Robotic Skull Base Surgery

Preclinical Investigations to Human Clinical Application

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Objective: To develop a minimally invasive surgical technique for the treatment of parapharyngeal space and infratemporal fossa skull base neoplasms using the technical and optical advantages of robotic surgical instrumentation.

Design: A robotics skull base surgery program at the University of Pennsylvania, Philadelphia, was initiated in the fall of 2005. Six experimental procedures focusing on developing approaches to the parapharyngeal space and infratemporal fossa were performed on a total of 2 cadavers and 1 mongrel dog. Based on the preclinical work, transoral robotic surgery (TORS) was then performed in February 2007 on 1 human patient with a parapharyngeal to infratemporal fossa cystic neoplasm as part of a large prospective human trial.

Setting: In each cadaver and in the dog, a TORS approach to parapharyngeal space and infratemporal fossa was performed bilaterally and in an approved training facility using the da Vinci Surgical System. For the human surgical case, a TORS approach was evaluated on one side for a benign neoplasm. The human patient underwent TORS of the parapharyngeal space and infratemporal fossa cystic neoplasm under an institutional review board–approved prospective clinical trial.

Patients: For the human clinical trial, a TORS approach was evaluated for a patient with a benign neoplasm of the parapharyngeal space and infratemporal fossa.

Main Outcome Measures: The ability to access and dissect tissues within the various areas of the parapharynx and infratemporal fossa was evaluated, and techniques to enhance visualization and instrumentation were developed.

Results: Using TORS approaches permitted excellent access, visualization, and tissue dissection within the parapharyngeal space and infratemporal fossa in both the cadaver and canine experiments. In the first known human surgical case, TORS was used to remove a parapharyngeal space and infratemporal fossa cystic neoplasm. Wide visualization, followed by complete resection using the identical techniques developed in the preclinical models, was achieved. The robotic procedure allowed adequate and safe identification of the internal carotid artery and cranial nerves, and excellent hemostasis was achieved with no complications during or after surgery.

Conclusions: The TORS approaches provided excellent 3-dimensional visualization and instrument access that allowed successful parapharyngeal space and infratemporal fossa surgical resections from cadaver models to the first known human patient application. Robotic surgery for the skull base holds potential as a minimally invasive approach to skull base neoplasms; however, continued development and investigation is warranted in a prospective human clinical trial before final conclusions can be drawn as to the full advantages and limitations of this approach.

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THE CONCEPT OF ROBOT-ASSISTED SURGERY IS GAINING POPULARITY FOR MULTIPLE DIFFERENT SPECIALTIES, INCLUDING CARDIAC SURGERY, UROLOGY, OBSTETRICS AND GYNECOLOGY, AND, MOST RECENTLY, MINIMALLY INVASIVE HEAD AND NECK SURGERY AND UPPER GASTROINTESTINAL TRACT SURGERY. THE OVERRIDING THEMES FROM THE PROponents OF ROBOT-ASSISTED SURGERY ARE THE EXCELLENT 3-DIMENSIONAL VISUALIZATION AND 2- OR 3-HANDED SURGERY THROUGH MINIMALLY INVASIVE APPROACHES THAT ARE AFFORDED BY THE INSTRUMENT. CARDIAC VALVE SURGERY, RADICAL PROSTATE SURGERY, BASE OF TONGUE CANCER SURGERY, AND SKULL BASE SURGERY ARE EXAMPLES OF HIGH-MORBIDITY SURGICAL PROCEDURES THAT TYPICALLY REQUIRE LARGE SURGICAL INCISIONS AND OPEN APPROACHES. HOWEVER, THESE PROCEDURES CAN NOW BE PERFORMED THROUGH SMALL OR NO INCISIONS WITH MINIMAL HEMOSTASIS AND LOW OVERALL RISK USING ROBOT-ASSISTED SURGERY.1,3 FURTHERMORE, REPORTS AMONG THE VARIOUS SPECIALTY APPLICATIONS TO DATE HAVE SHOWN THAT ACTUAL OPERATIVE TIME, INTENSIVE CARE UNIT...
stays, and overall patient hospitalization are reduced after robotic procedures compared with classic open procedures. We have previously reported on our development and refinement of a novel procedure called transoral robotic surgery (TORS) in preclinical experimental models. These foundational studies established the technical feasibility of TORS to gain access to the oral cavity, oropharynx, hypopharynx, supraglottis, and glottis, and they also introduced basic concepts of patient safety and methods for controlling active bleeding. Subsequent to these preclinical experiments, we prospectively investigated the application of TORS for tongue base neoplasms from cadaver to canine to human clinical application in an institutional review board–approved human clinical trial.

