Custom Implants for Medialization Laryngoplasty: A Model That Considers Tissue Compression

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Summary: Objective. Unilateral vocal fold paralysis can be treated with surgical medialization with a carved silastic implant. One challenge to this approach is anticipating the dimensions of the implant for adequate medialization. The purpose of this study was to develop a predictive model for implant design based on a patient's unique laryngeal anatomy and considering compression of the vocal fold.

Study Design. Retrospective chart review, prospective cadaver study, and prospective patient study.

Methods. A retrospective chart review was performed on patients who received silastic medialization laryngoplasty with favorable outcome and who had preoperative computed tomography. Data including Voice Handicap Index, maximum phonation time, and implant dimensions were collected from medical records, and laryngeal measurements were taken from preoperative imaging. Measurements were taken from computed tomography scans of three cadavers who underwent laryngoplasty for this study. Tissue compression (TC) was calculated and analyzed. A model to predict successful implant dimensions was developed and applied prospectively in 16 patients.

Results. Eleven patients from the chart review and three cadavers were included. Of all laryngeal metrics, width of the vocal fold at maximal medialization was most strongly correlated to TC ($r = 0.728$). Linear regression was performed ($y = 0.50x - 1.2$, $R^2 = 0.53$, $P = 0.005$, $F = 12.39$). Of the prospective patients, 15 of 16 demonstrated complete glottis closure with the premeasured silastic implant.

Conclusions. Vocal fold compression by silastic implants is linearly correlated with vocal fold-width at maximal medialization. A predictive formula was generated to anticipate TC and was successful in designing custom implants for patients.

Key Words: Medialization laryngoplasty–Thyroplasty–Vocal fold paralysis–Silastic.

BACKGROUND

Unilateral vocal fold paralysis (UVFP) is a condition that is multifactorial in etiology and may cause significant impairment in laryngeal function and quality of life.[1,2] Common sequelae include dysphonia, dysphagia, poor cough efficiency, and increased risk of aspiration because of glottic insufficiency.[1–3] The primary goal of treatment is to medialize the affected vocal fold, allowing better approximation to the opposite vocal fold. This can be achieved by four main strategies: reinnervation of the vocal fold, injection of connective tissue or biomaterial lateral to the affected vocal fold (injection laryngoplasty), rotation or repositioning of the arytenoid, or placement of a prosthetic implant via a surgical window in the thyroid cartilage (medialization laryngoplasty [ML]).[2,4,5] This study focuses on the latter strategy.

Implants are typically created at the time of surgery from silastic or *Gore-Tex* (W.L. Gore & Associates, Inc, Flagstaff, AZ) or prefabricated implants. There are different advantages and disadvantages to using these different approaches.[5] Prefabricated prostheses, such as the Montgomery implant (Montgomery Implant System; Boston Medical Products, Boston, MA),[6] come in a variety of sizes and are meant to fit most patients. Montgomery implants demonstrate good outcomes[7]; however, in one recent study, the authors noted that individual variation in thyroid cartilage anatomy led to difficulty in placing the implant in some patients.[8] These implants also do not well address a lateralized arytenoid cartilage. Unpredictable anatomy may require multiple attempts and implants to attain the best results, incurring high cost and prolonged operative times. These implants are also shaped so that the window must be large to allow placement of the implant, not only creating concerns for adequate posterior medialization but also making adjustments to the window challenging should a revision procedure be necessary.

Carved prostheses made from silicone products have demonstrated successful outcomes.[9,10] They also offer a solution to many of the problems with prefabricated implants, although they are not without their own drawbacks. Proponents argue that they may be designed so that the laryngoplasty window is small, allowing for potential adjustment, and that the wedge of the implant may extend posteriorly for additional medialization. Unlike prefabricated prostheses, they can be modified intraoperatively. The low cost of the carvable silicone and the ability to make real-time adjustments and customization to patient anatomy are significant benefits.

The disadvantages of this method include the time it takes to carve the implant, which may increase the length of surgery, although with experienced surgeons this time is minimal. Carving implants may, however, prove difficult for surgeons unfamiliar or less nuanced with the technique. One published survey demonstrated a learning curve for ML procedures, with findings suggesting that difficulties in carving the implant may increase complications if performed by a less experienced

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surgeon.[11] Other authors have promoted the use of Gore-Tex for these same reasons.[12,13] Therefore, we hypothesize that the development of a model to predict implant dimensions preoperatively may benefit patient outcomes.

