larynx are airway protection, respiration, and phonation.1 If the larynx is unable to provide adequate airway protection during deglutition, or the pharynx is unable to provide adequate bolus transit through the upper esophageal sphincter, oropharyngeal dysphagia (OPD) ensues. Causes of OPD include stroke, head and neck cancer, head injury, advancing age, cricopharyngeus muscle dysfunction, amyotrophic lateral sclerosis, pseudobulbar palsy, Alzheimer's...
disease, Parkinson’s disease, multiple sclerosis, muscular dystrophy, and myasthenia gravis. Estimates of the prevalence of OPD are staggering. Up to 16% of the general population may suffer from OPD. The prevalence of dysphagia in the elderly may be as high as 50%. Concurrent chemoradiation for head and neck cancer is associated with a 45% incidence of prolonged feeding tube-dependent OPD and an incidence rate for aspiration of 59%. The incidence of dysphagia after stroke, the third leading cause of death in the United States, has been reported to be as high as 81%. Up to 60% of nursing home residents suffer from OPD. The incidence of swallowing difficulties in persons with Parkinson’s disease is nearly 100%. By 2010, it is estimated that 16.5 million people will need treatment for dysphagia. Despite the high prevalence of dysphagia, current treatment options provide only partial relief.

The impact of OPD on quality of life, morbidity, mortality, and healthcare expenditure is significant. In a survey of nasopharyngeal cancer survivors, dysphagia was the most important predictor of diminished quality of life. Elevated anxiety and depression are associated with dysphagia in head and neck cancer patients. Dysphagia in persons after total laryngectomy is associated with markedly increased social isolation, significantly impaired global functioning, depression, and anxiety, and in the general population, dysphagia is associated with depression and reduced general health. Dysphagia is also associated with the feeling of helplessness, and the majority of persons with OPD believe that their condition is untreatable.

Complications of dysphagia include aspiration, dehydration, pneumonia, malnutrition, depression, and death. The dysphagia-specific mortality rate in persons treated with chemoradiation for head and neck cancer is 9%. Aspiration pneumonia is one of the most common causes of death after stroke and is the most common cause of death in persons with Parkinson’s disease. The The incidence of aspiration pneumonia and death is nearly 20% in poststroke dysphagic patients. Nursing home patients with OPD have a 45% 12-month mortality rate. The yearly expenditure for an individual dependent on tube feeding is $30,000, and Medicare spends 6% of its annual durable medical equipment budget ($670 million) on enteral feeding supplies. Because of the high economic cost of OPD, the significant impact of OPD on quality of life, and the associated morbidity and mortality, improved recognition and treatment of this disorder are warranted.

For persons with OPD, current treatment options include diet modification, swallowing therapy, intraoral prosthetics, nonoral feeding, and invasive surgery. If a comprehensive dysphagia assessment with videofluoroscopy or nasendoscopy reveals difficulty with certain food consistencies, dietary restrictions may be recommended or food rheology may be manipulated. Depending on the individual needs and the cognitive ability of the patient, swallowing therapy may include exercise, sensory enhancement, postural changes, transcutaneous electrical stimulation, and swallowing maneuvers. Dental prosthetics may be employed to restore function to defects of the palate and tongue. If conservative management is unsuccessful in mitigating OPD, surgery may be considered. Surgical procedures shown to improve swallowing function in certain individuals with OPD include esophageal and upper esophageal sphincter dilation, cricopharyngeus muscle botulinum toxin injection, cricopharyngeus muscle myotomy, medicalization laryngoplasty, arytenoid adduction, laryngohyoid suspension, pharyngoplasty, epiglottopexy, lateral thyrolaminectomy, great auricular to superior laryngeal neuorrhaphy, diverticulectomy and diverticulotomy in patients with a hypopharyngeal diverticulum, vocal fold closure, laryngotracheal separation, and total laryngectomy. The aim of these operations is to improve laryngopharyngeal sensation, airway protection, and upper esophageal sphincter (UES) opening. Regardless of our best efforts, these treatments fail in a significant percentage of individuals.

Biomedical devices are accepted and used commonly in medicine—artificial joints, cochlear implants, and pacemakers, to name a few. Cutting edge medical device research continues to move forward with, for example, clinical trials of retinal prostheses in blind persons and wireless telemetry of EMG signals being used to control upper extremity prostheses. Although great progress in biomedical devices has been made for many other disorders, there is currently no device available to assist with the act of deglutition.

The pharyngeal phase of deglutition requires intrinsic synchronization between lingual and pharyngeal contraction and relaxation of the UES. Opening of the UES requires elevation of the larynx off of the posterior hypopharyngeal wall, muscular relaxation of the tonically active cricopharyngeus muscle, and distention caused by the passing bolus. The most important factor responsible for UES opening is deglutitive laryngeal elevation. The most common cause of profound dysphagia is typically a combination of reduced lingual and pharyngeal contraction pressure and limited or absent laryngohyoid elevation. Some of the disease states associated with diminished lingual and pharyngeal function and diminished elevation include stroke, head and neck cancer, amyotrophic lateral sclerosis, head injury, skull base surgery, multiple sclerosis, and muscular dystrophy. For individuals with profound OPD who fail currently available methods of intervention, definitive treatment options are limited. Most procedures involve a permanent separation of the airway and food passage, as occurs with total laryngectomy and laryngotracheal separation. These surgeries are morbid and result in permanent functional deficits. Oropharyngeal dysphagia is a mechanical problem in need of a biomechanical solution. The author hypothesized that manual control of the UES was possible with a biomedical device.

