The Role of Reconstruction for Transoral Robotic Pharyngectomy and Concomitant Neck Dissection

Eric M. Genden, MD; Richard Park, MD; Claris Smith, BA; Tamar Kotz, BA

Objective: To evaluate the impact of primary reconstruction of postablative defects following transoral robotic surgery on function and the risk of orocutaneous fistula.

Design: Prospective nonrandomized clinical trial.

Setting: Tertiary academic medical center.

Patients: Thirty-one patients treated with transoral robotic pharyngectomy for malignant disease. Each case was analyzed for patient age, sex, primary site of the tumor, pathologic characteristics, stage of disease, complications, fistula rate, and functional outcomes. Functional outcomes were assessed using the Performance Status Scale for Head and Neck Cancer Patients and the Functional Oral Intake Scale.

Interventions: In 25 patients, the primary treatment was with transoral robotic pharyngectomy, and 6 cases were salvage procedures performed for recurrent disease following radiation (3 patients) or chemoradiation (3 patients). Twenty-six patients underwent a concomitant unilateral selective neck dissection, and 3 patients underwent concomitant bilateral selective neck dissections; 2 patients did not require a neck dissection for treatment of the primary malignant tumor.

Main Outcome Measures: Complication rate, fistula rate, and oral function.

Results: Primary intraoral reconstruction was performed in all 31 patients. Musculomucosal advancement flap pharyngoplasty was performed in 25 patients with a concomitant velopharyngoplasty (6 patients), and radial forearm free flap reconstruction was performed in 6 patients. There were no intraoperative complications; however, postoperatively, 1 patient developed a neck hematoma that was treated with bedside drainage and 4 patients sustained minor musculomucosal flap necrosis of the superior aspect of the flap. None of the patients developed a neck infection or salivary fistula. Endoscopic evaluation of swallowing demonstrated that none of the patients experienced aspiration or velopharyngeal reflux, and the performance Status Scale for Head and Neck Cancer Patients and the Functional Oral Intake Scale at 2 weeks, 2 months, 6 months, 9 months, and 1 year demonstrated a progressive improvement in diet, swallowing, and oral function.

Conclusions: Primary transoral robotic reconstruction may provide a benefit by decreasing the fistula rate in patients undergoing concomitant neck dissection. Patients regain excellent function following surgery and adjuvant therapy.


Until recently, the treatment of oropharyngeal malignant disease could be accomplished with a combination of high-dose chemotherapy and external beam radiotherapy (EBRT) or an en bloc resection achieved through a mid-line labiobihotomy and mandibulotomy. Over the past decade, the former has gained favor because of the inherent morbidity associated with the open surgical approach and the results of a series of prospective clinical trials conducted by the Radiation Therapy Oncology Group (RTOG) for locally advanced squamous cell head and neck cancer.1-3 More recently, several analyses have demonstrated the significant rate of both minor and major toxic effects associated with concurrent chemoradiation.4-6 These findings have prompted the investigators to consider minimally invasive surgical techniques in an effort to achieve tumor extirpation with minimal morbidity and potentially deescalate adjuvant therapy. Transoral laser microsurgery (TLM) has proven to be an effective alternative to the open mandibulotomy approach,7-9; however, this technique is limited in its ability to achieve both en bloc resection and reconstruction of extensive defects. Although the necessity for en bloc resection has been called into question, the inability to achieve reconstruction following an extensive ablation represents a considerable limitation. Because the treatment of advanced disease often results in an extensive mucosal defect and,
in some cases, direct connection with the soft tissues of the neck and exposure of the great vessels, it is important that a minimally invasive technique provide an opportunity to achieve a reliable reconstruction.

