Title
The dawn of robotic surgery in otolaryngology: head and neck surgery.

Permalink
https://escholarship.org/uc/item/80m941ct

Authors
Nakayama, Meijin
Holsinger, F Christopher
Chevalier, Dominique
et al.

Publication Date
2019-02-23

DOI
10.1093/jjco/hyz020

Peer reviewed

Review Article (Invited)

The dawn of robotic surgery in otolaryngology: head and neck surgery

Meijin Nakayama[1,*], F. Christopher Holsinger[2], Dominique Chevalier[3], and Ryan K. Orosco[4]

[1]Department of Otorhinolaryngology—Head and Neck Surgery, Yokohama City University, Yokohama, Japan, [2]Department of Otolaryngology, Division of Head and Neck Surgery, Stanford University, Palo Alto, California, USA, [3]Department of Ear, Nose, Throat-Head and Neck Surgery, Huriez Hospital, University of Lille, Lille, France, and [4]Department of Surgery, Division of Head and Neck Surgery, University of California San Diego, La Jolla (92093), California, USA

*For reprints and all correspondence: Meijin Nakayama, E-mail: meijin@se.netyou.jp

Abstract

Transoral robotic surgery (TORS) utilizing the da Vinci robotic system has opened a new era for minimally-invasive surgery (MIS) in Otolaryngology-Head and Neck Surgery. Awareness of the historical steps in developing robotic surgery (RS) and understanding its current application within our field can help open our imaginations to future of the surgical robotics. We compiled a historical perspective on the evolution of surgical robotics, the road to the da Vinci surgical system, and conducted a review of TORS regarding clinical applications and limitations, prospective clinical trials and current status in Japan. We also provided commentary on the future of surgical robotics within our field. Surgical robotics grew out of the pursuit of telerobotics and the advances in robotics for non-medical applications. Today in our field, cancers and diseases of oropharynx and supraglottis are the most common indications for RS. It has proved capable of preserving the laryngopharyngeal function without compromising oncologic outcomes, and reducing the intensity of adjuvant therapy. TORS has become a standard modality for MIS, and will continue to evolve in the future. As robotic surgical systems evolve with improved capabilities in visual augmentation, spatial navigation, miniaturization, force-feedback and cost-effectiveness, we will see further advances in the current indications, and an expansion of indications. By promoting borderless international collaborations that put 'patients first', the bright future of surgical robotics will synergistically expand to the limits of our imaginations.

Key words: transoral robotic surgery, otolaryngology, head and neck surgery

Evolution of surgical robotics

The term 'Robot' was first coined in the 1920s by Czech play writer Karel Capek (Czech 'Robota' + Slovakian 'Robotnik'). In his drama 'Rossum's Universal Robots', machines were created to do mundane work so that people could pursue more creative interests. However, as the fictional robotic technology improved, the machines became more intelligent, smart, stronger and finally harmful. Some interpreted this as a satirical view of robots and also a warning to human beings (1).

'Robotics' describes the field of study of robots and was first coined in the 1940s by American science fiction writer Isaac Asimov. In 'the three laws of robotics' described in his short story 'Runaround', the societal roles of robots were depicted as: (1) a robot may not injure a human being, (2) a robot must obey the orders given it by human beings and (3) a robot must protect its own existence as long as such protection does not conflict with the first or second laws (2). These first two rules in particular, remain a reasonable ethical background for the development of surgical robots today.

The progress of practical robots started from the 1940s motivated by the need to deploy them in hazardous industrial environments. As computer technology advanced, applications for robots extended beyond the industrial field into areas such as space and oceanographic exploration, agriculture, the military, education and ultimately medicine. In the 1980s, surgical robots were first introduced in orthopedic surgery (3). In the 1990s, surgical robotics was catapulted by the revolution in laparoscopic and minimally-invasive surgery (MIS). Since then, surgical robotics has progressed and become indispensable to surgical practice in many arenas. The current generation of operative robotic technologies rely on direct human input and guidance (4). Full-autonomy in surgical robotics is not currently a reality, but shared control and supervised autonomy processes aid in several present-day applications. Putting a robotic interface between surgeons and patients can enhance human capabilities, such as improving accuracy, stability and dexterity.

Another important primary concept in surgical robotics is 'telepresence', a term describing sensations to give the appearance of being present at a place other than the true location (1). The National Aeronautics and Space Administration (NASA) was interested in telepresence surgery as a method for providing remote surgery to orbiting astronauts in the 1970s, but the concept faced the technological limitation of time-delayed communication latency. In the 1980s and 1990s, the few groups working on telerobotics included Stanford Research Institute (SRI) (5), International Business Machines Corporation (IBM) Watson Research Center (6), Massachusetts Institute of Technology (MIT) (7) and NASA's Jet Propulsion Laboratory (8). A prototype of the telepresence surgical system was introduced in the 1990s by the Stanford Research Institute (now SRI International, Menlo Park, CA), with funding from the National Institutes of Health (NIH). The early success of the SRI system soon caught the attention of the Defense Advanced Research Projects Agency (DARPA), an agency of the US Department of Defense. DARPA, known to develop the Internet and Global Positioning System, envisioned telepresence surgery to be used by military surgeons to operate on wounded soldiers on remote battlefields. These seminal works set the cornerstones of the current surgical robotics. In 1995, SRI's intellectual property, supported by IBM and MIT, was licensed to a new start-up company, 'Intuitive Surgical'.

Road to da Vinci surgical system

Founded in 1989, Computer Motion (Santa Barbara, CA) was the leading supplier of surgical robots. The company's robotic arm to assist in laparoscopic surgery, Automated Endoscope System for Optimal Positioning (AESOP), was the first telepresence surgical robot to be approved by Food and Drug Administration (FDA), in 1994 (1). The company soon launched the Zeus surgical robot as the successor of AESOP, and after being approved by the FDA in 2001, it was subsequently used in the first transatlantic laparoscopic cholecystectomy. This milestone surgery known as the 'Lindbergh operation', was the first complete telepresence operation carried out between surgeons in New York and a patient in Strasbourg, France (9). In 2003, Computer Motion and Intuitive Surgical merged into a single company to end the litigations between each other and combine their knowledge to promote future surgical robotics. As a result, Zeus was phased out in favor of the da Vinci system.