The UES is a 2- to 5-cm long high-pressure zone located between the pharynx and esophagus. Because of its location, this region has more appropriately been called the pharyngoesophageal segment or PES. The UES refers specifically to the intraluminal high-pressure zone measured by manometry. The PES refers to the anatomic components that make up the high-pressure zone. The terms UES and PES are synonymous and may be used interchangeably. The cricopharyngeus muscle
(CPM) makes up only one component of the PES. The CPM is not synonymous with the UES and PES. The UES can be modified with therapy and surgery. It is for this reason that the UES has captured the interest of numerous dysphagia clinicians and surgeons.

The UES is made up of the inferior pharyngeal constrictor, the CPM, and the most proximal portion of the cervical esophagus. All three muscles help maintain resting tone. The functions of the UES are to prevent aerophagia during respiration and phonation and to protect against regurgitation of refluxed gastric and esophageal contents into the pharynx and airway. The UES possesses basal tone and remains in a contracted state at rest. It opens reflexively during deglutition, eructation, and emesis. Esophageal distension, pharyngeal stimulation, emotional stress, and acid instilled into the esophagus all contract the UES reflexively. Of the three components that make up the UES, only the CPM constricts and relaxes during all reflex tasks. For this reason, many clinicians regard the CPM as the only true sphincter.

The CPM is a C-shaped muscle attached to the lateral lamina of the cricoid cartilage. It consists of a horizontal pars fundiformis and an oblique pars obliqua. A combination of slow type I and fast type II muscle fibers allows the CPM to maintain a constant basal tone and to rapidly expand and contract when necessary. Intricate microdissections in 27 persons undergoing total laryngectomy by Sasaki et al. suggest that the CPM receives dual ipsilateral innervation from the pharyngeal plexus (PP) and the recurrent laryngeal nerve (RLN). The PP projects to the posterior and the RLN projects to the anterior motor units of the muscle. Sensory information from the CPM is provided by the glossopharyngeal nerve and cervical sympathetics.

The act of swallowing depends upon adequate and timely UES opening. Opening of the UES depends upon muscular relaxation, elevation of the larynx, and pharyngeal contraction. Jacob et al. described five phases of UES opening. In phase I there is inhibition of tonic PES contraction. This is followed by elevation of the hyoid bone and larynx (phase II). In phase II, hyolaryngeal excursion provides active opening of the UES. The active opening provided by elevation appears to be more important than muscular inhibition. The UES can open by active distraction alone. Muscular relaxation without elevation will not open the UES. The larynx sits against the spine at rest (Fig. 1a). Without elevating the larynx away from the spine, there is no outflow tract to allow passage of a food bolus. If the larynx does not elevate to open the UES, relaxation of the CPM is inconsequential. This has significant clinical implications as swallowing in individuals with good hyolaryngeal elevation but incomplete CPM relaxation is possible and frequently encountered (CPM bar, Fig. 1b). Swallowing in individuals who can relax their CPM but cannot elevate their larynx and contract their pharynx to actively open the UES has not been observed. This accounts for the variability in surgical outcomes reported with cricopharyngeus muscle myotomy.

Phase III of UES opening involves distention of the UES through bolus size and weight. This phase relies upon pharyngeal and lingual peristalsis to propel the bolus past the spacious hypopharynx, through the narrowed but expanding UES, and into the cervical esophagus. The elasticity of the UES allows it to be opened by the increasing pressure exerted by the passing bolus. As the bolus passes, this elasticity causes a collapse of the UES (phase IV). Phase V involves UES closure through active muscle contraction. For reasons discussed subsequently, the author hypothesized that pulling the cricoid cartilage anteriorly will bypass these five stages and directly open the UES.

Fig. 1. Region of the upper esophageal sphincter (UES). (a) At rest, the larynx is in juxtaposition to the anterior cervical spine and the UES is closed (red line). There is no passage to accept a food bolus. In order to open the UES, the larynx must elevate off of the spine in an anterior and cranial direction. (b) The larynx has elevated during deglutition and the UES is open. There is incomplete relaxation of the cricopharyngeus muscle (CPM) and a CPM bar is present (red arrow).
The first report of a surgeon manipulating the larynx to open the UES was by Yrjo Meurman in 1957. He described a crico-hyoidopexia in two patients with tube-dependent OPD secondary to laryngeal trauma. His procedure utilized fascia lata to elevate the cricoid cartilage to the greater cornu of the hyoid bone bilaterally. By elevating the larynx, Dr. Meurman was able to improve swallowing function in both of these individuals. In 1959, Edgerton and McKee and DesPrez and Kiehn both described the use of laryngeal suspension in surgical reconstruction of large oral cavity tumors. In 1968, Bocca et al. described suspension of the larynx to the hyoid remnant in persons undergoing supraglottic laryngectomy. In 1969, Jabaley and Hoopes described various techniques of laryngeal suspension to improve swallowing function in three individuals with dysphagia after surgical treatment of squamous cell carcinoma of the tongue and floor of mouth. They reported 3 different techniques of laryngeal suspension: 1) elevating the thyroid cartilage to the mandibular symphysis, 2) pulling the base of the tongue forward and securing it to a mandibular bone graft, and 3) suspending the hyoid bone to the anterior mandible. They concluded that the technique of laryngeal suspension to the mandibular symphysis is effective in primary or secondary reconstruction of surgical defects. In 1971, Calcaterra described the successful use of a modification of the laryngeal suspension technique described by DesPrez and Kiehn in four patients after supraglottic laryngectomy. He noted that postoperatively “the larynx has enlarged the hypopharyngeal funnel and facilitated alimentary transit.” All patients were able to tolerate a regular diet by mouth.