Recent work has suggested that transoral robotic surgery (TORS) may provide a useful tool for minimally invasive extirpation of oropharyngeal neoplasms, however, to our knowledge, no data have published related to the role of reconstruction and TORS. Robotic technology offers a unique set of advantages over current transoral techniques owing to the 3-dimensional camera and bimanual control afforded by the robotic arms. These advantages enable the surgeon to have unparalleled visual access and the ability to manipulate the tissue in a way that cannot be accomplished using nonrobotic transoral techniques, such as TLM. Proponents of both TLM and TORS have advocated staged neck dissections in an effort to prevent the development of an orocutaneous fistula. When a neck dissection is performed concomitantly with TORS, fistula rates as high as 6.7% have been reported. In contrast to TLM, TORS provides the opportunity for soft-tissue reconstruction with either musculomucosal adjacent tissue flaps or free flap reconstruction. We evaluated the impact of primary reconstruction of postablative defects following TORS surgery on function and the risk of orocutaneous fistula.

METHODS

From June 2007 to March 2009, 31 patients were enrolled in a nonrandomized prospective trial designed to assess the rate of fistula and/or neck infection in patients treated with transoral robotic pharyngectomy and concomitant neck dissection for malignant disease. The project was approved by the institutional review board of The Mount Sinai School of Medicine and designed to evaluate the impact of primary reconstruction following TORS reconstruction of ablative defects involving the lateral or posterior pharyngeal wall. Complex defects involving multiple sites were included in the analysis if the defect involved the pharynx. Inclusion criteria for the study consisted of age 18 years or older, regardless of sex, race, or ethnicity, and having lesions involving the oropharynx and hypopharynx. Informed consent was obtained from all patients. Each case was analyzed for patient age, sex, primary site of the tumor, pathologic characteristics of the tumor and stage of disease, complications, fistula rate, and functional outcomes.

Functional outcomes were assessed preoperatively and postoperatively (at 2 weeks, 2 months, 6 months, 9 months, and 1 year after surgery) using the following: (1) endoscopic evaluation of swallowing performed by 1 of 2 physician’s assistants (1 of whom was T.K.) and assessed for aspiration or velopharyngeal reflux by an independent and uniformed speech swallowing therapist; (2) the Performance Status Scale for Head and Neck Cancer Patients (PSS) and (3) the Functional Oral Intake Scale (FOIS). The PSS is a validated questionnaire method for evaluation of subjective swallowing function. The domains include eating in public, understandability of speech, and normalcy of diet. Each domain minimum and maximum scores are 0 and 100, respectively. The maximum total score is 300. A higher score indicates better swallowing function. The FOIS is an ordinal scale designed to assess the current status and functional change in the oral intake of patients with dysphagia. This dietary scale consists of 7 levels that range from being unable to orally consume any food or liquid (level 1) to being able to consume an oral diet with no restrictions (level 7). The FOIS is a valid and reliable instrument and is reported to have an interrater reliability coefficient (rank correlation) of 0.98 to 0.99 with average $\kappa$ values ranging from 0.86 to 0.91 and adequate consensus validity (Kendall concordance, 0.90) and criterion validity (based on the Mann Assessment of Swallowing Ability). All the data were collected prospectively and analyzed with SPSS statistical software (version 15; SPSS Inc, Chicago, Illinois). Results were summarized using mean, medians, and ranges.