In 1999, four years after Intuitive Surgical (Sunnyvale, CA, USA) was founded, the first surgical robot da Vinci 'Standard' was launched. The company name, 'Intuitive', derived from an expectation to create a surgeon-robot interface so transparent that a

Figure 1. da Vinci Sp features an articulating 3D-HD camera and three articulating instruments through a single 25-mm single-port cannula.

surgeon's full set of skills could be used in an 'intuitive' manner. The name da Vinci stemmed for the 15th century inventor 'Leonardo da Vinci' who was known for advancing the study of human anatomy and leading the design of the first known robot, Mechanical Knight. The da Vinci surgical system consists of: (1) a surgeon's master console, (2) a patient-side cart with interactive EndoWrist instruments and a high-definition (HD) endoscopic camera and (3) a vision system with 3D image processor. By providing surgeons with superior visualization, enhanced dexterity, greater precision and ergonomic comfort, da Vinci has become the leading robotic system in MIS.

After FDA approval in 2000, the da Vinci standard was incorporated for the first robotic radical prostatectomy, performed in Paris (10). The patient was discharged four days after the surgery and was fully continent in 1 week. Differing from conventional laparoscopic surgery, the da Vinci system allows the surgeon to operate from a seated position with the eyes and hands positioned in line, resembling the feeling of conventional open surgery. The user-friendly surgical platform and enhanced surgical capabilities da Vinci provided are the ideal images for MIS.

The da Vinci standard was upgraded in 2003, with the addition of a fourth robotic arm. In 2006, the da Vinci S system was introduced, offering HD vision and multi-image display features. The succeeding model, da Vinci Si, was released in 2009, featuring a dual console capability, improved 3D resolution, multi-source screens and integrated control system. In 2014, Intuitive Surgical launched the next frontier model da Vinci Xi with an improved platform for instruments and vision, enabling highly complex, multi-quadrant somatic surgery and simpler single-quadrant localized surgery. Xi offers overhead docking, wider-field surgery without equipment repositioning, narrower arms and an improved motion range over the previous version. The upcoming Xi compatible model, da Vinci Sp, shares the same platform with Xi. It is the company's first single-port innovation featuring an articulating 3D-HD camera and three fully articulating instruments through a single 25-mm cannula (Fig. 1). The fully wristed 6 mm EndoWrist Sp Instruments have two more degrees of freedom than the conventional ones. The prototype Sp (SP999) was approved by the FDA in 2014 specific to urologic surgery (11). The marketing version Sp (SP1098) was just approved in 2018 for narrow access urologic surgery, and the company is

hoping to expand the FDA clearance of Sp for transoral, transanal and extraperitoneal applications.

The da Vinci system has been approved by the FDA since 2000 for use in both adult and pediatric robotic surgery (RS) procedures in urologic surgeries, general and gynecologic laparoscopic surgeries and general non-cardiovascular thoracoscopic surgeries. Recently, it was approved for thoracoscopically-assisted cardiotomy procedures and transoral surgeries. The FDA defines RS as the use of robotically-assisted surgical (RAS) devices which are one type of computer-assisted surgical system. In the most-technical view, the da Vinci is not actually a robot because it cannot perform surgery without direct human control. Therefore, the FDA is sensitive about the potential risks associated with RAS devices and encourages the patients to file a voluntary complication report through the adverse event reporting program.

Intuitive Surgical has been reported to hold more than 600 US patents facilitating the dominant position of the company in the RS marketplace. These patents have provided barriers to competitors from joining the market of surgical robotic systems, which are very complex, time-consuming to build, and above all must undergo an arduous process to obtain FDA approval. At 20 years after filing, several of the earliest patents of the da Vinci system will expire, but the company continues to file new patent applications for its latest technologies. Nevertheless, diminished barriers have attracted many competitors, such as Verb Surgical (Mountain View, CA, USA) a joint venture with Google and Johnson & Johnson, Mazor Robotics sponsored by Medtronic (Dublin, Ireland) and TransEnterix (Morrisville, NC, USA),

to join the surgical robotic market. Increasing players in the field will stimulate competitions resulting in technological advancements, which will be beneficial for both patients and medical operators.

Since RAS was approved, an increasing number of publications can be found in the literature. A PubMed search using the key word 'Robotic Surgery' revealed a soaring number of articles published in the last 20 years (PubMed search on October 2018, Fig. 2). The clinical application of surgical robots started with laparoscopic procedures and now has progressed to the upper aerodigestive tract and other natural orifice, along with a myriad of other minimally-invasive applications.

