

# Evaluation of Voice Prosthesis Placement at the Time of Primary Tracheoesophageal Puncture with Total Laryngectomy

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**Objectives/Hypothesis:** Primary tracheoesophageal puncture (TEP) is a well-described and accepted method of surgical voice restoration and is standardly completed with a catheter placement intraoperatively, which is replaced with a prosthesis at a later date. This study evaluates the intraoperative placement of the voice prosthesis at the time of the primary TEP in an effort to understand the potential advantages and disadvantages of voice prosthesis placement at the time of primary TEP completed in conjunction with total laryngectomy.

**Study Design:** Retrospective chart review within an academic medical center.

**Methods:** After approval by the institutional review board of the Massachusetts Eye and Ear Infirmary, a retrospective chart review was completed of all cases of primary tracheoesophageal prosthesis placement completed in conjunction with primary tracheoesophageal puncture performed at the time of total laryngectomy.

**Results:** Thirty patients were identified, 29 of whom underwent laryngectomy for advanced laryngeal carcinoma. Twenty-eight of 29 patients received preoperative full-dose radiation therapy. Twenty-nine of 30 patients had a 20F classic Indwelling Blom-Singer prosthesis (InHealth Technologies, Carpinteria, CA) placed. One had placement of 16F Indwelling Blom-Singer prosthesis. No complications were noted with intraoperative prosthesis placement. No prostheses were dislodged in the postoperative period. Twenty-nine of 30 subjects had initial success with tracheoesophageal voice production. At 1-year follow-

up, 23/30 subjects (77%) had successful voice restoration. Five failed because of recurrent disease, one subject never achieved successful voice, and one subject wanted the prosthesis removed although successful voice was achieved. Twenty-three of 25 (92%) disease-free subjects had functional voice restoration at 1-year post-total laryngectomy and primary prosthesis placement.

**Conclusions:** This study demonstrates that the voice prosthesis can be safely and effectively placed intraoperatively at the time of primary TEP and laryngectomy. Initial voice acquisition rates were high and long-term success was well within the acceptable range.

**Key Words:** Tracheoesophageal voice restoration, total laryngectomy.

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## INTRODUCTION

Since the description of the tracheoesophageal voice restoration technique of Blom and Singer in 1979,<sup>1,2</sup> numerous studies have demonstrated the efficacy, safety, and reproducibility of this form of postlaryngectomy voice rehabilitation.<sup>3–8</sup> There has been significant evolution of the prosthesis itself and the means of placing the prosthesis. Although the tracheoesophageal puncture (TEP) technique was originally described as a secondary procedure in which a stenting catheter was endoscopically placed well after the laryngectomy, authors soon described the technique of primary TEP in which the tract for the speech fistula was placed primarily at the time of laryngectomy.<sup>9,10</sup>

The original descriptions of primary TEP in the United States involved the placement of a stenting catheter extending through the TEP site and into the distal esophagus or stomach. This catheter could be used for tube feedings during the postoperative period, and then a tracheoesophageal voice prosthesis could be placed in the tract in anticipation of tracheoesophageal speech training and acquisition. Yet, authors in Europe described experience with placing the prosthesis, and not a catheter, primarily at the time of laryngectomy.<sup>7,11–13</sup> Subsequent studies demonstrated the

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reliability and potential advantages of this technique, yet mainstream application of primary prosthesis placement has not gained general acceptance or application in the US. This study evaluates the efficacy and applicability of voice prosthesis placement at the time of primary tracheoesophageal puncture during total laryngectomy.

## MATERIALS AND METHODS

After approval by the institutional review board of the Massachusetts Eye and Ear Infirmary, a retrospective chart review was completed of all cases of primary tracheoesophageal prosthesis placement completed in conjunction with primary tracheoesophageal puncture performed at the time of total laryngectomy. Charts were reviewed for demographic data including gender, indication for laryngectomy, radiation therapy history, type of prosthesis placed, associated complications, success of initial voice restoration, and 1-year follow-up voice restoration status. Successful voice restoration was defined as the production of consistent voice and utilization of tracheoesophageal voice restoration as a primary communication modality.