In 1976, Dr. Richard Goode extended the indications for laryngeal suspension beyond supraglottic laryngectomy. He used a slight modification of Calcaterra’s technique combined with cricopharyngeus muscle myotomy in 19 patients who underwent major resection of head and neck cancer. He was able to elevate the larynx 1.5 to 3 cm, although he noted that postoperative “dropping” of the larynx was likely to occur. A tracheotomy was performed in all cases. Swallowing was determined to be adequate in only 50% of cases treated with the operation. Dr. Goode concluded, “laryngeal suspension is not a panacea to provide swallowing in this difficult group of cases.”

Seeking to improve on his initial results, Hillel and Goode described a lateral laryngeal suspension in 1983. They reported that lateral suspension of the larynx to the mandibular condyle provided a greater degree of laryngeal suspension than midline elevation. They achieved satisfactory swallowing results in 13 of 14 patients (93%). Complications were relatively common and included wound infection, fistula, VIIth nerve palsy, and vocal fold paralysis. In 1992, Herrmann reported the use of fascia lata to achieve laryngeal suspension in patients with severe neurogenic dysphagia, and in 2008, Aviv et al. described the use of laryngeal suspension as an adjunct to myotomy and greater auricular to superior laryngeal microneurorrhaphy in two patients. In 2008, Kos et al. reported the most comprehensive experience with laryngeal suspension combined with UES myotomy in 17 patients with severe OPD. The mean follow-up for their cohort was approximately 4 years. The surgery was deemed a complete success in 53% (9/17) of the patients, a partial success in 18% (3/17), and a failure in 29% (5/17). Because the surgery permanently opens the esophageal inlet, the authors cautioned against performing the procedure in patients with gastroesophageal reflux disease, and citing perioperative airway concerns, have recommended tracheotomy at the time of surgery. Limitations of the procedure include its potential to cause airway compromise, its inability to produce dynamic on-demand opening, the risk of aspiration associated with esophagohypharyngeal reflux, variable success, and the possibility of failure over time. Although the laryngeal suspension is appealing, the use of this procedure as a treatment of dysphagia has been limited primarily to the reconstruction of surgical defects.

The author hypothesized that manual control of the UES is possible. In order to expand the anterior-posterior diameter of the UES, the body must pull the larynx cranially. Direct manipulation should permit anterior displacement, and anterior traction on the cricoid cartilage should open the UES, perhaps more efficiently than vertical elevation. The author placed a suture around the cricoid cartilage of patients being evaluated for laryngeal suspension. Anterior traction on the suture in some patients opened the UES to superphysiologic dimensions (Fig. 2). Based on these initial observations the author designed a device to externally and manually control the upper esophageal sphincter.

The purpose of this investigation was to evaluate the effectiveness of manual control of the UES. The specific aims were 1) to evaluate UES opening on fluoroscopy with anterior traction on a suture placed around the anterior rim of the cricoid cartilage in persons with OPD, 2) to design and fabricate a swallow expansion device that mechanically opens the UES, 3) to evaluate the ability of the Swallow Expansion Device (SED) to open the UES in fresh cadavers, and 4) to evaluate the safety and efficacy of the SED in an ovine model of OPD.

**MATERIALS AND METHODS**

**Effectiveness of the Cricoid Traction Suture**

Permission to conduct this aspect of the study was approved by the University of California, Davis, Human Subjects Institutional Review Board. The records of all persons having had a cricoid suture placed by the author were retrospectively reviewed. Data regarding patient age, gender, and dysphagia etiology were recorded into a clinical database. Each patient had 2-0 monofilament nylon suture on a C-14 cutting needle (SN-75 8; Syneture, Norwalk, CT) placed around the anterior rim of the cricoid cartilage under local anesthesia in the office (Fig. 3). Great care was taken to maintain the needle tips along the internal aspect of the cricoid cartilage, keeping the stitches submucosal.

After suture placement, patients underwent a dynamic fluoroscopic swallow study with and without anterior traction on the suture. All studies were conducted in accordance with...
the routine radiographic protocols approved by our institution. Equipment used included a properly collimated OEC Medical Systems (Salt Lake City, UT) 9800 Radiographic/Fluoroscopic unit that provided a 63-kV, 1.2-mA type output for the full field of view mode (12-inch input phosphor diameter). In accordance with our protocol, subjects swallowed a 1 mL, 3 mL, and 20 mL liquid bolus (EZ-PAQUE Barium Sulfate Suspension, 60% wt/vol; 4 1% wt/wt; E-Z-EM, Inc., Westbury, NY) from a spoon or cup. Bolus size was measured with a syringe or graduated medicine cup.

