Assessment of Intraoperative Safety in Transoral Robotic Surgery

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Introduction: Robotic technology has been safely integrated into thoracic and abdominopelvic surgery, and the early experience has been very promising with very rare complications related to robotic device failure. Recently, several reports have documented the technical feasibility of transoral robotic surgery (TORS) with the daVinci Surgical System. Proposed pharyngeal and laryngeal applications include radical tonsillectomy, base-of-tongue resection, supraglottic laryngectomy, and phonomicrosurgery. The safety of transoral placement of the robotic endoscope and instruments has not been established. Potential risks specific to the transoral use of the surgical robot include facial skin laceration, tooth injury, mucosal laceration, mandible fracture, cervical spine fracture, and ocular injury. We hypothesize that these particular risks of transoral surgery are similar with robotic assistance compared with conventional transoral surgery. Methods: To test this hypothesis, we attempted to intentionally injure a human cadaver with the daVinci Surgical System by impaling the facial skin and pharyngeal and laryngeal mucosa with the robotic instruments and endoscope. We also attempted to extract or fracture teeth and fracture the cadaver's mandible and cervical spine by applying maximal pressure and torque with the robotic arms. Experiments were documented with still and video photography. Results: Impaling the cadaver's skin and mucosa resulted in only superficial lacerations. Tooth, mandible, and cervical spine fracture could not be achieved. Conclusions: Initial experiments performing TORS on a human cadaver with the daVinci Surgical System demonstrate a safety profile similar to conventional transoral surgery. Additionally, we discuss several strategies to increase patient safety in TORS. Key Words: Robotic, endoscopic, minimally invasive surgery, microsurgery, larynx, partial laryngectomy, laryngeal cancer, DaVinci, transoral robotic surgery (TORS), complications.

INTRODUCTION

The application of robotic technology to transoral surgery has been described in mannequins, cadavers, and animal models.1–5 Potential advantages include excellent optics, wristed microinstrumentation, and increased precision with motion scaling and tremor filtration. Additionally, robotic surgery does not require line-of-site like CO2 laser microlaryngeal surgery. The safety record of the daVinci system in its application to thoracoscopic and laparoscopic surgery establishes a solid background of overall device safety,6,7 but transoral placement of the robotic arms potentially exposes patients to new risks. Before widespread clinical use, patient safety must be ensured. Although all of the risks of transoral robotic surgery (TORS) cannot be predicted, many potential complications related to device misuse or malfunction are foreseeable. To assess some of the potential intraoperative injuries, we performed several experiments.

METHODS

A fresh, dentate, male human cadaver was placed in the supine position on an operating room table. The pharynx and larynx were exposed with a mouth gag and the operating room table was rotated as previously described.1,2 The daVinci Surgical System was positioned and its 30°, upward-facing, three-dimensional (3-D) endoscope and two robotic arms with 8-mm wristed microinstruments were inserted through the mouth into the pharynx. Experiments were documented with both still and video photography.

Several experiments were performed and each was repeated multiple times. First, the 8-mm spatula Bovie and the 30° endoscope, while in the robotic arms, were each driven directly into the posterior pharyngeal wall and the endolarynx to assess the potential to lacerate the mucosal tissues while setting up the robot. The same instruments, under robotic control, were then driven into the mucosa overlying the arytenoid cartilages to determine potential injury during operating conditions. Next, the endoscope and robotic instruments were manually driven into the
facial skin to determine the potential for facial injury during robot setup. Each experiment was repeated five times.

We did not intentionally impale the orbits with the robotic instruments or endoscope because it seemed obvious that injury would occur. The potential to break Opti-guard safety goggles (Dupaco, Inc., Oceanside, CA; Fig. 1), frequently used when patients are placed in the prone position, was tested by intentionally impaling them with the robotic monopolar cautery and instrument trocar, 10 times each, to determine if the goggles could be broken.

To determine if teeth could be fractured or extracted, three experiments were performed. First, an 8-mm robotic forceps was driven into the left lower first molar five times. Next, the endoscope was driven into the same tooth five times. Finally, a spatula Bovie was wedged between the left lower first molar and second molar and rotated to determine if an instrument could achieve sufficient force to fracture an intact tooth. The cadaver’s left lower canine and third molar were very unstable before beginning the experiments and the same experiments were performed on these unstable teeth.

To determine the potential to fracture the mandible and cervical spine, the 8-mm robotic instruments and the endoscope were driven into the internal aspect of the angle, body, and parasymphyseal region of the mandible. Next, the instruments and endoscope were driven into the floor of mouth past the inferior border of the mandible, and we attempted to lift, fracture, or dislocate the mandible several times. Finally, to determine the potential to fracture the cervical spine, we attempted to lift the head off of the operating room table by retracting on the mandible with the endoscope as previously stated and then rotating the head using the endoscope the generate traction on the mandible.

**RESULTS**

The 8-mm spatula Bovie lacerated the posterior pharyngeal wall mucosa and some superficial submucosal tissues after repeatedly impaling the same area. The depth of the laceration was less than 5 mm (Fig. 2). The endoscope did not lacerate the pharyngeal mucosa as it skidded or slipped along the posterior pharyngeal wall. Similarly, we were not able to lacerate the laryngeal mucosa with either the spatula Bovie or with the endoscope because it slipped or skidded off of the arytenoid into either the pyriform sinus or the endolarynx. Although it did not appear as if the arytenoid cartilage was dislocated, we could not conclusively determine cricoarytenoid joint integrity in this cadaver.

Driving the spatula Bovie into the facial skin resulted in superficial lacerations to the skin, but no subdermal tissue was exposed. Driving the endoscope into the facial skin denuded some sloughing epidermis but did not cause any significant laceration. Neither the spatula Bovie nor the endoscope was able to fracture the face of the maxilla. There was no difference with robotic or manual control.