Transoral endoscopic-head and neck surgery

The surgical innovations and an increasing awareness of the late effects of radiation therapy have led to an increased role of transoral endoscopic-head and neck surgery (eHNS) within the multidisciplinary treatment paradigm (12). Transoral laser microsurgery (TLM) is a well-studied effective MIS in treating oropharyngeal and laryngopharyngeal cancers (13). The overall complication and survival rates of TLM are known to be significantly correlated with the surgeons' experience (14). Surgical robot use is expected to ease the surgeons' learning curve and therefore bring optimal results to patients with limited adverse event. Another important fact facilitating the need for MIS is the recent increasing epidemiology of human papilloma virus (HPV) associated oropharyngeal cancers (OPC) (15). Efforts to avoid dysphasia, often associated with open approaches and concurrent
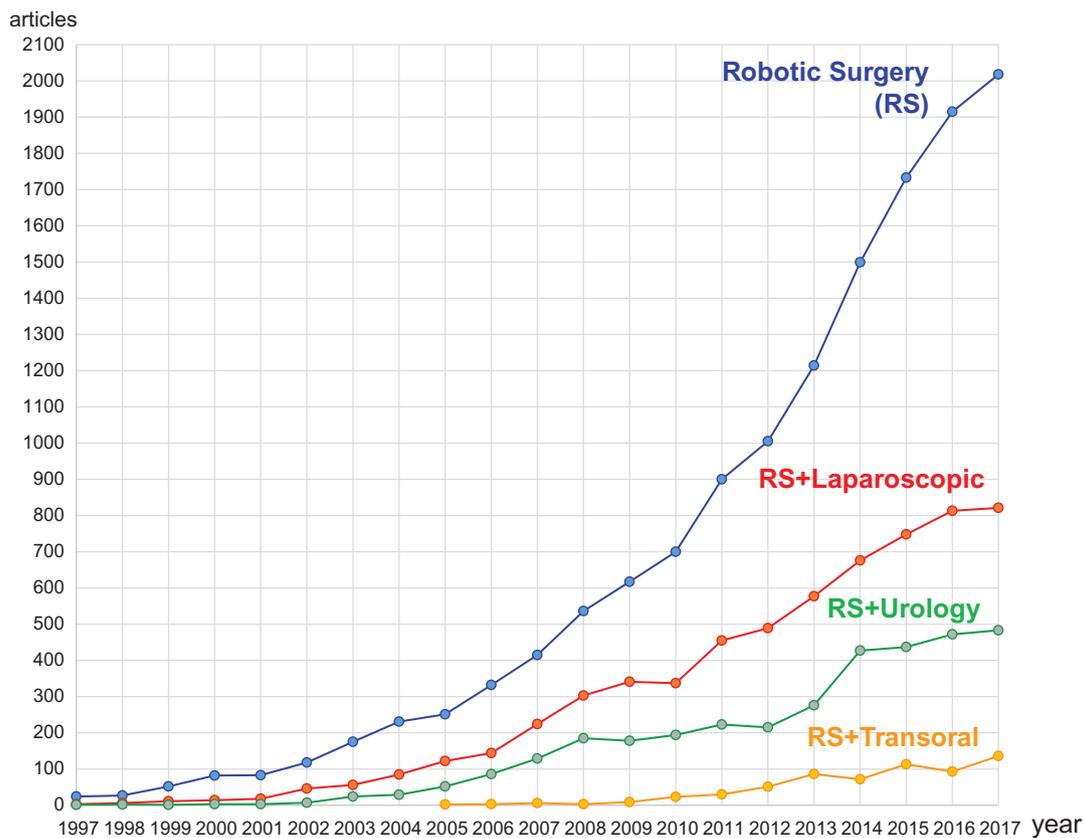

Figure 2. Number of articles related to robotic surgery (RS) published in the last 20 years (PubMed search October 2018).

chemoradiation therapy, accelerated the development of the transoral robotic approach.

Transoral robotic surgery (TORS) was first developed in 2004–2005 by Weinstein and O'Malley utilizing a da Vinci surgical robot as a new approach for MIS (16,17). Subsequently, they conducted research to demonstrate the feasibility and efficacy of this technique (18,19). In light of these data, the FDA approved the da Vinci system to perform TORS in 2009. TORS for oropharyngeal tumors utilizes a retractor, such as FK-WO model (Olympus, Tokyo, Japan). The endoscopic camera is introduced transorally followed by two robotic arms carrying interchangeable 5- or 8-mm-wide working Endowrist instruments (e.g. Maryland forceps and monopolar cautery spatula). The surgeon looks into a binocular 3D visual display while controlling master handles that direct movements of the robot's instruments. One advantage of TORS is that en bloc resection of the primary tumor, whereas TLM often necessitates division of the specimen.

Clinical applications of TORS

HPV prevalence in OPC significantly increased over time and will likely constitute a majority of all head and neck cancers in the USA in the next decades, highlighting the need for defined therapies for this patient population (15). OPC is the most common lesion in the head and neck suitable for TORS. In the largest multicenter report of 410 head and neck cancer patients undergoing TORS, 88.8% originated from the oropharynx (20). Another multicenter study reporting 177 patients operated on with TORS also included 78.5% with OPC; the tonsil and tongue base were the two most common subsites (21). In both reports, more than 80% of the patients had T1–T2 early-stage cancers. Oncologic and functional outcomes following TORS were promising. Almeida et al. reported a 2-year locoregional control rate of 91.8%, disease-specific survival of 94.5% and overall survival of 91% (20). Weinstein et al. reported a long-term tracheotomy rate of 2.3%, a long-term gastrostomy rate of 5% and an average hospital stay of 4.2 days (21). TORS is generally indicated for primary treatment but is applicable as salvage intervention as well (22).

TORS can also be utilized for supraglottic laryngectomy (SGL). Whereas the oropharynx is more-readily accessed, TORS for the supraglottis requires markedly refined techniques to gain adequate exposure and visualization. Altering the tongue blade position and optimizing the 30-degree face-up endoscope and instrument arm configurations is imperative (22).

Park et al. required all TORS SGL patients to go through a planned tracheotomy for a better view of the surgical field and also to prevent postoperative airway obstruction; decannulation was conducted after an average of 11.2 days (23). On the contrary, Ozer et al. performed TORS SGL with transnasal intubation by keeping the tube posterior to the oropharynx and extubated all patients in the operating room (24). Appropriate perioperative airway management of TORS SGL is important and requires further scrutiny. Preliminary functional and oncological outcomes of TORS SGL were also reported to be promising, which justifies additional trials (23–25).

TORS for both oropharyngeal and supraglottic cancers often requires concurrent open neck dissection. The neck dissection can be performed at a separate session before TORS or at the time of the primary site resection. Prophylactic ligation of external carotid system is recommended to decrease post-TORS bleeding (26). Mandal et al., reported that prophylactic transcervical arterial ligation did not significantly decrease overall postoperative bleeding rates but

may decrease the severity of hemorrhagic events (27). When performing concurrent neck dissection with TORS, the oropharynx defect may communicate with the neck. Kucur et al. reported that among 113 OPC patients treated with TORS, six (5%) developed communications that were closed by submandibular gland or adjacent muscular pedicle flaps (28). For larger communications, a free flap may also be deployed robotically for closure (29).