The primary outcome variable for this experiment was UES opening (cm). The quantitative assessment of UES opening has been reported previously but will be described briefly.49 Fluoroscopy trials were recorded digitally using a Sony MD-1000 DVD recorder (Sony Corp. of America, New York, NY). Anterior traction on the suture was performed under fluoroscopy by the author. The suture was pulled anteriorly until additional force resulted in no further anterior UES displacement (UES max) or until the patient reported discomfort with the procedure. The force required to maximally displace the UES was measured with a digital force gauge (Imada, Inc., Northbrook, IL). A digital still image at the point of maximum UES opening with and without anterior traction on the cricoid suture was captured and imported into ImageJ 1.41 for the Macintosh (National Institutes of Health, Bethesda, MD) for the largest bolus administered. The software was calibrated to the known length of a 2-cm fluoroscopic marker placed directly beneath the chin. The distance between the anterior and posterior pharyngoesophageal segment at the point of maximum UES opening was calculated using the analysis software with ImageJ. All

Fig. 2. Manual control of the upper esophageal sphincter (UES). (a) Lateral fluoroscopic view. The UES is closed at rest (small arrows). A marker is placed on the anterior rim of the cricoid cartilage (large arrow). Anterior traction on the suture pulls the larynx directly forward and opens the UES to superphysiologic proportions (small arrows). (c) Flexible office endoscopic view. There is no anterior traction on the cricoid suture. The UES is closed (arrowheads). (d) Flexible office endoscopic view. Anterior traction is applied to the cricoid suture. The UES is open to superphysiologic proportions (arrowheads) exposing the posterior cricoid region. C = posterior lamina of cricoid cartilage; cp = cricopharyngeus muscle.
recordings were made from deidentified, prerecorded, randomly presented digital video with and without anterior traction of the suture with no knowledge of the presence or absence of tension on the suture. All data were coded and recorded into SPSS 17.0 for the Macintosh (SPSS Inc., Chicago, IL). Maximum UES opening with and without anterior traction on the suture was compared with the paired sample \( t \) test and the nonparametric Mann-Whitney \( U \) test.

**Design and Fabrication of the SED**

This aspect of the study was supported by a technology transfer grant from the University of California, Davis. Device development was structured through a series of five phase gates. These phase gates included orientation and project kickoff (phase 0), empiric cadaver testing (phase 1), concept development (phase 2), final concept refinement (phase 3), and functional prototype development (phase 4). To achieve these goals, the author partnered with an International Organization for Standardization (ISO) 9001:2000 certified medical device design company (Product Development Technologies, Inc., Chicago, IL). At the conclusion of this aspect of the study, a looks-like/works-like functional prototype was developed for use in the cadaver and animal testing. The device included an implant that was secured to the cricoid cartilage and an external magnetic device that attached to the internal device across intact skin. Pulling the external device forward mechanically opens the UES.

**Effectiveness of the SED in Fresh Cadavers**

Permission to conduct this aspect of the study was approved by the University of California, Davis donated body program. The internal component of the SED was affixed to the cricoid cartilage in 10 fresh cadavers. A 3-cm curvilinear incision was made in the cervical skin over the region of the cricothyroid membrane. The strap muscles were divided in the midline and the cricoid cartilage was identified (Fig. 4a). Five 2-0 monofilament nylon sutures (SN-75 8; Syneture) or five 2-0 Gore-Tex sutures (2N05; Gore Medical, Flagstaff, AZ) were utilized to secure the implant to the anterior aspect of the cricoid cartilage. A horizontal mattress was utilized for the center suture (Fig. 4b). Care was taken to maintain the needle tips along the internal aspect of the cricoid cartilage, keeping the stitches submucosal. The strap muscles were reapproximated over the device and the skin was closed in two layers (Fig. 4c, Fig. 4d). The primary outcome variable for this experiment was UES opening. A Dedo laryngoscope (Pilling Surgical, Horsham, PA) was utilized to expose the UES. Opening of the sphincter with and without use of the SED was measured with an Aerocizer airway sizing device (Alveolus, Inc., Charlotte, NC). Five pulls of the SED were performed for each cadaver. All data were coded and recorded into SPSS 17.0 for the Macintosh (SPSS Inc.). The mean UES opening with and without anterior traction on the SED was evaluated with the paired sample \( t \) test and the nonparametric Mann-Whitney \( U \) test.

To evaluate safety of the implant on the cricoid, the external magnet of the SED was affixed to the internal implant across the skin, and 5,000 pulls were performed. At the end of the safety trial the implant was removed and the skin, subcutaneous tissue, muscle, and cartilage were inspected for damage.