### Technique

Prosthesis placement was completed by the senior author in all cases in the following manner. A primary tracheoesophageal puncture was created using a right angled clamp in the technique originally described by Haymaker and Singer<sup>10</sup> and recently outlined by Pou<sup>14</sup> (Fig. 1). This was standardly done 10 to 12 mm below the superior edge of the posterior tracheal wall (Fig. 2A). A moistened 16F rubber catheter was then pulled through the puncture site from the tracheal side into the esophageal lumen and passed upward into the laryngectomy defect (Fig. 2B). The tab of the standard 20F Indwelling Blom-Singer voice prosthesis (InHealth Technologies, Carpinteria, CA) was then sutured to the end of the rubber catheter. The catheter and prosthesis were then moistened with normal saline and the catheter was withdrawn, pulling the prosthesis through the laryngectomy defect and into the esophagus (Fig. 2C). The tab of the prosthesis was then brought through the puncture tract and grasped with a clamp. As described in the technique of retrograde placement of the Indwelling prosthesis by Deschler et al.,<sup>15</sup> the tracheal flange of the prosthesis was then gently delivered to the tracheal side of the puncture tract. A mosquito clamp and forceps were used to facilitate this step, and care was taken not to inadvertently pull the prosthesis completely through the puncture site (Fig. 2D). The positions of the esophageal and tracheal flanges were verified under direct visualization. Creation of the neopharynx, closure of the neck, and stoma formation were completed in the standard manner. A nasogastric tube was placed in cases when a pre-existing gastrostomy tube was not present. The tab of the prosthesis was left attached and placed superiorly in the stoma. A small Steri-Strip (3M, St. Paul, MN) was used to secure this orientation. If necessary, a soft Silastic Blom-Singer laryngectomy tube was placed in the immediate to assure stoma patency without complication. Tube feedings continued until a pharyngogram revealed no evidence of salivary leak or fistula. Active tracheoesophageal (TE) speech training was begun 1 to 2 weeks following the resumption of oral diet.

## RESULTS

Between January of 2003 and March of 2008, 30 patients underwent primary placement of the tracheo-

esophageal prosthesis at the time of primary tracheoesophageal puncture during total laryngectomy. There were 26 males and four females. The indication was advanced laryngeal cancer in 29/30 cases. The one exception was for trauma. Twenty-eight of the 29 cancer patients had preoperative full-course radiation therapy. Standard total laryngectomy with appropriate neck dissections were completed in all cases. Cases with partial and complete pharyngectomy requiring flap reconstruction and salivary bypass tube placement were excluded.

A 12-mm 20F standard Blom-Singer Indwelling prosthesis was placed in 29/30 cases. Because of limited availability, a 16F Blom-Singer Indwelling prosthesis was placed in one case. No complications were noted in the immediate postoperative period. One prosthesis, the 16F Indwelling, was inadvertently pulled through the puncture tract at the time of placement. The tract was successfully recannulated and prosthesis placed without incident on second attempt. There were no cases of inadvertent prosthesis dislodgement in the postoperative phase. Twenty-nine of the 30 subjects had initial successful production of tracheoesophageal speech. At 1-year follow-up, 23/30 subjects had successful tracheoesophageal speech production. Five subjects failed because of recurrent disease, one never achieved successful voice production, and one subject requested prosthesis removal although successful TE speech was achieved. Successful voice restoration was therefore achieved in 23/25 patients (92%) surviving 1 year following total laryngectomy.

## DISCUSSION

Numerous studies have demonstrated the safety, efficacy, and reproducibility of the tracheoesophageal puncture technique of surgical voice restoration as originally described by Blom and Singer.<sup>1</sup> The introduction and utilization of primary tracheoesophageal puncture at the time of laryngectomy was similarly found to be safe and effective with the advantage of avoiding a secondary procedure.<sup>8,10</sup> Although radiation therapy administered after primary puncture can shorten the life of a particular prosthesis and affect speech during the periradiation therapy period, primary puncture was also shown to be effective in this clinical scenario.<sup>16,17</sup> The technique of primary puncture, as described in the original and subsequent publications was a reduplication of the technique of secondary placement in which a catheter is placed in the tract to allow adequate stabilization and maturation until which time a prosthesis can be placed. This was usually 3 to 7 days in the standard secondary setting, but often longer in the primary setting if the catheter was also used to administer gastric tube feedings.<sup>9,10</sup> A reluctance to place the prosthesis at the time of primary puncture may also have been related to a fear of prosthesis dislodgement and subsequent tract loss as the early generation prosthesis had small flanges. This allowed ease in subsequent prosthesis removal and replacement but could allow for less secure positioning in the primary setting.

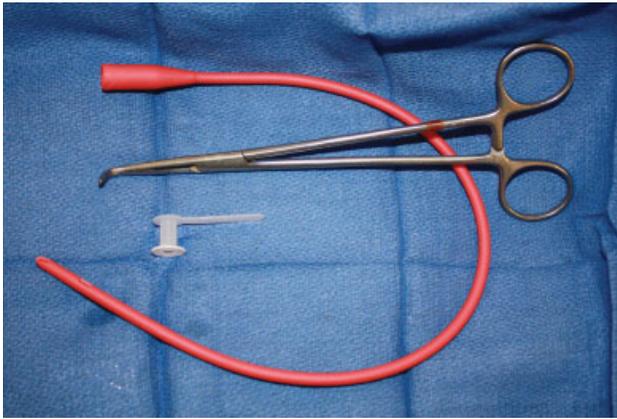


Fig. 1. Instruments required for primary puncture and prosthesis placement: Right angled clamp, 16F rubber catheter, and 12 mm 20F Indwelling Blom-Singer voice prosthesis.