Extended applications of TORS

Other than the above two standard applications, TORS has been utilized for surgeries involving the hypopharynx (30,31), nasopharynx (32), skull base (33) and parapharynx (34,35). Most recently, TORS has also been applied for total laryngectomy (TL) (36–38), thyroidectomy (39,40) and tongue base exploration for unknown primary tumors (26).

Exposure is challenging for TORS hypopharyngectomy and refined techniques are necessary because it is anatomically deeper and narrower than the supraglottis. Park et al. reported 10 patients with T1–T2 pyriform sinus and posterior pharyngeal wall cancers operated on by TORS with acceptable results (30). In these cases, appropriate perioperative management of the airway is critical.

TORS nasopharyngectomy is only indicated for salvage since the primary treatment option for nasopharyngeal cancers (NPC) is concurrent chemoradiation therapy. The TORS approach is cosmetically and functionally advantageous compared with the standard open maxillary swing approach. Tsang et al. reported 12 patients with recurrent NPC operated on by TORS with satisfactory functional and oncologic results; for exposure, the procedure requires midline soft palate splitting (32). The absence of a tactile sensation on using da Vinci instruments may create technical challenges for console operators since identification of the bony clivus and internal carotid artery by palpation is essential for salvage nasopharyngectomy.

TORS for the skull base can be applied to symptomatic sellar tumors by accessing via the nasopharyngeal cavum and then drilling through the sphenoidal rostrum; although this is only applicable for selected sphenoid sinus type tumors, the TORS approach involves minimal invasiveness compared with the conventional transnasal approach (33). For a fully robotized resection of the intracranial solid pituitary adenoma, further refined robotic instruments are needed.

Parapharyngeal space tumors may be removed by TORS or combined transcervical endoscopic and transoral robotic approaches to avoid classical entry by mandibulotomy. In this combined approach, extracapsular circumferential separation of the tumor from vital neurovascular structures was done through a transcervical maneuver and then the tumor was removed en bloc by TORS via a lateral palatal incision (34). While classical blunt and blind finger dissections may be avoided with this combined approach, extra precautions need to be taken to avoid accidentally rupturing the tumor capsule due to using the less-tactile laparoscopic and robotic instruments (35).

TORS TL was reported by several authors in 2013 (36–38). The procedure begins with a transcervical session: (1) A 4- to 5-cm horizontal lower-neck incision followed by a standard tracheostomy, (2) separation of the strap muscles from the trachea and cricoid cartilages and (3) transection of the trachea after thyroid isthmusectomy. The procedure continues to a transoral robotic session: (1) incision of the laryngopharyngeal mucosae, (2) mobilization of the pyriform sinus mucosae from the lateral thyroid cartilage and (3) separation of the external thyroid perichondrium from the overlying strap muscles. The hyoid bone is left in place for stenting purposes to enhance

the diameter of the pharyngeal space. After detachment has been completed, the larynx is delivered transorally. The pharyngeal mucosa is sutured endoscopically in a horizontal orientation. The maximal integrity of the pharyngeal mucosa and strap muscles preserved by TORS may be advantageous in wound healing, particularly with a salvage status. Achieving adequate exposure and visualization is crucial for TORS TL; a narrow mandibular arch, anteriorly displaced larynges and intact dentition are considered to impair exposure. TORS TL warrants further clinical study for consideration of feasibility, applicability and patient benefit.

Minimally-invasive endoscopic thyroidectomy was initially developed for cosmetic purpose and a variety of routes have been described including the infra-clavicular, breast and axillary. In addition, TORS thyroidectomy was developed based on the surgical advancement of the transoral endoscopic thyroidectomy vestibular approach (39). In the TORS approach, robotic trocars are inserted from the lower vestibule, via the mandibular protuberance, and then submental space, until the central neck compartment; the anterior neck is insufflated with carbon dioxide for visualization and manipulation (40). Although it is a semi-sterilized surgery, TORS thyroidectomy is considered more cosmetically advantageous than the conventional open approach. It is indicated for well-selected thyroid tumors, such as small benign goiters and papillary microcarcinoma without metastasis (41).

Patients with unknown primary neck metastasis commonly go through an array of examinations, such as flexible endoscopic assessment, palpation of the tonsils and base of the tongue, and PET-CT. If the primary tumor remains elusive, TORS palatine and lingual tonsillectomy can be employed as part of the staging algorithm (42). The lymphoepithelial tissue of the tongue base from the circumvallate papillae to vallecula can be removed by TORS (26). TORS combined with other available diagnostic options was reported to identify 77.3% of previously unknown primary sites in patients (43).

Although, most of the above-mentioned surgeries were off-label uses of the da Vinci surgical system, they represent the ingenious potential of future robotic applications. Owing to these efforts, various technological problems and limitations have been brought to light; most will be solved technologically in due time. Above all, with such innovative applications of surgical robotics, patients must be properly informed unbiasedly of the potential risks and benefits compared with conventional approaches.

A hybrid system: endoscopic surgery with a robotically-driven scope (Flex System)

The Flex System by Medrobotics (Raynham, MA, USA) is another novel robotic system developed specifically for transoral eHNS. Its robotically-driven scope was approved by CE-Mark (European Union) in 2014 and the FDA in 2015. It consists of an operator-controlled robot-assisted scope and manually controlled flexible instruments designed to maneuver through the natural orifice. Using a joystick-like controller, the surgeon inserts the flexible HD scope and accompanying instrument-guiding tubes into the patient's mouth and maneuvers it into the oropharynx. Once positioned, the scope becomes rigid, forming a stable surgical platform from which the surgeon can manually control flexible 3-mm surgical instruments through the guiding tubes. The surgeon uses their hands to manipulate instruments such as a grasper, needle driver, scissors, monopolar spatula and laser. With its novel flexible robotic camera, this system has been reported to have advantages in terms of

accessibility, visualization, tactile feedback and affordability compared with its competitor the da Vinci surgical system (44,45). A multicenter study including 80 patients' experience revealed that the Flex system has the potential to improve surgical access to the oropharynx and supraglottis but not glottis (46). Notably, the current Flex system offers a platform with angles of approach and instrumentation specifically-designed for laryngeal applications. The introduction of a new robotic system to the TORS market is desirable, which may be able to increase competition, drive scientific improvements and reduce financial burdens.

