History and Acceptance of Transoral Robotic Surgery

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KEYWORDS

• Robotic surgery • Head and neck cancer • Surgical innovation

KEY POINTS

- Development of TORS was swift.
- Education and training was key to broad use and acceptance.
- Surgical innovation is a specialty-wide process, and acceptance takes time.

HISTORY OF ROBOTIC SURGERY

Transoral robotic surgery (TORS) in current parlance generally refers to any transoral surgery involving the da Vinci surgical system. Although other robotic systems have been trialed and many are in development currently, these are beyond the scope of this retrospective article. The purpose of this article is to trace the history and evolution of TORS to its current practice. This is worth considering as an exercise in understanding surgical innovation and a medical specialty's adaptation to rapid and marked change in surgical practice.

The term "robot" is credited to the Czech playwright, Karel Capek, in his 1920 play, Rossom's Universal Robots ("rabota" in Czech means forced labor). The development of robotics and computer science took off some decades later, with integration of robots in industry in the 1960s. Medical implementation of robotics was somewhat slower to evolve. Robotic surgery was first performed by Kwoh and colleagues[1] in 1985, to perform precision neurosurgical biopsies. These surgeons used a device called the Puma 560, which was simply an adapted industrial robotic arm. This and other systems were further developed in a collaborative effort that included the National Air and Space Administration, the Stanford Research Institute, and the Department of Defense. Extensive research and development in the 1990s led to the creation of Intuitive Surgical (founded in 1995 in Mountain View, CA), which built on Stanford Research Institute's designs and other companies' developments through mergers, to produce several early prototype surgical robots, first used in humans in the late 1990s. The da Vinci system uses a console where the operating surgeon controls the robot through grips that mimic movement of the robotic arms, a moveable "robot"

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with a light source, camera, and multiple robotic arms, and a video tower with visual display of the surgical procedure. The da Vinci system has gone through multiple generations, including the S, Si, SIHD, X, XI, SP, and ION, with improvements in technology and instrumentation along the way, and some adaptations especially designed for particular surgical specialties.

DEVELOPMENT OF TRANSORAL ROBOTIC SURGERY

The development of TORS occurred in the early 2000s. Early on, this was done largely through the work of Drs O'Malley and Weinstein at the University of Pennsylvania. At Penn, as was the case in many institutions, the da Vinci robot was initially used for some cardiac procedures, then more broadly adopted by urology for prostatectomy and by gynecology for various procedures. The Penn Otolaryngology Department's interest was stimulated by resident physician, Dr Neil Hockstein, and many otorhinolaryngology applications were considered. The concept of transoral use of the robot, particularly for head and neck cancer, seemed most appropriate, particularly because traditional methods for access to site of pathology were limited; technically difficult; or involved extensive, open procedures. A research strategy was put in place involving sequential testing of mannequin and cadaver models, to assess feasibility, accessibility, and safety of the use of the robot in surgery on the pharynx and glottis.[2] The results of this, reported by Hockstein and colleagues,[3] showed that TORS had a safety profile similar to conventional transoral surgery in assessing for risks, such as skin laceration, dental injury, mucosal laceration, mandible fracture, and ocular injury.

Next, a canine model was used to assess live surgery, with attention to secretions and hemostasis. In 2005, Weinstein and coworkers[4] published their findings on this phase of their research. In this paper, they described a successful canine supraglottic partial laryngectomy, with excellent hemostasis and visualization. Furthermore, the robotic system allowed for tremor abolition, motion scaling, and three-dimensional vision. Finally, with institutional review board approval, a human clinical trial was undertaken to assess exposure and safety of the robotic approach. This was undertaken for patients with supraglottic and base of tongue neoplasms. In these efforts, it was determined that key anatomic structures, such as the regional cranial nerves and arteries, could be identified and preserved. In addition, techniques for control of hemostasis, including arterial, were established. In the human subjects, complete resection with negative margins were accomplished.[5] Some other refinements in technique were accomplished in these early efforts. For example, Dingman and Crowe-Davis retractors were not found to be ideal. An FK-WO laryngopharyngoscope retractor was developed by Drs O'Malley and Weinstein, specifically for TORS, to better facilitate visualization and access. In their first three supraglottic partial laryngectomy patients, Weinstein and colleagues[6] were able to complete the procedure in 120 minutes, with no intraoperative or postoperative complications and with complete tumor resection, suggesting the TORS approach may be an alternative to open or conventional approaches.