The evolution of the longer duration prostheses, such as the Provox I, Provox II (Atos Medical AB, Hörby, Sweden), and the Blom-Singer Indwelling prostheses, provided for prostheses with wider flanges, which provided greater stability within the tracheoesophageal tract and longevity.<sup>7,12,18</sup> Such longevity of placement did come at the expense of necessitating practitioner removal and replacement of the prosthesis, as opposed the patient management, as had been done with original 16F Blom-Singer Duckbill and Low-Pressure prostheses. Yet, review of the literature indicates no significant movement occurred within the US towards primary placement of the prosthesis.

Meanwhile, in Europe, primary prosthesis placement was first described in 1984 by Manni et al. in a small series using the Groningen prosthesis (Atos Medical AB, Hörby, Sweden).<sup>11</sup> In 1990, Hilgers described the successful primary placement of the Provox I

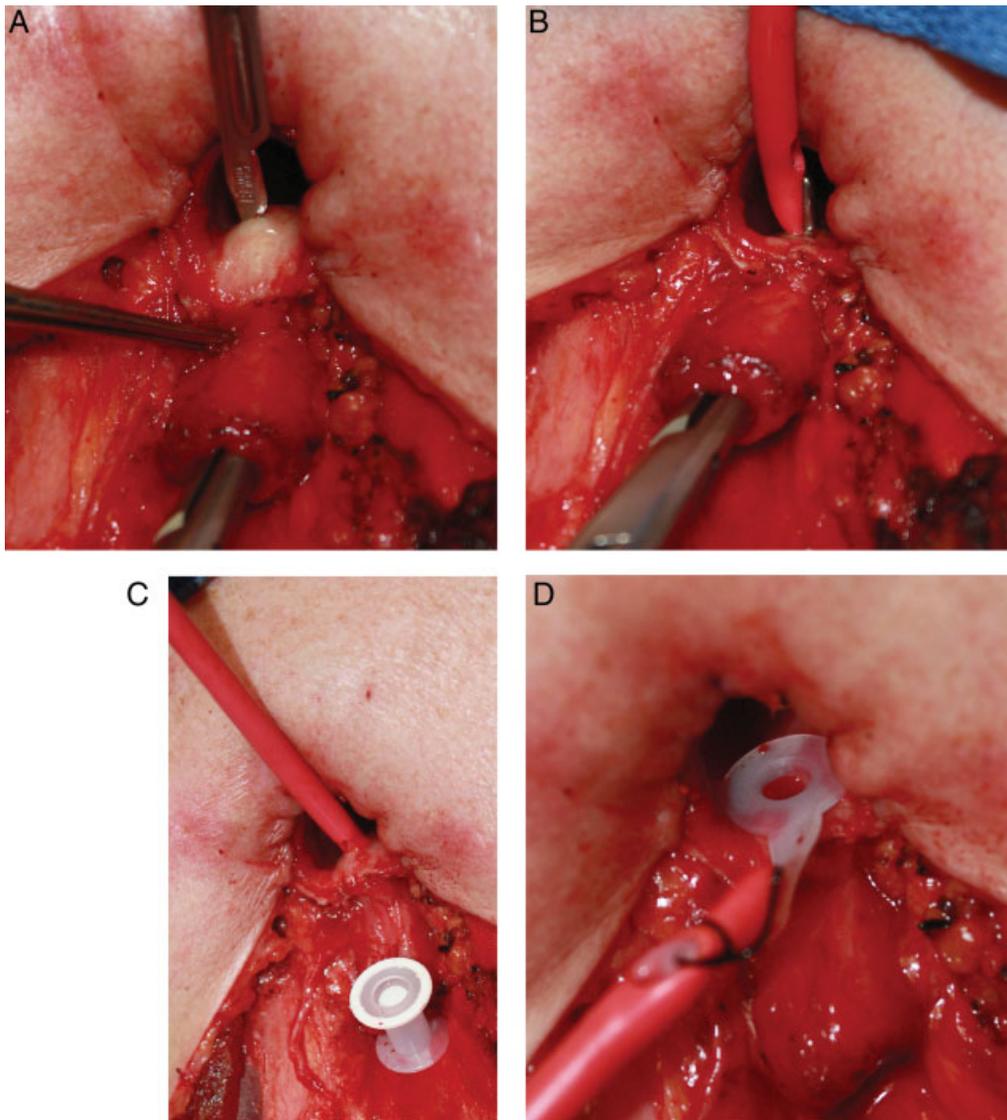


Fig. 2. (A) Right-angled clamp pointing anteriorly from esophageal lumen to the posterior tracheal wall 10 mm below superior edge of posterior tracheal wall. A 15 blade used to incise the posterior wall and allow the tip of the clamp through. (B) Catheter is grasped and then pulled through the puncture tract and out the esophagus. (C) Prosthesis is attached to catheter with silk suture and then drawn through the esophagus to the puncture tract. (D) Tab and tracheal flange are delivered through the puncture tract to the tracheal side.

prosthesis in 12 patients.<sup>12</sup> Both the Groningen and Provox prostheses had significantly larger flanges than the original Blom-Singer prostheses, allowing enhanced stability after placement but more involved prosthesis removal and replacement. Subsequent European studies describe large experiences with primary placement and no adverse effects.<sup>7,13</sup>

The Blom-Singer Indwelling prosthesis was introduced in 1996, and subsequent studies have demonstrated its efficacy and success as an alternative for long-term indwelling prosthesis.<sup>18</sup> Although a practitioner must place this prosthesis, the Indwelling device's innovative and atraumatic placement technique and ease of airflow for voice creation have made patient acceptance high. As with all prosthesis, issues related to fungal overgrowth and prosthesis leakage have fostered further modifications. Yet, this prosthesis has flanges of sufficient size to allow dependable primary placement. Although Freeman and Hamaker described primary placement of the Indwelling prosthesis in 1998,<sup>19</sup> and Singer mentioned this method in a review of the history of tracheoesophageal voice restoration in 2004, subsequent peer-reviewed publications of US series are not available.<sup>20</sup>

This study is the first to specifically address primary prosthesis placement with the Blom-Singer Indwelling prosthesis in a US patient cohort. Similar to the European experience, there were no negative sequelae related to the primary placement of the prosthesis. The initial rate for successful voice production was comparatively high at 97%, and the successful voicing rate at 1 year in surviving patients was likewise acceptable at 92%. The incidence of preoperative radiation therapy exposure in this group was also much higher than in comparative European studies.