Disadvantages of TORS

Since the first introduction of TORS in 2004–2005, da Vinci, the leading robotic system, has become the prerequisite for MIS. As for the selection of treatment for OPC, the use of surgery decreased from 41.4% in 1998 to 30.4% in 2009 but, after the FDA approval of TORS in 2009, the surgical trend reversed and it increased to 34.8% in 2012 (47). Nearly, a decade after its introduction, several issues regarding the da Vinci robotic system have been brought to light, including: (1) start-up and maintenance cost, (2) institutional disparity and (3) instrumental limitations.

The cost-effectiveness of the da Vinci system has been questioned in the health economics literature (48,49). The cost burdens are certainly a major disadvantage of the da Vinci system, and they may limit its accessibility to both medical operators and patients. However, for the carefully selected OPC patient with minimal risk of needing postoperative radiation therapy, frontline transoral eHNS might actually save as much as 10–24% compared to radiation therapy with concurrent chemotherapy (50). In developing countries, cost burdens are even larger obstacles and thus become a hindrance to global development. It is understandable that cutting edge robotic technologies and instruments require substantial investments; in the future, a more-economical robotic system may come through marketing developments and corporate competition.

Institutional disparity is another potential disadvantage of TORS because this is a specialized technique that comes with the risk of potentially-serious complications. The incidence of postoperative complications was reported to be significantly correlated with the surgeons' case volume (>50 cases). Postoperative hemorrhage was the most common complication encountered and the only reported cause of death after TORS (51). Due to the clinical concept of being minimally invasive, TORS patients are commonly discharged in a few days without tracheotomy. If postoperative hemorrhage occurs, the patients are often not under surgeons' close care, and marked bleeding with the lack of airway protection may result in a catastrophic outcome (27). The mortality rate directly attributed to TORS was reported to be 0.01% (2/169 cases) in a French report (52); one patient died from aspiration pneumonia followed by a fatal hemorrhage nine days postoperatively, and the other from cervical spondylitis. Zevallos et al. reported a higher rate of positive surgical margins in TORS oropharyngectomy at low-case-volume centers, suggesting the importance of surgeons' experience and the expected learning curve of TORS (53). They stressed that TORS should be performed in multidisciplinary head and neck cancer centers and by highly trained head and neck surgical oncologists. This may further expand the institutional disparity in handling novel surgical procedures and may unfavorably affect accessibility for patients.

Instrumental limitations are the third potential disadvantage of TORS. The upper aerodigestive tract is characterized by delicate

anatomical features with narrow and curved pathways. Manipulation to this region requires sophisticated skills to perform the necessary dissection while avoiding traumatic complications. Although the da Vinci robotic system is a superb and innovative device, it was not specifically developed for use in the upper aerodigestive tract. With rigid robotic instruments entering the surgical field from unique trajectories, mechanical collision may occur, particularly deep in the laryngopharyngeal region. Even with the non-robotic 3-mm instruments of the Flex system, false vocal cords and vocal cords may be difficult to expose (46). Further refinements of robotic instruments are necessary. The achievement of further miniaturization without losing instrumental rigidity, strength and dexterity may be challenging. Innovative solutions to these challenges should be attainable through creative translational engineering and also through international collaborations.

Adequate exposure of the natural orifice is another important factor for the success of TORS. Presently, exposure can be achieved with the Feyh-Kastenbauer retractor (Gyrus), FK-WO retractor (Olympus), Flex retractor (Medrobotics), Crowe-Davis Mouth gag (Medline), laryngeal advanced retractor system (Fentex) and Dingman Mouth Gag (Bausch+Lomb Instruments). In most of these retractors, the tongue blade plays a pivotal role in retraction, but at the same time, it frequently interferes with robotic instruments. Paradoxically, our present-day retractors rely on compression of the very structures that we view and manipulate. Upright positioning without retractor has been explored as an alternative exposure method (54). Advantages of the seated position included increased posterior airway and operative space by ~2 cm, ability to manipulate the surgical field, and improved visualization. It allows surgeons to optimally operate in the inferior pharynx and larynx without the limitation of line of site access and visualization.

Prospective clinical trials for TORS

The initial functional and oncologic results of TORS are promising but are largely-based on a single or multicenter retrospective case series. Randomized prospective trials examining the role of endoscopic and robotic surgeries versus radiation-based treatment options are needed. We are likely to learn a great deal from several prospective trials focused on transoral eHNS in OPC patients: the European Organisation for Research and Treatment of Cancer (EORTC) 1420 and the Eastern Cooperative Oncology Group (ECOG) 3311.

EORTC 1420 is a multicenter prospective phase III trial that examines functional and oncologic outcomes of patients treated with TLM/TORS + neck dissection and postoperative adjuvant IMRT or primary radiation therapy for both HPV-positive and -negative OPCs (55). In ECOG 3311 phase II trial, patients are risk-stratified following transoral surgery and neck dissection based on the HPV status (p16), surgical margins, extracapsular spread and node metastases (12). This trial is innovative, with lower-risk patients receiving less intensive therapy, and so may contribute to the de-intensification of radiation therapy. The evidence from these prospective randomized trials is important and will help to further define indications, functional outcomes and oncologic outcomes of TORS among multidisciplinary paradigms.