The experiments described herein were designed to test the hypothesis that robotic surgical technology could be applied to approaches and actual surgical resections of the parapharyngeal space and infratemporal fossa. To test this hypothesis we performed 6 preclinical experiments on 2 cadavers and 1 live mongrel dog and then applied the novel techniques we developed to a human patient with a cystic-appearing neoplasm of the infratemporal fossa and cranial nerves IX, X, XI, and XII (not shown) were performed (Figure 1). Using a 30° angled high-magnification, 3-dimensional camera rotated cephalad, the dissection of the carotid artery, jugular vein, and cranial nerves could be performed to their bony skull base foramina and then into the jugular bulb by making a venotomy in the jugular vein (Figure 2). To gain access superiorly and laterally, the styloid musculature

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**METHODS**

The da Vinci Surgical System (Intuitive Surgical Inc, Sunnyvale, California) was used for 2 cadaver experiments and 1 live canine experiment for a total of 9 preclinical procedures. The surgical techniques and strategies developed were then applied with TORS for a skull base approach and tumor resection on 1 human patient.

For the canine preclinical experiment, the robotic procedures evaluated were performed completely transorally and in accordance with Public Health Service Policy on Humane Care and Use of Laboratory Animals, the National Institutes of Health Guide for the Care and Use of Laboratory Animals, and the Animal Welfare Act. The mongrel dog weighed approximately 30 kg and received preanesthesia with intramuscular injections of atropine sulfate (AmVet; Neogen Corp, Lexington, Kentucky), then a mixture of tiletamine hydrochloride and zolazepam hydrochloride (Telazol; Fort Dodge Animal Health, Fort Dodge, Iowa), and then xylazine base (Tranquiel injection; Vedco Inc, St Joseph, Missouri). Propofol (Abbott Laboratories, North Chicago, Illinois) was used for induction, and then the orotracheal intubation was achieved using a No. 9 cuffed endotracheal tube. Ongoing anesthesia was achieved via inhalation using isoflurane (Isosol; Rhodia Organique Fine Ltd, Avonmouth, Bristol, England). Intravenous pancuronium bromide injection (Baxter, Irvine, California) was given for paralysis. Positive pressure ventilatory support was achieved throughout the procedure with an Ohmeda ventilator (model 7000; Ohmeda BOC Health Care, Madison, Wisconsin). Monitoring of cardiac status and oxygenations was performed using a Datex-Ohmeda cardiac monitor (model S/5; Datex-Ohmeda Division, Instrumentarium Corp, Helsinki, Finland).

For the preclinical cadaver experiments, standard operating room tables and instrument set-up were used, and a Crowe-Davis retractor (Storz, Heidelberg, Germany) was applied to maintain oral opening and caudal retraction of the tongue. For the human TORS skull base surgical procedure, standard induction and inhalational anesthesia was delivered via a reinforced oral endotracheal tube. The pathologic diagnosis was uncertain, and the mass appeared to be a cystic neoplasm arising in the parapharyngeal space and extending to the infratemporal fossa. Details of the first known human application and surgical procedure, performed in February 2007, are outlined in the “Results” section. Included in our evaluations were standard oral retractor and exposure set-up and preparation time vs added time for robotic set-up plus surgical procedure time.

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**RESULTS**

TORS ACCESS AND TECHNICAL FEASIBILITY AND LIMITATIONS TO THE PARAPHARYNGEAL SPACE AND INFRATEMPORAL FOSSA IN CADAVERS AND THE CANINE MODEL

Two cadavers, 1 edentulous and 1 dentate, and 1 mongrel dog were used in these 6 individual experimental surgical approaches. Exposure to parapharyngeal space and infratemporal fossa was successfully achieved using the Crowe-Davis retractor (Storz) in the cadavers. Although the fresh cadavers allowed wide excursion of the jaw, we tested the ability to perform TORS skull base approach using more standard jaw opening distances of 4 to 6 cm and were able to access the parapharynx and infratemporal fossa throughout each of these distances.