A recent Brazilian study explored the possibility of designing thyroplasty implants using preoperative computed tomography (CT) scanning in excised cadaveric larynges.[14] This approach is appealing as these implants were specific to patient anatomy and allowed for creation of the implant before surgery, potentially reducing operating room times and costs. Although the authors did show that it is possible to design custom implants, they neglected to account for the potential compression of vocal fold tissue nor did they translate their techniques into living patients with UVFP. One would anticipate an implant to not simply displace tissue but that some compression would also occur affecting the extent of medialization. Therefore, being able to predict compression would be essential to the development of prefabricated implants. In our study, we have found that tissue compression (TC) may be significant in patients with successful medialization outcomes. The aim of our study was to develop a model for implant design that accounts for this compression.

METHODS

Retrospective chart review

This study was approved by the institutional review board before the commencement. Data were collected by retrospective chart review from a group of patients who had received silastic ML at our institution from November 2009 to September 2013. Patients who had a preoperative CT scan that was available to review were identified. Because routine CT scanning is primarily only performed in patients with idiopathic paralysis, these represented only a small subset of the entire ML population. From these patients, those who had a favorable outcome were further reviewed. All surgeries were performed by two experienced laryngeal surgeons (M.S.B. and P.C.B.). The authors keep very explicit descriptions of the laryngeal implant prosthesis in their operative reports in multiple dimensions so that these could be reproduced to compare to the CT scans. Favorable outcome was defined by patient satisfaction, satisfactory medialization visualized intraoperatively via flexible laryngoscopy, and complete glottic closure visualized at office follow-up via videostroboscopy. The patients also required improvements of Voice Handicap Index (VHI) scores and improved postmedialization maximum phonation times (MPTs). The VHI is a validated patient-based self-assessment tool for evaluating voice handicap.[15] The MPT is a measure of how long the patient is able to sustain phonation and has been found to be a sensitive way to assess glottic closure before and after treatment of UVFP.[16] Both VHI and MPT scores were collected from patients preoperatively and postoperatively when available to further illustrate operative outcomes (Table 1). A variety of metrics were obtained from CT scans of preoperative larynges, and dimensions of prostheses were collected from the operative note (Figure 1). CT scans were viewed and measured in our electronic medical record, Epic Hyperspace 2010 (Epic Systems Corporation, Verona, WI).

Patients were excluded from this study if there was no available preoperative neck CT. Patients with available CT scans were also excluded for the following reasons: (1) imaging was taken before onset of dysphonia or after ML surgery, (2) the presence of radio-opacity in the vocal folds on imaging from either recent vocal fold injection or arytenoid calcification because of the possibility that this would alter the compressibility of the vocal folds, and (3) the patients had a calcium hydroxylapatite injection after their imaging but within 24 months of ML surgery. Previous studies have suggested that the persistence of calcium hydroxylapatite is possible for up to 24 months after injection.[17] Additionally, no patients with vocal fold scarring, atrophic vocal folds, or other pathology that might affect compressibility were included in this study.

All CT scans were measured at the level of the anterior vocal processes of the arytenoids to capture the true vocal fold at the level of the maximal medialization of the silastic implant placement. CT scans of any protocol were used in this study so long as they contained the larynx at the level of the vocal processes. Laryngeal measurements (Figure 1) were chosen to capture the general size and shape of the larynx and for ease of measurement and reproducibility to ensure standardization between different patients.

The point of planned medialization was defined as the point on the vocal fold in contact with the largest aspect of the silastic prosthesis (dimension y). Measurements E and D were measured at this point along the vocal fold. Because compression forces are expected to be the greatest on this point of the vocal fold, TC was determined here. The point of planned medialization was determined on each CT scan from detailed operative notes and measurements of anatomic landmarks.

Initial cadaver study

ML was performed on two fresh cadavers based on preliminary estimates of TC from the retrospective chart review. CT scans of the neck were taken both before and after medialization and analyzed in *Syngo FastView* (Siemens AG, 2004–2009, Berlin, Germany) and *OsiriX* v5.8.1 (Pixmeo, Geneva, Switzerland). Laryngeal measurements were taken in the same manner as patients in the retrospective chart review.

Statistical analysis

Patient information was deidentified before further analysis. In the retrospective chart review, compression of laryngeal tissues was calculated based on the width of the vocal fold at the point of planned medialization, the maximal width of the silastic implant, and the distance from the inner thyroid perichondrium to the midline of the glottis (measurements E, y, and D in Figure 1, respectively). Flexible laryngoscopy and videostroboscopy that demonstrate medialization and complete glottic closure allows the assumption that the silastic implant has brought the true vocal fold to or near the midline of the glottis. Therefore, TC can be calculated from the metrics shown in