All surgical procedures were performed by the principal investigator (E.M.G.) with the aid of a scrubbed assistant. The daVinci Surgical System S model (Sunnyvale, California) was used for all procedures. The system consists of a surgeon’s console, a surgical cart, a manipulator unit with 2 laterally placed instrument arms, and a centrally located endoscopic arm holding the 3-dimensional (3D) camera. As previously described, the patient was placed in the supine position on an operating room table. After standard endotracheal intubation with a laser tube, the daVinci robot was positioned at a 30° to 45° angle to the operating room table. Oral cavity retraction was achieved using the Dingman retractor or Feyh-Kastenbauer retractor (Gyrus ACMI, Maple Grove, Minnesota). In each case, the retractor was suspended from a retraction arm fastened to the operating room bed. The 0° or 30° high-magnification 3D camera was inserted into the oral cavity followed by positioning of the dual robotic arms. Surgical resections and reconstructions were performed using 5-mm robotic instruments, including needle drivers, bipolar forceps, Maryland forceps, and either a Bovie cautery, a 200-µm spot-size flexible carbon dioxide laser (OmniGuide Co, Cambridge, Massachusetts) with a 20-W NovaPulse laser (Lumenis, Santa Clara, California) or a the Relix 2-µm Holmium surgical laser (Lisa Laser USA, Katlenburg-Lindau, Germany). In those cases in which a composite resection was performed, a marginal resection was also performed at the retromolar trigone using a reciprocating saw with a right angle cutting blade transorally. In order to place the reciprocating saw, all of the mucosal cuts were completed, the robotic arms were withdrawn from the oral cavity, and the marginal resection was completed.

In each case in which a muscular mucosal flap was used for reconstruction, the transoral robotic resection and reconstruction were completed using the robot, and then the robot was removed from the field and the neck dissection was performed. In the cases where a free flap was used for reconstruction, the transoral robotic resection was completed, the robot was moved out of the surgical field, the neck dissection was performed, and the donor vessels were prepared. The flap was then harvested, and the robot was again brought into the field and used to suture the flap into the oropharynx defect. Common to non-TORS free flap reconstructions performed at Mount Sinai Medical Center, the free flap is sutured into the defect under ischemic time, and the microvascular anastomosis is performed as the last step. Once the defect was reconstructed, the robot was again removed from the field and the microscope was brought into the surgical field for the microvascular anastomosis. Finally, the neck was closed with a suction drain.

Included in this study were 25 men and 6 women, with a mean age of 61 years (range, 41-85 years). Their tumors were clinicopathologically staged as follows: T1N0 (2 cases), T1N1 (11 cases), T1N2 (4 cases), T2N0 (1 case), T2N1 (9 cases), T2N2 (0 cases), T3N0 (2 cases), T3N1 (1 case), and T3N2 (1 case). In 25 cases the primary treatment was with TORS, and 6 cases were salvage procedures per-
formed for recurrent disease following radiation (in 3 cases) or chemoradiation (in 3 cases). Histopathologic diagnoses included squamous cell carcinoma (29 cases) and adenoid cystic carcinoma (2 cases). The primary sites included the lateral pharyngeal wall alone (17 cases), and a variety of complex defects involving the lateral pharyngeal wall in combination with the tongue base, the soft palate, and/or the posterior pharyngeal wall (14 cases) (Figure 1). In all cases, the pharyngeal constrictors were resected with the specimen to serve as the lateral resection margin. This was confirmed by exposure of the parapharyngeal fat or exposure of the carotid artery. The surgical resection was performed using the spatula cautery attachment (6 cases), carbon dioxide flexible laser (9 cases), or the Holmium laser (16 cases).

**RECONSTRUCTIVE TECHNIQUE**

Primary intraoral reconstruction was performed in all 31 patients. Musculomucosal advancement flap pharyngoplasty was performed in 25 patients with a concomitant velopharyngoplasty (in 6 patients), and radial forearm free flap reconstruction was performed in 6 patients with extensive defects. The tumors were as follows: 19 tonsil/pharynx tumors (55%), 6 tongue base/pharynx tumors (26%), 3 pharynx/soft palate tumors (10%), and 3 posterior pharynx tumors (10%). The musculomucosal flap was created by dissection of the posterior pharyngeal wall or lateral pharyngeal wall mucosa and underlying constrictor muscle. A transverse incision was used to gain flap rotation of the flap, and the flap was sutured robotically to the free lateral edge of the mucosal defect using 2.0 absorbable Vicryl suture (Ethicon, Somerville, New Jersey). In some cases, a mucosal releasing incision was performed to gain rotation and advancement of the flap. In several cases, when we attempted to raise the musculomucosal flap with sharp dissection, we found that bleeding obscured the field of view. When the spatula cautery was used, there was extensive burn and tissue necrosis. In contrast, the carbon dioxide and Holmium lasers were particularly useful in developing the musculomucosal flaps because they provided a method for hemostatically cutting the tissue with minimal tissue necrosis. For the purpose of raising the musculomucosal flap, the lasers systems provided a superior method for precise control of the tissue incisions when compared with cautery.