With these early successes, Weinstein and O'Malley began to expand their efforts, using TORS for radical tonsillectomy in 27 patients with previously untreated squamous cell carcinoma of the tonsillar region. In these patients, final negative margins were achieved in 93% of patients with limited acute morbidity and 96% recovery of normal swallowing function.[7] Further prospective investigation showed similar results, with the addition of concomitant neck dissection and in some cases, intraoral reconstruction. A rapid decrease in the setup time was noted over the time course of the study.[8]

An important part of the development of TORS was the early recognition that training and teaching of fellow head and neck surgeons was important to the adoption of this approach. The first training workshop for TORS was held at Intuitive Surgical in 2006, at which 12 head and neck surgeons attended didactic sessions and laboratory cadaver dissections. Nearly all of these surgeons went on to develop their own TORS programs. This model was brought to Penn in 2007, where surgeons from around the world have come for a week-long experience, including observation in the clinic and operating room and robotic certification in a training laboratory. After Food and Drug Administration approval was obtained in 2009 for transoral use of the da Vinci robot for T1 and T2 oral cavity, pharyngeal, laryngeal cancer, and benign disease, American surgeons started training at Penn in a TORS Masters Training Program in 2010 with a combination of hands-on porcine robotic training, observation of cadaver and live surgery TORS cases, and didactics.

With world-wide dissemination of TORS in progress, other institutions began to report on their experiences with the surgery. Iseli, and colleagues[9] reported on functional outcomes after TORS in their case series of 54 patients. They looked at airway management, swallowing function, and enterogastric feeding, and found that: all patients were either extubated (78%), or decannulated by 14 days; 83% commenced oral intake by 2 weeks; and 17% retained a feeding tube at 12 months postoperative. Complications were limited and managed without major sequelae. Moore and colleagues[10] reported on TORS for oropharyngeal carcinoma of all stages in a prospective case study of 45 patients. In their group, previously untreated patients with oropharyngeal squamous cell carcinoma (T1-T4a) underwent TORS with negative margins and no reported major complications. All patients were extubated or decannulated and of the 22% of patients who required a feeding tube of some sort, all eventually had these removed.

About the same time as these case series were published, articles started to appear on a paradigm shift in the management of patients with head and neck cancer with the advent of TORS.[11,12] These papers suggested that TORS allows for comparable or improved oncologic and functional outcomes over traditional therapies: open and other transoral techniques, and primary chemotherapy and radiation. That this paradigm shift was beginning to occur only 5 years after the first reported canine experimentation is truly remarkable. Also reflective of the beginning of more widespread adoption of TORS as a surgical innovation for the management of pharyngeal and laryngeal cancer, was the rapid increase in number of peer-reviewed publications on the topic per year. Using a PubMed search: in 2009, three English language papers regarding its use were published; in 2010, eight such papers were published; in 2011, 13 papers were published; in 2012, 24 papers were published; and in 2013, 39 papers were published.

In addition, head and neck surgeons were beginning to explore further applications of TORS in surgical tumor management. O'Malley[13] reported on the use of TORS for management of benign and malignant parapharyngeal space tumors with no carotid encasement or bone erosion. In their series, 9 of 10 patients were able to have resection of their tumors with acceptable operative time and blood loss, no significant complications, and with 100% local control of the seven patients in the series with pleomorphic adenomas. Selber[14] wrote about the benefit of using the robot to reconstruct defects left from large oropharyngeal tumor resections, using either free flaps or a facial artery myomucosal flap based on the facial artery to provide tissue coverage. Microvascular anastomoses were performed successfully, transorally with the robot.[14] Weinstein and colleagues[15] reported on TORS for advanced oropharyngeal carcinoma. In their series of 47 patients with stage III and IV cancer of the oropharynx, resection margins were positive in one patient, and disease-specific survival was 90% at 2 years. Using risk stratification, 38% of patients avoided chemotherapy, and 11% of patients did not require adjuvant radiation and concurrent chemotherapy. At 1-year follow-up, only one patient had a gastrostomy tube. Their conclusion was that TORS allowed for disease control, survival, and safety commensurate with traditional therapy, with the added benefit of improved functional outcome.