With respect to the cadaver approaches, the TORS skull base incisions were made lateral to the anterior tonsillar pillar, and dissections of the branches of the external carotid, the jugular vein, internal carotid, and cranial nerves IX, X, XI, and XII (not shown) were performed (Figure 1). Using a 30° angled high-magnification, 3-dimensional camera rotated cephalad, the dissection of the carotid artery, jugular vein, and cranial nerves could be performed to their bony skull base foramina and then into the jugular bulb by making a venotomy in the jugular vein (Figure 2). To gain access superiorly and laterally, the styloid musculature

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**Figure 1.** High-magnification view using a 30° robotic endoscope of the infratemporal fossa and cranial nerves IX, X, XI (white arrows), the carotid artery (CA) (red arrow), and the jugular vein (JV) (blue arrow) dissected to the level of the bony skull base (BSB) (yellow arrow).
was transected, and the pterygoid musculature required partial release. Although both the 8-mm and the 5-mm instruments were evaluated, we found the 8-mm instrument to be ideal for reaching the high infratemporal fossa and bony skull base because of the curvature at the distal portion of the robotic end effectors. Although these parapharyngeal space and infratemporal fossa surgical dissections were technically feasible and in no way cumbersome using the robot, it became apparent that there were certain limitations of this technique in approaching skull base neoplasms. For one, given the minimally invasive approach, we noted that wide resection, which may be needed for more invasive or malignant neoplasms, would not be possible. Also, there are no rongeur or drill instruments on the robot, and thus the bony middle skull base cannot be resected or drilled, which prevents use of this approach when bony margins or intracranial access is required. Thus, it seems that this approach would be best suited for well-circumscribed benign lesions, such as cysts, adenomas, or schwannomas, and possibly limited parapharyngeal metastatic lymph nodes. We could not get adequate access below the carotid bifurcation, which precludes this approach for use in formal neck dissections.

For the canine experiments, the lower jaw was simply held open with suture that was tied to a standard retractor holder attached to the side of the patient table. Using the techniques for the approach as developed in the cadaver experiments, we performed right and left parapharyngeal and infratemporal fossa approaches in the live dog. Although access was possible in the dog, the actual location of the nerves, vessels, and musculature were somewhat different; however, the live canine experiments proved quite valuable in our demonstration that the carotid artery, jugular vein, and cranial nerves could be dissected transorally using the conventional robotic equipment without incurring damage to these critical structures. This model also allowed us to demonstrate that the procedures could be performed under adequate hemostasis and retraction and suction methods were refined for the assistant.

**TORS in a Human Patient with a Parapharyngeal Cystic Neoplasm Extending into the Infratemporal Fossa**

Although the preclinical experiments defined the technical approach and identified limitations, these cadaver and canine experiments do not always translate into human application. We identified a human patient with a well-circumscribed benign-appearing neoplasm of the parapharyngeal space and infratemporal fossa that would serve as 1 case proof of principle for human patient application. This first known human TORS approach, resection, and suture closure was performed on 1 male den- tense patient who presented with a cystic neoplasm of the parapharyngeal space and infratemporal fossa as identified on axial and coronal magnetic resonance imaging (Figure 3). Regarding the standard operating room set-up for a transoral procedure regardless of what instrumentation was to be used, we recorded the time required to turn and drape the patient and introduce the chosen oral retractor. We then recorded the additional set-up time required for the robotic component. Robotic set-up time included camera calibration with both black-and-white balancing, mobilization and positioning of the robot base and arms, and placement of the selected robotic instruments into the oral cavity at the surgical site. We recorded the time to complete the actual surgical procedure and total operating room time from entry to exit of the operating suite. The times for set-up and surgery are as follows: standard set-up time, 1 minute 12 seconds; robotic set-up time, 3 minutes 23 seconds; total surgical time, 2 hours 32 minutes; blood loss, 50 mL; and duration of hospitalization, 2 days.