Four of the 6 patients who underwent a reconstruction procedure with a radial forearm free flap had salvage surgery performed for recurrent disease. In 3 cases, a transoral marginal mandibular resection was included in the resection. The patients who required a radial forearm free flap reconstruction had sustained complex defects involving the lateral pharynx in combination with the soft palate or base of tongue. In all of these cases, the defect was too extensive to reconstruct using a local musculomucosal flap. In each case, following the surgical ablation and neck dissection, the flap was raised using a standard technique and placed into the oral cavity defect. Using the robotic needle drivers, the flap was sutured into position using 2.0 Vicryl suture. The vascular pedicle was transposed into the neck through the pharyngotomy, and the microvascular anastomosis was performed in a standard fashion using 9.0 microsurgical suture.

Twenty-six patients underwent a concomitant unilateral selective neck dissection, 3 patients underwent concomitant bilateral selective neck dissections, and 2 patients did not require a neck dissection for treatment of the primary malignant tumor. Six patients required a tracheotomy performed at the time of the ablative surgery, and 1 patient required a tracheostomy on postoperative day 2 because of excessive edema.

There were no intraoperative complications. Postoperatively, 1 patient developed a neck hematoma that was treated with bedside drainage, and 4 patients sustained minor musculomucosal necrosis of the superior aspect of the flap. This resulted in partial dehiscence of the flap. This was observed and did not result in complications. None of the patients developed a neck infection of salivary fistula. The mean estimated blood loss related to the robotic component of the surgery for the study group was 80 mL (range, 20-200 mL). There were no cases of intraoperative or postoperative hemorrhages. None of the patients required transfusion during or after surgery.

In all cases, frozen section was used to assess resection margins. Margins were obtained from both the specimen (inked in the operating room at the time of surgery) and as separate specimens taken from the periphery of the resection bed. Negative margins, defined as no microscopic tumor or carcinoma in situ within the free margin, were obtained and confirmed on formalin-fixed pathologic specimens in 23 of 31 cases.
The tumors of patients were upstaged from the clinical staging: clinical stages T1N0 (2 cases), T1N1 (11 cases), T1N2b(4 cases), T2N0 (1 case), T2N1 (9 cases), T2N2 (0 cases), T3N0 (2 cases), T3N1 (1 case), and T3N2a (1 case) were upstaged to pathological stages T1N0 (1 case), T1N1 (9 cases), T1N2b (7 cases), T2N0 (1 case), T2N1 (9 cases), T2N2 (0 cases), T3N0 (2 cases), T3N1 (1 case), and T3N2a (1 case) (Figure 2). The decision to recommend adjuvant therapy was predicated on National Comprehensive Cancer Network guidelines. Briefly, adjuvant EBRT was recommended to patients with N2 or N3 nodal disease or if there was evidence of perineural or lymphovascular invasion in the primary tumor specimen. Adjuvant concurrent chemoradiation was recommended for patients with extracapsular spread or positive margins. Based on these criteria, postoperative radiation was administered to 20 patients (68%). In those patients who were treated with EBRT, the dosage was deescalated in 80% from the standard therapeutic dose of 7000 to 7200 cGy to an adjuvant dose of 5200 to 6200 cGy. Adjuvant chemoradiation was administered to 14 patients (47%). The median follow-up was 18 months (range, 12-29 months). One patient experienced a local recurrence, which was treated with surgery, and to date has had no evidence of regional or distant recurrence.