The safety goggles could not be broken and intentionally driving the robotic endoscope and instruments into the goggles resulted in skidding of the instruments or trocar off of the goggles. When the monopolar cautery was driven directly into the goggles, the instrument bent before any apparent compromise of the goggles.

Driving the robotic instruments and endoscope into intact teeth did not grossly change the integrity of the tooth and we were unable to cause any tooth fracture. When wedging the spatula Bovie between two intact teeth and rotating the instrument, the distal tip of the spatula Bovie broke before causing any tooth injury (Fig. 3). The unstable canine and third molar were easily extracted with a robotic forceps.

Driving the robotic Bovie and endoscope into the mandible at an angle nearly perpendicular to the body, ramus, and parasympysis resulted in slipping or skidding of the instrument and did not fracture the mandible or cause any mucosal injury. Attempts to lift the mandible with the robotic instrument resulted in bending of the instrument and alarming of the robot and entry of the robot into a “safe mode” in which further instrument movement against resistance cannot be performed. Attempts to lift and rotate the mandible with the endoscope also resulted in alarming of the robot followed by entry of the robot into the “safe mode.” The head could not be lifted off of the operating room table and the cervical spine could not be fractured.

**Fig. 1.** Commercially available Opti-guard safety goggles can be placed to add an additional margin of safety to the eyes.

**Fig. 2.** Laceration of the posterior pharyngeal wall resulted from repeatedly impaling the same area with the spatula Bovie. The wound of the left was intentionally created during another experiment.
DISCUSSION

The introduction of new surgical technologies and the adaptation of these technologies to new fields offer an exciting potential to improve patient outcomes. In the early stages of research, care must be taken to ensure that these potential improvements in surgical outcome are not overshadowed by increased risk to patients. Although it is impossible to predict all adverse events that may be associated with new technologies, attempts to assess safety are of paramount importance.

To assess the potential adverse effects of adapting a surgical device to a new field, three approaches can be taken. First, the device safety profile in its current uses can be examined. Second, the risks associated with conventional procedures can be extrapolated to the use of the new device and other potential risks can be hypothesized. These projected risks can then be tested in a preclinical setting using surgical models. Finally, if the device has a strong safety record and preclinical testing is successful, clinical trials may be undertaken.

The daVinci Surgical System has an excellent track record with no patient deaths related to device failure. Like any device, electrical or mechanical, system failure may occur. Similar to other endoscopic devices, there are reports of camera failure requiring use of a spare camera or, if a spare camera was unavailable, conversion to an open procedure or aborting the procedure. Additionally, there is a report of inadvertent transection of a major vessel during a robotic-assisted nephrectomy resulting in a patient’s death, but the event was not the result of device failure. Overall, several reports of hundreds of cases, including phase I and phase II U.S. Food and Drug Administration trials, document the excellent track record with no device-related major medical complications, few conversions to open procedures, and only rare minor complications, which caused only surgical delay without other apparent morbidity.

In conventional transoral surgery with laryngoscopes, some of the procedure-specific risks include: lip and tooth injury, facial injury, mandible injury, cervical spine injury, and, in any procedure performed near the eyes, ocular injury. Similarly, in TORS, we hypothesized that these are potential risks. We performed several experiments on a human cadaver to determine the degree to which these risks would be altered by using a surgical robot. We have demonstrated that the forces generated by the daVinci Surgical System and the application of these forces to the cadaver skin, mucosa, mandible, and cervical spine are not sufficient to cause severe injury under intentionally reckless conditions.

The applied forces that can be transferred from the robotic arms to the body are not easily computed and change as a function of the instrument’s distance past the “remote center” as well as the speed at which you contact the tissue. The applied force is also a function of how much force is being generated by the distal, wrist axes versus the more proximal, outer axes. The ultimate force, which may be applied to the tissues, in our experiments was not sufficient to cause severe injury to a human cadaver. Although these forces were not measured, maximal forces were intentionally generated to demonstrate the greatest potential for injury. Superficial skin laceration and mucosal lacerations were generated with the spatula Bovie when it was intentionally impaled into the skin and mucosal surfaces. The spatula Bovie was chosen because it is the most pointed, non-“sharp” instrument. There was no clinical evidence of mandible and cervical spine fracture and bending of the instrument shaft was apparent before the robot entered the “safe” mode and alarming. Similarly, intact teeth could not be extracted, but loose teeth were easily removed. We did not attempt to impale the unprotected orbit with either the robotic instruments or with the endoscope because it seemed obvious that ocular injury would occur. We recommend exercising great care when placing the robotic arms through the mouth. Additionally, safety goggles may offer increased protection to patients’ eyes.

CONCLUSIONS

Experiments designed to intentionally injure a human cadaver by gross robot device misuse have yielded
promising results. Intact teeth could not be fractured, and attempts to cause tooth injury resulted in either instrument failure (breakage) or alarming of the robot. Forcefully impaling the skin and mucosa with the robotic arms and endoscope (either manually or under robotic control) failed to cause significant injury and resulted in only superficial lacerations. Similarly, the mandible or cervical spine could not be fractured, and attempts to lift the cadaver’s head resulted in alarming of the robot and entrance into a safe mode, precluding further movement of the robotic arms against resistance. During robotic positioning, failure to exercise care around the orbits may result in ocular injury; however, once the instruments are in the mouth, risk to the eye is essentially eliminated. Overall, careful use of a surgical robot in a cadaver model does not appear to add substantially to the typical risks associated with transoral surgery. Further study evaluating patient safety in TORS is warranted and ongoing in our laboratory.

BIBLIOGRAPHY