TORS in Japan

In 2009, the Japan Pharmaceuticals and Medical Devices Agency (PMDA) approved the da Vinci surgical system for urologic surgeries, general and gynecologic laparoscopic surgeries, and general non-cardiovascular thoracoscopic surgeries. Surgeons are requested by the Japan Health, Labor and Welfare Ministry to meet certain criteria, including having board-certified laparoscopic skills and undergoing a certified robotic training program. Regarding national healthcare coverage, urologic laparoscopic RS (Prostatectomy 2012 and Nephrectomy for malignant diseases 2016) has been initially approved. Additional 12 surgical procedures, such as mediastinal, thoracic, cardiac, abdominal and gynecologic robotic applications, were approved for coverage in 2018.

TORS has been approved in the USA, Australia, Canada, China and Korea. TORS was approved by Japan PMDA in 2018 but national healthcare coverage is still not granted. A multi-institutional clinical trial (Kyoto University, Tottori University and Tokyo Medical University) was done to assess the safety and feasibility of TORS for PMDA approval and for national healthcare coverage (56,57). The reasons for the lingering process of TORS approval in Japan may be related to concerns over liability and the potential risks associated with highly advanced robotic systems and may also be related to the cost burdens. Meanwhile, Japan has developed a variety of modified TLM approaches to cope with the paradigm shift of transoral MIS (57,58).

Since Japan has the longest life expectancy in the world, there is marked concern regarding increased social security expenses. In addition, the trade deficits due to imported medical devices and drugs have increasingly become socioeconomic burdens to Japan. On the other hand, Japanese medical societies and governmental officials are fully aware of the important role of the da Vinci robotic system in MIS, particularly for the super aging population. Overall, Japan has already become the second largest market for the da Vinci robotic system, and gradually the indication will expand and the healthcare coverage will follow. While keeping the door open to global innovative medical devices, Japanese governmental authorities also urge domestic multidisciplinary professionals to expedite the development of original and affordable surgical robotic systems. In reality, international collaboration that brings together all innovative robotic intelligences may be the best way to steer through the global infringements associated with hundreds of patents.

Future robotics with augmented virtual reality and hyperspectral vision

For years, the art and science of surgery were limited to the hands and eyes of skillful surgeons. For patients with cancer, such skills led to cure and remission. Over the past few decades, a new set of technologies have transformed what is possible in surgery. The surgical microscope and operating endoscopes ushered in the era of MIS. Surgical robotics further accelerated refinement of the surgeon's craft. Robotic systems now translate and scale the movements of the surgeon's fingers to robotic arms that manipulate miniature surgical instruments. This allows surgeons to free up their hands and perform complex tasks in small spaces. For the first time in history, surgeons are moving beyond the physical limitations of the human hand, and exploring ever smaller anatomic regions with greater insight and precision. However, despite these improvements, surgeons still rely upon human visual processing to distinguish normal from diseased anatomies, blood vessels from nerves and tumors from normal tissue.

As tools emerge to integrate computer-assisted vision into augmented and virtual reality environments, surgeons can also move beyond the perception and perspective of the human eye. The next-generation of surgical robotics comes with exciting opportunities: to refine and apply next-generation robotic surgical systems to human

use, using prospective clinical trials and an international registry for patient-focused outcome data; to improve surgical vision by developing a platform for using augmented reality and hyperspectral optics which will facilitate the safe implementation of artificial intelligence (AI) as a reliable surgical assistant; to develop these surgical technologies in an incremental and stepwise manner such that new innovations can be used globally, affordably and equitably across established and emerging health systems.

Medical robotics and AI are rapidly growing and are likely to be engrained in future evolution from this point forward. Surgeons learn through experience and also by making the same mistakes as their predecessors. Surgical robotics and AI are expected to ease the learning curve and to keep surgeons from having to learn through making mistakes.

In 2017, the French Otolaryngological Society (La Société Française D'ORL et de Chirurgie Cervico-Faciale, SFORL) issued an overview report of robotics and digital guidance in OHNS (59), which was delivered at the IFOS 2017 meeting (24-28 June 2017) in Paris. This comprehensive report covered state-of-the-art knowledge of surgical robotics and navigations and marked the beginning of a new era of robotic medicine. The future will evolve at breathtaking speed as the editors of this report stated 'Despite the high quality of the works in this report, it is likely that in less than 5 years what we have reported here will be entirely obsolete, which is in fact our greatest wish.'

Conclusions

By effectively incorporating interfaces of 3D visualization, motion scaling, tremor filtration and enhanced dexterity, the da Vinci robotic system has dominated the field of surgical robotics. In the MIS of OPC, TORS utilizing the da Vinci system has proved capable of preserving the laryngopharyngeal function without compromising oncologic outcomes, and minimizing adjuvant radiation therapy (60,61). Future robotic systems are likely to bring improved visualization and user-interface, spatial navigation, miniaturization, force-feedback and hopefully cost-effectiveness. Yet, advanced technologies can only advance the art and science of HNS as far as the understanding of the surgeon. Thus, transoral minimally-invasive approaches to HNS will likely continue to leverage concepts first codified and espoused in conservation laryngopharyngeal surgery (62,63).

If the future direction of surgical robotics lies on the path of always benefiting patients but not humanistic ego, innovations will always proceed swiftly and effectively. By promoting borderless international collaborations that put 'patients first', the future of surgical robotics will continue to be bright and full of surprises beyond our imagination.

Funding

Conflict of interest statement

None declared.