FUNCTIONAL OUTCOME

Preoperatively, all the patients included in this study were able to tolerate a regular diet. Postoperatively, all 31 patients began an oral diet an average of 2 days after surgery (range, 1-7 days) without clinical evidence of aspiration or velopharyngeal reflux. Nasogastric tubes were placed in the patients treated with a microvascular free flap for 5 days if they had no history of radiation and for 7 days if there was a history of radiation therapy. In all cases, the nasogastric tubes were removed and not replaced. Gastrostomy tubes were placed in 7 patients. In all cases, the gastrostomy tubes were placed if the patient demonstrated an inability to maintain an oral diet and appropriate caloric intake as determined by the medical and radiation oncologists in consultation with the cancer center nutritionist. For those who had a gastrostomy tube placed, at 6 months the gastrostomy tube had been removed in all of the patients.

Endoscopic evaluation of swallowing demonstrated that none of the patient experienced aspiration or velopharyngeal reflux. The PSS demonstrated progressive improvement in mean (SD) scores at 2 weeks, 2 months, 6 months, 9 months, and 1 year for eating in public (87.4 [9.2]), speech (90.3 [7.1]), and diet (89.1 [4.2]) (Figure 3). Of the 31 cases, a musculomucosal flap was used in 25 and a free flap in 6. The FOIS at 2 weeks, 2 months, 6 months, 9 months, and 1 year also demonstrated a progressive improvement.

While TORS is a relatively new technique, many of the surgical principles are analogous to those established in TLM. In most TLM series, the authors advocate a staged neck dissection to decrease the risk of orocutaneous fistula. Arguably, the most clinically significant advantage of TORS when compared with TLM is the ability to raise local flaps and suture tissue and to achieve a mucosal reconstruction that heretofore was not possible using standard TLM surgical techniques. Transoral radical pharyngectomy nearly always requires resection of the pharyngeal constrictors to achieve a negative tissue margin. This exposes the parapharyngeal and pericarotid fat and may directly expose the great vessels. It also increases the risk of a postoperative pharyngocutaneous fistula if a neck dissection is performed in the same setting. A review of the previously published data demonstrates orocutaneous fistula rates as high as 6.7% in patients who undergo simultaneous TORS and neck dissection.13 The risk of developing an orocutaneous fistula increases when there is a fistula or direct opening into the neck from the oral cavity at the time of surgery. The development of a fistula can lead to clinically significant complications and may delay the onset of adjuvant therapy. Because of this, most surgeons choose to stage the neck dissection 1 to 2 weeks after the initial TORS. Iseli et al16 performed concurrent neck dissections when the risk of a fistula or direct opening between the oral cavity and neck is considered low (ie, in cases in which the pharyngeal constrictors were not resected). Otherwise, neck dissections were performed approximately 4 weeks after TORS. In this series, 16 patients (29.6%) had simultaneous neck dissections and 6 (11.1%) had staged neck dissections. Only 1 patient developed an orocutaneous fistula (1.9%). Moore et al15 performed neck dissections in 43 patients. Thirty-one underwent unilateral neck dissections, and 12 underwent bilateral neck dissections. All of the neck dissections were performed in a concurrent fashion. In this series, 14 patients had neck dissections performed just prior to TORS in order to isolate the great vessels and ensure their separation and protection when the risk of surgical opening to the neck was deemed high. Eighteen patients ultimately developed a fistula or direct opening between the neck and the pharynx, which was recognized and closed. An orocutaneous fistula developed in 3 patients (6.7%). In contrast, Boudreaux et al17 performed neck dissec-
tions in 17 patients. Eleven patients who had a robotic resection underwent simultaneous selective neck dissection. Six patients had neck dissections in a staged fashion. No orocutaneous fistulas resulted from concomitant neck dissection, and no increase in the complication rate was seen.