The advantages of primary prosthesis placement are multiple. Primary placement precludes the need of a separate consultation specifically for prosthesis placement. The Indwelling prosthesis, because of the snug fit from the larger flanges, is more stable in its position at the posterior stoma than is a catheter, which must be secured with an external stitch. We had no cases of prosthesis dislodgement in the postoperative phase, which is an improvement over the catheters, which are invariably coughed out or displaced at some point during the hospitalization. Similarly, the prosthesis is a smaller physical presence in the stoma. This allows easier stoma care and easier placement of laryngectomy tubes when they are required for stoma patency in the early postoperative period. The prosthesis also has a lower profile presence on the esophageal side. This can be important in cases in which one is considering placement of a salivary bypass tube (SBT) at the time of laryngectomy. The presence of both a TEP catheter and a SBT could predispose to esophageal erosion, and some surgeons will delay voice restoration until after the SBT is removed. Such concern is obviated with primary prosthesis placement. Finally, the direction of the fistula tract will rest in a more natural horizontal position with primary prosthesis placement. With catheter placement, the tract will

be more vertically oriented to allow passage of the catheter into the distal esophagus.

Disadvantages of primary placement are few. The absence of the catheter through the TEP site usually precludes feeding administration through the TEP, although some have described passing a feeding catheter through the prosthesis.<sup>21</sup> Because many patients have a pre-existing gastric tube from prior organ preservation treatment protocols and advanced disease status, feeding through the TEP is not necessary. In the remaining cases, a nasogastric feeding tube is placed and well-tolerated. Others postulate that primary placement leads to earlier required change-out of the primary prosthesis secondary to suboptimal sizing and increased cost. Yet, according to Op de Coul et al., the mean time for initial prosthesis replacements for prostheses placed primarily at laryngectomy was 135 days.<sup>7</sup> This compared favorably to the report of Leder and Sasaki, which noted a mean of 26 days before initial resizing after secondary puncture.<sup>22</sup>

## CONCLUSION

The decision whether to proceed with primary puncture as part of tracheoesophageal voice restoration is based on many factors. This study demonstrates that the voice prosthesis may be safely and effectively placed at the time of primary puncture as opposed to a catheter as originally described. No cases of prostheses dislodgement were noted and immediate, and long voice acquisition rates were quite high indicating the value of this alternative during primary surgical voice restoration.

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