**The Safety and Efficacy of the SED in an Ovine Model of OPD**

This aspect of the investigation was approved by the University of California, Davis Institutional Animal Care and Use Committee (IACUC). It was supported by a development grant from Medtronic, Inc. (Minneapolis, MN). To assess the safety of the SED, eight Dorper cross wethers (castrated male sheep) were anesthetized and placed under general anesthesia. Anesthesia was induced with ketamine/valetam (10 mg/kg and 0.25 mg/kg). A 4-cm curvilinear incision was performed at the level of the cricoid cartilage. The strap muscles were separated in the midline, and the cricoid cartilage was identified. The internal aspect of the SED was secured to the cricoid cartilage (Fig. 5) with five 2-0 monofilament nylon sutures (SN-75 8; Syneture). The strap muscles were reapproximated over the implant, and the incision was closed in two layers and allowed to heal for 4 weeks.

After the 4-week healing period, the animals were lightly restrained once a week for 8 weeks. The handheld magnetic external component of the SED was affixed to the internal SED across intact skin, and 5,000 sequential pulls on the device were performed per session to open the UES. The author chose 5,000 pulls because this number greatly exceeds what would be utilized during routine use (approximately 50 swallows per...
meal), and this is a number that is tolerated by a lightly restrained animal and feasible to perform during the allocated test period.

Two weeks after the last session of SED pulls, the animals were euthanized with an intravenous injection of sodium pentobarbital (10 mL/100 lb), and the SED implant was removed. The cricoid cartilage was examined and evaluated for signs of infection and irritation. The implant site was grossly evaluated for damage to the cricoid cartilage, strap muscles, subcutaneous tissue, and overlying skin. A biopsy of the cricoid cartilage was obtained with a #11 scalpel blade (Canemco Inc., Quebec, Canada) perpendicular to the cricoid surface. This was compared histologically to a biopsy taken from the proximal thyroid cartilage lamina at a location distant to where the implant was located. For histologic examination, the cartilage specimens were fixed in 10% neutral buffered formalin, decalcified with 10% Na₂ ethylenediaminetetraacetate, buffered at pH 7.4, and embedded in paraffin. Sections were cut to 5 μm thickness on a rotary microtome and stained with toluidine blue and basic fuchsin stain in Epon-Araldite plastic. The primary outcome variable for this experiment was damage to the cricoid cartilage caused by use of the SED. To quantify cartilage damage, the degree of infiltration of inflammatory cells and cartilage destruction was classified according to the cartilage damage scale (CDS) as developed by Magari et al. and adapted by others. The CDS ranges from a low of 0 (no cartilage damage) to a high of 3 denoting severe cartilage inflammation and damage. To provide a less-biased assessment of cartilage damage, the histologic CDS was determined by an examiner blind to the site of cartilage biopsy (cricoid vs. laryngeal control site).

To assess the efficacy of the SED, the device was evaluated under fluoroscopy in the same animals used in the above-outlined safety trial. One week prior to implant removal and euthanasia, the animals were placed under general anesthesia. A deep level of anesthesia was achieved with inhaled isoflurane to suppress all swallowing activity. The animals were secured

Fig. 4. Placement of the swallow expansion device in a human cadaver. (a) The cricoid cartilage is exposed through a small skin incision. (b) The implant is secured with five 2-0 nylon sutures (SN-75 8; Syneture, Norwalk, CT) around the anterior rim of the cricoid cartilage. (c) The strap muscles are closed over the implant. (d) The skin is closed in two layers.
in a 60° upright position (Fig. 6). A properly collimated fluoroscopy unit with a 12-inch input phosphor (OEC Medical Systems) was then centered on the cervical region. An 18-French red rubber catheter (Bard Medical Division, Covington, GA) was placed through the nasal cavity and advanced under fluoroscopic guidance until the tip of the catheter was positioned in the pharynx just proximal to the tip of the epiglottis. A total of 20 mL of thin liquid barium sulfate (E-Z-EM Inc., Lake Success, NY) was delivered through the catheter tubing directly into the pharynx. The barium administration was performed under real-time fluoroscopy and digitally recorded. All studies were performed in the lateral view. To provide a less biased assessment, two 20-mL swallow trials were performed without the SED employed, and two 20-mL swallow trials were performed with anterior traction on the SED. The four study trials were randomly ordered. The ability of the SED to open the UES and reduce aspiration was evaluated. The primary outcome variable for this experiment was UES opening (cm). This variable was calculated by a blinded investigator using the identical technique described at the beginning of the Materials and Methods section on the effectiveness of the cricoid suture. The secondary outcome variable for this experiment was elimination of aspiration. Aspiration was defined as any barium traversing the vocal folds on fluoroscopy. The mean UES opening with and without anterior traction on the SED was evaluated with the paired sample $t$ test and the nonparametric Mann-Whitney $U$ test. The presence of aspiration with and without anterior traction on the SED was evaluated with the $\chi^2$ test.