The surgery was performed using the Endowrist spatula-tipped cautery as well as the Endowrist Maryland forceps (Intuitive Surgical Inc). An assistant was employed for the procedure to suction both smoke and blood as needed. The neoplasm was approached via TORS alone, and a Bovie cutting incision was made lateral to the anterior tonsillar pillar. Dissection was performed through the palatopharyngeus and palatoglossus muscles to the parapharyngeal fat. The tonsillar branches from the external carotid artery were then dissected and ligated using endoscopic surgical clips, and the glossopharyngeal nerve was dissected and preserved. The internal maxillary artery was then dissected anterolaterally, and a well-circumscribed and encapsulated neoplasm was encountered. The capsule of the neoplasm was then dissected superiorly along the styloid to the poststyloid and infratemporal fossa region. The posterior border of the mass was dissected off the internal carotid artery, leaving a small layer of facial tissue overlying the internal carotid artery. As the dissection of the layers of fascia and muscle was performed, we were able to mobilize the deep-seated neoplasm medially into the superficial aspects of the wound (Figure 4). This was quite helpful because this medical mobilization of the mass facilitated the deeper and lateral dissection off the internal carotid artery without mandating a curved or angulated and therefore higher risk carotid artery dissection. After removing the cystic neoplasm, the wounds were irrigated; we noted that he-
mostasis was present. The incisions were then closed in 1 layer using 3-0 chromic gut suture with the robotic needle driver instruments. The patient was extubated and brought out of anesthesia without complications and was discharged after 2 days in the hospital. The patient was fully swallowing clear liquids in the immediate postoperative period and was tolerating a full diet after 1 week. The final pathologic findings showed a benign cystic neoplasm.

On completion of the surgical procedures, the robotic instruments, the endoscope, and the retractors were removed. There was no inadvertent trauma or injury to the lips, gums, teeth, palate, or pharyngeal walls except for the incision, and after successfully being brought out of anesthesia the patient had no evidence of bleeding or oropharyngeal or tongue base edema. Overall, there were no surgical complications or adverse events. The level of pain control needed was minimal, and the patient was able to take clear liquids immediately after the surgery. The patient was followed-up postoperatively, and the intraoral surgical incisions healed with no complications.

Our preclinical experiments in 2 cadavers and 1 live dog support our hypothesis that TORS is technically feasible and can be applied to surgery in the parapharyngeal space and infratemporal fossa. The 30° angled high-magnification 3-dimensional camera optics permitted tremendous visualization, which then allowed careful identification and dissection of the carotid artery, jugular vein, and cranial nerves to their entry points at the middle skull base. Because of the identical anatomy, the cadaver experiments were most valuable for the development of the actual surgical technique and strategies for identifying the critical structures and the bony skull base. Although the canine anatomy differs from the human, these live animal experiments were critical for our demonstration that the carotid artery, jugular vein, and key cranial nerves could be dissected and mobilized without incurring considerable damage or incurring unmanageable bleeding. The live canine experiment was therefore quite important to our development of techniques that were to be applied to human patients, thus supporting our study design rationale of cadaver to live canine to human clinical trial evaluation.

With respect to technical limitations and challenges for this TORS approach, the bony skull base could not be resected, and intracranial work could not be performed given the technical limitations of the existing robotic instruments and lack of robotic drills and burrs. Also, dissection below the level of the carotid artery bifurcation could not be readily performed; thus, a transoral formal neck dissection for cervical metastases is not presently feasible.

Subsequent to the preclinical investigations, we demonstrated the successful application of TORS to the skull

Figure 3. Magnetic resonance imaging (MRI) scans of the human patient. A, Axial MRI scan of infratemporal fossa and parapharyngeal space cystic neoplasm (red arrow). B, Coronal MRI scan demonstrating a cystic neoplasm (red arrow) extending from the parapharyngeal space to the infratemporal fossa and skull base.

Figure 4. Intraoperative view of the infratemporal fossa and parapharyngeal space neoplasm that had been dissected and mobilized into the medial aspect of the wound and incision.
base in a human patient with a parapharyngeal to infra-temporal fossa benign cystic neoplasm. This is the first known application of robotics for skull base surgery, and although this is only 1 human case example, it supports the feasibility and techniques we developed in the cadaver and mongrel dog experiments.

In conclusion, our findings suggest that TORS holds potential for parapharyngeal and infratemporal fossa neoplasms, but further instrument development and continued investigation are warranted before this approach can be touted as an exciting alternative to present surgical techniques and standard approaches.

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Author Contributions: Drs O’Malley and Weinstein had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Drs O’Malley and Weinstein are joint first authors. Study concept and design: O’Malley and Weinstein. Acquisition of data: O’Malley and Weinstein. Analysis and interpretation of data: O’Malley and Weinstein. Drafting of the manuscript: O’Malley and Weinstein. Critical revision of the manuscript for important intellectual content: O’Malley and Weinstein. Administrative, technical, and material support: O’Malley and Weinstein. Study supervision: O’Malley and Weinstein.

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REFERENCES