References

1. Camarillo DB, Krummel TM, Salisbury JK. Robotic technology in surgery: past, present, and future. *Am J Surgery* 2004;118:2S–15S.
2. Runaround AI. *I, Robot short stories*. New York: Street and Smith Publications, 1942;26.
3. Yates DR, Vaessen C, Roupret M. From Leonardo to da Vinci: the history of robot-assisted surgery in urology. *BJU Int* 2011;108:1708–14.
4. Yip M, Das N. Robot autonomy for surgery. *World Sci Rev* 2017;9:1–32.
5. Green P, Hill J, Jensen J, Shah A. Telepresence surgery. *IEEE Eng Med Biol* 1995;14:324–9.
6. Taylor R, Funda J, Eldridge B, et al. A telerobotic assistant for laparoscopic surgery. *IEEE Eng Med Biol* 1995;14:279–88.
7. Madhani A, Niemeyer G, Salisbury J. The Black Falcon: a teleoperated surgical instrument for minimally invasive surgery. *IEEE/RSJ Int Conf Intell Rob Syst Proc* 1998;2:936–44.
8. Charles S, Das H, Ohm T, et al. Dexterity-enhanced telerobotic microsurgery. *ICAR'97 8th Int Conf Adv Rob Proc* 1997;5–10.
9. Marescaux J, Leroy J, Gagner M, et al. Transstlantic robot-assisted telesurgery. *Nature* 2001;413:379–80.
10. Abbou C, Hoznek A, Salomon L, et al. Remote laparoscopic radical prostatectomy carried out with a robot. *Rep Case Prog Urol* 2000;10:520–3. (in French).
11. Kaouk JH, Haber GP, Autorino R, et al. A novel robotic system for single-port urologic surgery: first clinical investigation. *Eur Urol* 2014;66:1033–43.
12. Holsinger FC, Ferris R. Transoral endoscopic head and neck surgery and its role within the multidisciplinary treatment paradigm of oropharynx cancer: robotics, lasers, and clinical trials. *J Clin Oncol* 2015;33:3285–92.
13. Haughey B, Hinni M, Salassa J, et al. Transoral laser microsurgery as primary treatment for advanced-stage oropharyngeal cancer: a United States multicenter study. *Head Neck* 2011;33:1683–94.
14. Bernal-Sprekelsen M, Blanch JL, Caballero-Borrego M, Vilaseca I. The learning curve in transoral laser microsurgery for malignant tumors of the larynx and hypopharynx: parameters for a levelled surgical approach. *Eur Arch Otorhinolaryngol* 2013;270:623–8.
15. Chaturvedi A, Engels E, Pfeiffer R, et al. Human papillomavirus and rising oropharyngeal cancer Incidence in the United States. *J Clin Oncol* 2011;29:4294–301.
16. Weinstein G, O'Malley B, Hockstein N. Transoral robotic surgery: supraglottic laryngectomy in a canine model. *Laryngoscope* 2005;115:1315–9.
17. O'Malley B, Weinstein G, Hockstein N. Transoral robotic surgery (TORS): glottic microsurgery in a canine model. *J Voice* 2006;20:263–8.
18. Weinstein G, O'Malley B, Snyder W, Sherman E, Quon H. Transoral robotic surgery: radical tonsillectomy. *Arch Otolaryngol Head Neck Surg* 2007;133:1220–6.
19. Weinstein G, O'Malley B, Snyder W, Hockstein N. Transoral robotic surgery: supraglottic partial laryngectomy. *Ann Otol Rhinol Laryngol* 2007;116:19–23.
20. Almeida J, Li R, Magnuson J, et al. Oncologic outcomes after transoral robotic surgery: a multi-institutional study. *JAMA Otolaryngol Head Neck Surg* 2015;141:1043–51.
21. Weinstein G, O'Malley B, Magnuson J, et al. Transoral robotic surgery: a multicenter study to assess feasibility, safety, and surgical margins. *Laryngoscope* 2012;122:1701–7.
22. White H, Ford S, Bush B, et al. Salvage surgery for recurrent cancers of the oropharynx comparing TORS with standard open surgical approaches. JAMA. *Otolaryngol Head Neck Surg* 2013;139:773–8.
23. Park YM, Kim WS, Byeon HK, Lee SY, Kim SH. Surgical techniques and treatment outcomes of transoral robotic supraglottic partial laryngectomy. *Laryngoscope* 2013;123:670–7.
24. Ozer E, Alvarez B, Kakarala K, Durmus K, Teknos T, Carrau R. Clinical outcomes of transoral robotic supraglottic laryngectomy. *Head Neck* 2013;35:1158–61.
25. Olsen S, Moor E, Koch C, Price D, Kasperbauer J, Olsen K. Transoral robotic surgery for supraglottic squamous cell carcinoma. *Am J Otolaryngol* 2012;33:379–84.

26. Hamilton D, Paleri V. Role of transoral robotic surgery in current head & neck practice. *Surgeon* 2017;15:147–54.

27. Mandal R, Duvvuri U, Ferris R, Kaffenberger T, Choby G, Kim S. Analysis of post-transoral robotic-assisted surgery hemorrhage: frequency, outcomes, and prevention. *Head Neck* 2016;38:E776–82.

28. Kucur C, Durmus K, Gun R, et al. Safety and efficacy of concurrent neck dissection and transoral robotic surgery. *Head Neck* 2016;38:E519–23.

29. Biron V, O'Connell D, Barber B, et al. Transoral robotic surgery with radial forearm free flap reconstruction: case control analysis. *J Otolaryngol Head Neck Surg* 2017;46:1–7.

30. Park YM, Kim WS, Byeon HK, Virgilio AD, Jung JS. Feasibility of transoral robotic hypopharyngectomy for early-stage hypopharyngeal carcinoma. *Oral Oncol* 2010;46:597–602.

31. Sims JR, Robinson NL, Moore EJ, Janus JR. Transoral robotic medial hypopharyngectomy: surgical technique. *Head Neck* 2016;38:E2127–9.

32. Tsang RK, To VS, Ho AC, Ho WK, Chan JY, Wei WI. Early results of robotic assisted nasopharyngectomy for recurrent nasopharyngeal carcinoma. *Head Neck* 2015;37:788–93.

33. Chauvet D, Hans S, Missistrano A, Rebours C, Bakkouri WE, Lot G. Transoral robotic surgery for sellar tumors: first clinical study. *J Neurosurg* 2016;23:1–8.

34. Duek I, Amit M, Sviri GE, Gil Z. Combined endoscopic transcervical-transoral robotic approach for resection of parapharyngeal space tumors. *Head Neck* 2017;39:786–90.