**RESULTS**

**Effectiveness of the Cricoid Traction Suture**

The cricoid traction suture was placed in six individuals with feeding tube-dependent OPD (Table I). The mean age of the cohort was 67 years (±11). The etiology of dysphagia was chemoradiation for head and neck carcinoma (4/6) and stroke (2/6). All patients were feeding tube-dependent for 100% of their nutritional requirements. The mean (± standard deviation) maximum UES opening improved from 0.16 cm (±0.14) without traction on the suture to 0.52 cm (±0.07) with traction on the suture ($P < .01$). The amount of improved UES opening ranged from 0.02 to 0.59 cm. Anterior traction on the suture eliminated aspiration in three out of four patients who aspirated without traction on the suture (Fig. 7). Patients adapted easily to autonomous control of their UES with the suture. The mean force required to maximally open the UES was 4.18 pound-force (±0.68). Improvement in swallowing function was so pronounced that three patients went home with the suture in place so that they could eat. The suture caused local skin irritation in all patients and was removed (range, 2–9 days) without complication.

**Design and Fabrication of the SED**

The final prototype of the SED was designed with an internal and an external component. The internal component is a titanium-coated ferrous implant that is secured to the cricoid cartilage through a small skin
Fig. 7. Efficacy of the cricoid suture. (a) There is no anterior traction on the cricoid suture. The upper esophageal sphincter (UES) is closed (red arrow). There is penetration of barium sulfate over the arytenoid cartilage (*) and gross aspiration (red arrowheads). (b) The cricoid stitch is pulled anteriorly. Opening of the UES is improved (red arrow). There is penetration over the arytenoid (*) but no aspiration.

Fig. 8. Internal component of the swallow expansion device (SED). (a) Schematic of the internal aspect of the SED. (b) Exposure of the anterior rim of the cricoid cartilage (black arrows). (c) The SED is secured around the cricoid cartilage with five sutures. A horizontal mattress is used to secure the center of the implant around the cartilage, c = cricothyroid muscle.
incision (Fig. 8). Titanium implants have precedent in biomedical devices and are used frequently in maxillofacial, mandibular, and orbital reconstruction plates. Titanium is of a low density, strong, corrosion resistant, and highly biocompatible. It is an optimal material to house the iron core that is needed to provide magnetic attraction to the external component of the device. Placement of the implant on the cricoid cartilage is minimally invasive and can be performed through a small skin incision with local anesthesia (Fig. 8b, Fig. 8c). The procedure is technically simple and the implant can be removed without difficulty. The skin and strap muscles are closed over the implant and allowed to heal.

The external component of the SED houses a magnet that can be attracted to the implant across intact skin (Fig. 9). The external device is utilized only during swallowing. The patient places the external device on the anterior cervical skin. Squeezing the handles of the external device delivers the magnet to the surface attracting it to the implant (Fig. 9b). The size of the external magnet and ferrous implant was based on the clinical dimensions of cadaveric cricoid cartilages obtained from the author’s laboratory and from the results of the force testing in the human suture experiments. Pulling the external device forward during deglutition mechanically opens the UES (Fig. 9c). Releasing the handles frees the magnet from the internal implant (Fig. 9a). The distance of the magnet from the base of the housing can be adjusted to control attractive force between the external device and implant (Fig. 9a).

Experience with the cricoid suture suggests that patients readily adapt to autonomous control of their UES. The device was designed so that it would be similar in size to an electrolarynx (OptiVox; Smith Medical,

Fig. 9. External component of the swallow expansion device (SED). (a) The handles (h) are released and the magnet (m) is recessed within the housing. When the device is placed on the skin with the handles released there is minimal magnetic attractive force with the internal SED implant. The device may be placed on or removed from the cervical skin. The screw (black arrow) can be adjusted to fine-tune the amount of magnetic force required. The quantity of attractive force that is necessary will vary according to individual patient skin thickness, amount of subcutaneous fat, muscle thickness, and tissue pliability. (b) The handles (h) are depressed and the magnet (m) is delivered to the base of the housing. This engages magnetic attractive force with the internal SED implant. (c) SED usage scenario. The external SED is placed on the anterior cervical skin and the handles are depressed. The user pulls the device forward and opens the upper esophageal sphincter. (d) Image of the functional external SED prototype.

Fig. 10. The effect of the swallow expansion device (SED) on the cricoid cartilage of a human cadaver. (a) The cricoid cartilage prior to SED implantation. (b) The cricoid cartilage after 5,000 pulls of the SED. There is no gross damage.
Watford, UK. Patients in need of electronic speech have adapted well to placing an electrolarynx on the neck, and preliminary experience suggests that a similar degree of manual dexterity is necessary to control the SED.

**Effectiveness of the Swallow Expansion Device in Fresh Cadavers**

The SED was placed on the cricoid cartilage of 10 fresh cadavers. The mean time required for device implantation was 12 minutes (±4). Fifty thousand anterior pulls of the device were performed for safety evaluation. There was no gross damage to the underlying cricoid cartilage or overlying skin upon device explantation (Fig. 10). The device opened the UES from a mean baseline of 0.00 mm (±0.00) to a mean opening of 11.6 mm (±2.18) (Table II, Fig. 11; P < .001). This is considerably greater than normal gender and age-matched UES opening with a 3 mL bolus (5.2 mm, P < .001).