Those in favor of staged neck dissections argue that the risk of developing an orocutaneous fistula increases with simultaneous neck dissections. Some argue that performing a staged procedure gives the surgeon the ability to resect additional margins if necessary. While these statements may have some validity, there are several disadvantages to staging a neck dissection: it subjects the patient to a second procedure and the inherent risks of such. It also may require further hospitalization, which may raise the cost of care. Patients also have a lengthened duration of treatment that may delay the initiation of adjuvant therapy that may ultimately compromise outcome.

Our data suggest that primary reconstruction with either a pharyngeal musculomucosal flap or a free flap obviates the need for a staged neck dissection and does not seem to place the patient at an increased risk for neck infection or orocutaneous fistula. We found that in the most cases, a musculomucosal flap could be raised and rotated into the pharyngectomy defect. In patients who have been treated with radiation and patients with extensive defects, a free flap was necessary because the mucosa was often friable, poorly vascularized, and/or less pliable than the mucosa of a patient who has not undergone radiation. Although sharp dissection can be used to raise the musculomucosal flap, we found that the carbon dioxide and thulium lasers were superior because of their ability to make the incisions without clinically significant tissue necrosis or bleeding. The flap tissue necrosis that was observed in 3 patients occurred in cases in which both the cautery and the thulium laser were used. This highlights that the pharyngeal flaps are nonaxial flaps. The blood supply is segmental and random. As a result, it is important to maintain a wide tissue base to preserve the blood flow to the distal aspect of the flap. It is also important to raise the flap as a muscular and mucosal composite to preserve the blood supply.

We found that postoperatively, patients regained excellent function as demonstrated by near-normal scores on the FOIS and PSS assessments 1 year after surgery. There are several shortcomings associated with this study; for example, it is not clear if the functional recovery observed in this study population is related to the reconstruction or the desescalation of adjuvant therapy that was instituted as part of our treatment protocol. If a nonsurgical protocol had been used for primary treatment of this study population, most patients enrolled in this study would have been treated with EBRT at doses of 7000 to 7200 cGy with adjuvant chemotherapy. Without a randomized stage-matched control group, we were not able to determine the independent impact of TORS surgery, primary reconstruction, or adjuvant therapy on function. In addition, it should be noted that free flap reconstruction, although effective in select cases, requires a large operating room and a complex setup that allows for moving the robot in and out to the surgical field in addition to accommodating the microscope for the microvascular surgical portion of the procedure. The logistics of such a setup require staff training and a great deal of preoperative planning. Similarly, although most reports have addressed radical tonsillectomy and base of tongue resection, as we extend the limits of TORS to evaluate marginal resection, free flap reconstruction, and salvage surgery, practical considerations, such as robotic operative time, operating room setup, and staff training, are essential considerations. Although we have an extensive experience with TORS, a great deal of time has been dedicated to training our staff. Because our nursing staff is dedicated to head and neck surgery and TORS, they are instrumental in our ability to move both the robot and the microscope in and out of the field. At our institution, a robot is dedicated to urology and head and neck surgery, or adjuvant therapy on function.

Our aim was to evaluate the feasibility and safety of performing TORS and neck dissection in a single operation given that the standard approach at most institutions is to stage the resection and neck dissection. To this end, we did not assess long-term survivorship,
human papillomavirus status, or advantages or disadvantages of TORS in oropharyngeal cancer. These are important and compelling questions but are beyond the scope of this trial.

In conclusion, the aim of this study was to assess the role of primary reconstruction in patients following TORS surgery and to determine the risk of fistula formation in patients treated with concomitant neck dissection. Our study suggests that primary reconstruction may provide a benefit by decreasing the fistula rate in patients undergoing concomitant neck dissection. There are several shortcomings related to the study design. Although we present our functional outcomes, the impact of these data are limited without a randomized staged-matched control group. We have organized a randomized surgical trial to address these questions.

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Correspondence: Eric M. Genden, MD, Department of Otolaryngology–Head and Neck Surgery and Immunobiology, The Mount Sinai Medical Center, One Gustave Levy Place, New York, NY 10029 (eric.genden@mssm.edu).

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