35. Jason YK, Tsang R, Eisele DW, Richmon JD. Transoral robotic surgery of the parapharyngeal space: a case series and systematic review. *Head Neck* 2015;37:293–8.

36. Dowthwaite S, Nichols AC, Yoo J, et al. Transoral robotic total laryngectomy: report of 3 cases. *Head Neck* 2013;35:E338–42.

37. Smith R, Schiff BA, Sarta C, Hans S, Brasnu D. Transoral robotic total laryngectomy. *Laryngoscope* 2013;123:678–82.

38. Lawson G, Mendelsohn AH, Vorst SV, Bachy V, Remacle M. Transoral robotic surgery total laryngectomy. *Laryngoscope* 2013;123:193–6.

39. Anuwong A. Transoral endoscopic thyroidectomy vestibular approach: a series of the first 60 human cases. *World J Surg* 2016;40:491–7.

40. Russell J, Noureldine S, Al Khadem M, et al. Transoral robotic thyroidectomy: a preclinical feasibility study using the da Vinci Xi platform. *J Robot Surg* 2017;11:341–6.

41. Dionigi G, Tufano RP, Russell J, Kim HY, Piantanida E, Anuwong A. Transoral thyroidectomy: advantages and limitations. *J Endocrinol Invest* 2017;40:1259–63.

42. Ofo E, Spiers H, Kim D, Duvvuri U. Transoral robotic surgery and the unknown primary. *ORL J Otorhinolaryngol Relat Spec* 2018;80:148–55.

43. Durmus K, Rangarajan SV, Old MO, Agrawal A, Teknos TN, Ozer E. Transoral robotic approach to carcinoma of unknown primary. *Head Neck* 2014;36:848–52.

44. Schuler P, Hoffmann T, Veit J, et al. Hybrid procedure for total laryngectomy with a flexible robot-assisted surgical system. *Int J Med Robot* 2017;13:e1749.

45. Friedrich DT, Scheithauer MO, Greve J, et al. Potential advantages of a single-port, operator-controlled flexible endoscope system for transoral surgery of the larynx. *Ann Otol Rhinol Laryngol* 2015;124:655–62.

46. Lang S, Mattheis S, Hasskamp P, et al. A European multicenter study evaluating the flex robotic system in transoral robotic surgery. *Laryngoscope* 2017;127:391–5.

47. Liederbach E, Lewis CM, Yao K, et al. A contemporary analysis of surgical trends in the treatment of squamous cell carcinoma of the oropharynx from 1998 to 2012: a report from the National Cancer Database. *Ann Surg Oncol* 2015;22:4422–31.

48. Wright JD, Ananth CV, Lewin SN, et al. Robotically assisted vs laparoscopic hysterectomy among women with benign gynecologic disease. *JAMA* 2013;309:689–98.

49. Sher DJ, Fidler MJ, Tishler RB, Stenson K, al-Khudari S. Cost-effectiveness analysis of chemoradiation therapy versus transoral robotic surgery for human papillomavirus associated, clinical N2 oropharyngeal cancer. *Int J Radiat Oncol Biol Phys* 2016;94:512–22.

50. Tam K, Orosco R, Colevas A, et al. Cost comparison of treatment for oropharyngeal carcinoma. *Laryngoscope* 2019;Epub ahead of print.

51. Stanley H, Cross ND, Richmon JD. Surgeon experience and complications with transoral robotic surgery (TORS). *Otolaryngol-Head Neck Surg* 2013;149:885–92.

52. Aubry K, Vergez S, de Mones E, et al. Morbility and mortality revue of the French group of transoral robotic surgery: a multicentric study. *J Robotic Surg* 2016;10:63–7.

53. Zevallons JP, Mitra N, Swisher-McClure S. Patterns of care and perioperative outcomes in transoral endoscopic surgery for oropharyngeal squamous cell carcinoma. *Head Neck* 2016;38:402–9.

54. Moore E, Van Abel K, Olsen K. Transoral robotic surgery in the seated position: rethinking our operative approach. *Laryngoscope* 2017;127:122–6.

55. Simon C, Caballero C, Gregoire V, et al. Surgical quality assurance in head and neck cancer trials: an EORTC Head and Neck Cancer Group position paper based on the EORTC 1420 'Best of' and 24954 'larynx preservation' study. *Eur J Cancer* 2018;103:69–77.

56. Fujiwara K, Fukuhara T, Kitano H, et al. Preliminary study of transoral robotic surgery for pharyngeal cancer in Japan. *J Robotic Surg* 2016;10:11–7.

57. Tateya I, Shiotani A, Satou Y, et al. Transoral surgery for laryngo-pharyngeal cancer—the paradigm shift of the head and cancer treatment. *Auris Nasus Larynx* 2016;43:21–32.

58. Nakayama M, Katada C, Mikami T. A clinical study of transoral pharyngectomiesto treat superficial hypopharyngeal cancers. *Jpn J Clin Oncol* 2013;43:782–7.

59. Lombard B, Céruse P. Robotics and Digital Guidance in ENT-H&N Surgery. *Rapport de la Société Française D'ORL et de Chirurgie Cervico-Faciale*. Paris: Elsevier Masson, 2017.

60. Bhayani M, Holsinger C, Lai S. A shifting paradigm for patients with head and neck cancer: transoral robotic surgery (TORS). *Oncology* 2010;24:1010–5.

61. Orosco R, Arora A, Jeanon J, Holsinger C. Next-generation robotic head and neck surgery. *ORL J Otorhinolaryngol Relat Spec* 2018;80:213–9.

62. Nakayama M, Laccourreye O, Holsinger H, Okamoto M, Hayakawa K. Functional organ preservation for laryngeal cancer: past, present, and future. *Jpn J Clin Oncol* 2012;42:155–60.

63. Holsinger C, McWhorter A, Ménard M, Garcia D, Laccourreye O. Transoral lateral oropharyngectomy for squamous cell carcinoma of the tonsillar region: I. Technique, complications, and functional results. *Arch Otolaryngol Head Neck Surg* 2005;131:583–91.