Although the focus of TORS surgical developments remained predominantly in head and neck cancer management, surgeons began to investigate its' use for other, benign pathologies and disorders. One arena where there was significant early adoption of its use was in the surgical management of obstructive sleep apnea (OSA). Several institutions in America and internationally began investigating the use of TORS for tongue base resection in the surgical management of OSA. Vicini and his group in Italy were the first to publish on this in 2010.[16] In this paper, 10 patients underwent tongue base resection to manage their OSA, with a reduction in apnea-hypopnea index (AHI) from 38.3 $\pm$ 23.5 standard deviation to a mean postoperative AHI of 20.6 $\pm$ 17.3 standard deviation, with good functional results as measured by pain, swallowing, and quality of life (QOL), and rare or minor complications.[16] Lee and colleagues[17] published a series of 20 patients who reported on robot-assisted lingual tonsillectomy and uvulopalatopharyngoplasty, with reduction of AHI by 56.7% from 55.6 to a mean postoperative value of 24.1 (P<.001), and improvement of minimum arterial oxygen saturation from the mean preoperative value of 75.8% to the mean postoperative value of 81.7% (P = .013). The mean Epworth Sleepiness Scale score improved from 13.4 to 5.9 (P = .003). One patient required postoperative cauterization for a bleeding episode without further sequela. Vicini was instrumental in organizing a consortium of institutions performing this surgery to produce a first major case series on patients with sleep apnea undergoing TORS in 2014. This groups' paper on the clinical outcomes and complications of 243 patients who had undergone TORS for OSA showed that the surgery was safe and effective, with a mean preoperative and postoperative AHI of 43.0 $\pm$ 22.6 and 17.9 $\pm$ 18.4, respectively (P<.001), and a reduction in Epworth Sleepiness Scale from 12.34 $\pm$ 5.19 to 5.7 $\pm$ 3.49 (P<.001).[18]

Another clinical domain where application of the surgical technique expanded was the use of TORS for the management of salivary gland neoplasms. Villaneuva and colleagues[19] reported early on the use of TORS for the management of oropharyngeal minor salivary gland tumors. In their series of 10 patients with T1 or T2 malignancies, TORS was used for resection with no surgical complications, negative margins, and excellent functional outcomes. This surgical innovation has expanded to include submandibular gland resection, submandibular stone resection, and resection of salivary gland neoplasms of the parapharyngeal space.

More recently, TORS has been used for resection of skull base neoplasms. A first, cadaveric study investigating the feasibility of a transoral approach to the sella turcica was published by Chauvet and colleagues[20] in 2014. Other clinical studies have followed, but perhaps reflective of the limited utility of TORS in this region, have not abounded. For example, it was not until 3 years later, in 2017, that a clinical study was reported by Chauvet and colleagues[21] on a series of four patients who had undergone a TORS approach for resection of pituitary neoplasm.

ACCEPTANCE OF TRANSORAL ROBOTIC SURGERY

As with all surgical innovation, the ultimate test of the technique is in whether there is sufficient added benefit in outcomes to justify its incorporation in treatment paradigms. This takes years after implementation, because data can only be slowly collected over time to assess outcomes. In the case of head and neck cancer, the outcomes are adjudicated in terms of disease (survivorship) and function. In these regards, TORS for the management of pharyngeal and laryngeal cancer has passed the test of time.

In recent years, numerous studies have been published on survivorship and functional outcomes of patients who underwent TORS as part of their treatment of head and neck cancer. For example, in 2015, de Almeida and colleagues[22] looked at 410 patients who had undergone TORS for laryngeal and pharyngeal cancers, in terms of locoregional control, disease-specific survival, and overall survival. Their 2-year locoregional control rate was 91.8%, disease-specific survival was 94.5%, and overall survival was 91%, which they concluded supported the role of TORS within the multidisciplinary treatment paradigm for head and neck cancer. A more recent systemic review of QOL outcomes after TORS looked at 103 articles assessing QOL and/or swallow outcomes for 659 patients after treatment. Their conclusion was that patients have good QOL and swallowing outcomes after treatment.[23] These outcomes studies have compared favorably with prior treatment paradigms for such patients with head and neck cancer supporting the use of primary chemotherapy and radiation. Although the latter remains the primary treatment of many patients with pharyngeal and laryngeal head and neck cancer, the use of TORS as a component of primary treatment seems to provide comparable or better survivorship and better functional outcomes.[24,25]

Over the course of the past 15 years, TORS has cemented its' place in the treatment of pharyngeal and laryngeal cancer, and has been advocated for as an important surgical innovation in other disease states. The use of robots in otorhinolaryngologic surgery is here to stay.

DISCLOSURE

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