**DISCUSSION**

The data from this investigation suggest that manual control of the UES is possible. Anterior traction suture on the cricoid cartilage in a cohort of individuals with tube-dependent OPD improved UES opening by 0.36 cm (±0.19) (P < .01). Aspiration was eliminated in 75% (3/4). All of these patients had failed treatment with extensive swallowing therapy. Three patients desired to leave the suture in place so that they could enjoy oral intake at home. The patients participated in a brief biofeedback session under real-time videofluoroscopy by the speech language pathologist. The immediate feedback provided by the fluoroscopy allowed

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**TABLE II. Opening of the UES in Fresh Cadavers With the SED.**

<table>
<thead>
<tr>
<th>Cadaver Number</th>
<th>Gender</th>
<th>Age (yr)</th>
<th>Cause of Death</th>
<th>UES Opening With SED (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>F</td>
<td>60</td>
<td>Unknown</td>
<td>1.00</td>
</tr>
<tr>
<td>2</td>
<td>F</td>
<td>86</td>
<td>Stroke</td>
<td>0.80</td>
</tr>
<tr>
<td>3</td>
<td>F</td>
<td>96</td>
<td>Unknown</td>
<td>1.11</td>
</tr>
<tr>
<td>4</td>
<td>M</td>
<td>91</td>
<td>Unknown</td>
<td>1.33</td>
</tr>
<tr>
<td>5</td>
<td>M</td>
<td>72</td>
<td>GI bleed</td>
<td>1.07</td>
</tr>
<tr>
<td>6</td>
<td>M</td>
<td>79</td>
<td>Unknown</td>
<td>1.07</td>
</tr>
<tr>
<td>7</td>
<td>F</td>
<td>58</td>
<td>Breast CA</td>
<td>1.27</td>
</tr>
<tr>
<td>8</td>
<td>M</td>
<td>79</td>
<td>Prostate CA</td>
<td>1.47</td>
</tr>
<tr>
<td>9</td>
<td>F</td>
<td>87</td>
<td>RF</td>
<td>1.00</td>
</tr>
<tr>
<td>10</td>
<td>M</td>
<td>75</td>
<td>Lung CA</td>
<td>1.47</td>
</tr>
</tbody>
</table>

UES = upper esophageal sphincter; SED = Swallow Expansion Device; F = female; M = male; GI = gastrointestinal; CA = cancer; RF = respiratory failure.
the patients to readily adapt to autonomous control of their UES with the suture. All sutures were removed within 10 days of placement (4, 7, and 9 days) after erythema or induration developed in the skin around the suture site. The irritation resolved spontaneously after suture removal without the need for antibiotics in all cases. Patient success with the cricoid traction suture stimulated interest in the development of a permanent method of manual UES control. The irritation caused by the retained sutures influenced the decision to use an internal and external device affixed across intact skin with the use of a magnet. Use of magnets has precedent in otolaryngologic surgery. Magnets are used routinely to hold the external sound and speech processor of a cochlear implant in place and are also used to help identify the injection port on various tissue expansion

Fig. 12. Ovine cricoid cartilage 3.5 months after device implantation. (a) Lateral view of a sheep neck showing the outline (arrowheads) of the Swallow Expansion Device (SED) prior to explantation. (b) Fibrous capsule around the SED. (c) Incised fibrous capsule around the SED. (d) Remodeled (flattened) cricoid cartilage (arrowheads).

Fig. 13. Histology of the cricoid cartilage beneath the implant and from a control site taken from the distant thyroid cartilage after prolonged use (2 months) of the device. (a) Control laryngeal cartilage specimen. Toluidine blue and basic fuchsin stain in Epon-Araldite plastic (10×). (b) Cricoid cartilage specimen immediately adjacent to the implant. Toluidine blue and basic fuchsin stain in Epon-Araldite plastic (10×). There is no inflammatory infiltrate or evidence of cartilage erosion. Arrow = perichondrium.
The magnet in the external aspect of the SED was effective at opening the UES. The mean UES opening with the SED was 1.16 cm in cadavers and 1.42 cm in sheep. This is more than twice the mean UES opening in normal individuals with a 3 mL bolus (0.51 cm).2

In order to open the UES, the body must elevate the larynx. The hyoid bone serves as a fulcrum so that the suprahyoid musculature (geniohyoid, mylohyoid, thyrohyoid, digastric, and stylohyoid) can elevate the larynx anteriorly and superiorly off of the spine. The elevation provided by the body in normal individuals is not adequate in and of itself to open the UES. Opening does not occur until the elastic sphincter is distended by the advancing food bolus.3,2 Opening of the UES with bolus distention (phase III of UES opening) relies upon pharyngeal and lingual peristalsis to push the bolus through the narrowed sphincter. Patients with tube-dependent OPD secondary to lingual and pharyngeal weakness do not possess the ability to open the UES because they lack the ability to propel a bolus and distend the sphincter. Based on the Pythagorean theorem, a surgeon would have to elevate the larynx 15.18 cm toward the mandibular symphysis and beyond in order to obtain the PES opening the author achieved with the SED by pulling the UES directly anteriorly (Fig. 16; UESo). This is analogous to elevating the larynx to the approximate level of the nasal tip. This degree of permanent elevation is not possible. Laryngeal suspension surgery is capable of elevating the larynx 3 cm.3,5

There are several potential advantages to manual control of the UES with the SED over traditional laryngeal suspension surgery. Placement of the implant on the cricoid is minimally invasive and can be performed through a small skin incision with local anesthesia in less than 15 minutes. The procedure is technically simple and can be performed by a clinician with minimal instruction and no subspecialty training. A perioperative tracheotomy is not necessary. If the device gets infected or needs to be explanted to perform an imaging study it can be removed easily. Manual control of the UES with the SED is a dynamic process. The larynx does not need to be permanently secured to the mandible. The patient can open the UES on demand. Airway protection from esophagopharyngeal reflux is not compromised. Finally, the SED resulted in superphysiologic opening. Pulling the cricoid anteriorly is more efficient at opening the UES than elevating the larynx anteriorly and superiorly. We anticipate that when human trials with the SED commence, patients will require a brief instruction session with the speech language pathologist under real-time fluoroscopy. This will assure swallowing safety with the device and educate the patient on safe and proper use. Preliminary experience with the cricoid suture suggests that this may be a 10-minute addition to the traditional videofluoroscopic swallowing study.

Potential limitations of the SED include the possibility of infection and damage to the cricoid cartilage. There was no gross damage to the cricoid cartilage in

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### TABLE III.
Opening of the UES in Sheep with the SED.

<table>
<thead>
<tr>
<th>Sheep No.</th>
<th>Gender</th>
<th>Weight (lb)</th>
<th>UES Opening at Rest (cm)</th>
<th>UES Opening With SED (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>M</td>
<td>76</td>
<td>0.09</td>
<td>1.44</td>
</tr>
<tr>
<td>2</td>
<td>M</td>
<td>77</td>
<td>0.08</td>
<td>N/A</td>
</tr>
<tr>
<td>3</td>
<td>M</td>
<td>74</td>
<td>0.24</td>
<td>2.17</td>
</tr>
<tr>
<td>4</td>
<td>M</td>
<td>75</td>
<td>0.14</td>
<td>1.22</td>
</tr>
<tr>
<td>5</td>
<td>M</td>
<td>75</td>
<td>0.13</td>
<td>1.03</td>
</tr>
<tr>
<td>6</td>
<td>M</td>
<td>81</td>
<td>0.11</td>
<td>1.39</td>
</tr>
<tr>
<td>7</td>
<td>M</td>
<td>77</td>
<td>0.24</td>
<td>1.73</td>
</tr>
<tr>
<td>8</td>
<td>M</td>
<td>104</td>
<td>0.08</td>
<td>0.99</td>
</tr>
</tbody>
</table>

UES = upper esophageal sphincter, SED = Swallow Expansion Device; M = male; N/A = not available; device got infected and was removed before testing.
our cadaver or animal experiments in over 350,000 pulls of the device. Remodeling of the cricoid cartilage did occur with prolonged use in sheep (Fig. 12d). This did not narrow the lumen of the subglottic airway nor did it cause any noticeable airway compromise. Infection necessitated early removal in one animal (12.5%). Cervical erythema and swelling at the implant site was noticed in the second postoperative week. The animal was treated with broad spectrum antibiotics for 7 days and the signs of infection did not improve. A localized abscess was identified and the implant was removed in the third postoperative week. The animal recovered without incident. There was no histologic evidence of damage or infection to the cricoid cartilage in this animal. The majority of people who benefited from the cricoid suture and who would likely benefit from the SED are irradiated head and neck cancer patients. Infection and cricoid damage are of even greater concern in this population. Safety of the device in cadavers and in nonirradiated sheep is not sufficient to conclude that the device is safe in irradiated, living individuals. Because of the iron core, the device would need to be removed prior to a magnetic resonance imaging study. This is another concern, specifically in the cancer and stroke populations.

Another limitation of this investigation is the modest sample size. The cricoid suture was studied in six patients. The initial excitement with the therapeutic efficacy of the suture was tempered by the fact that all patients sent home with the stitch in place developed local irritation and had to have the suture removed within 10 days time. This experience restricted forthcoming suture placement and focused attention on development of the SED. The sample size for the cadaver study was 10 subjects, and the animal trial was limited to eight subjects. The primary analytic goal of these investigations was to evaluate the ability of the SED to open the UES. Although the sample size of these experiments was limited, pretrial power calculations revealed that these studies had 85% power to detect a 0.6 standard deviation improvement in UES opening.
The primary experimental goal was met in all three experiments. The data provide strong evidence that anterior traction of the cricoid cartilage with suture or with the assistance of the SED opens the UES. The secondary goal of these studies was to evaluate the safety of the device. The initial sample size calculation for the sheep study determined that the experiment had an 88% chance of identifying at least one adverse event, such as infection that occurred in 10% or more of sheep with the SED implant. One infection necessitating early implant removal was experienced. Now that efficacy has been established, future investigation is necessary to determine the true cumulative incidence of implant infection in a larger population of living animals.

CONCLUSION

Manual control of the upper esophageal sphincter is possible. A simple anterior traction suture placed around the anterior aspect of the cricoid cartilage improved UES opening by 0.36 cm (±0.19) in a cohort of dysphagic patients. An internal implant on the cricoid cartilage affixed to an external magnet across intact skin opened the UES of fresh cadavers and living sheep to supraphysiologic proportions.

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