Forces Applied at the Skull Base during Transnasal Endoscopic Transsphenoidal Pituitary Tumor Excision

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Abstract

Objectives Our laboratory is developing a surgical robotic system to further improve dexterity and visualization that will allow for broader application of transnasal skull base surgery. To optimize this system, intraoperative force data are required. Using a modified curette, force data were recorded and analyzed during pituitary tumor excision.

Design A neurosurgical curette was modified by the addition of a force sensor. The instrument was validated in an in vitro model to measure forces during simulated pituitary tumor excision. Following this, intraoperative force data from three patients during transnasal endoscopic excision of pituitary tumors was obtained.

Setting Academic medical center.

Main Outcome Measures Forces applied at the skull base during surgical excision of pituitary tumors.

Results Average forces applied during in vitro testing ranged from 0.1 to 0.15 N. Average forces recorded during in vivo testing ranged from 0.1 to 0.5 N. Maximal forces occurred with collisions of the bony sella. The average maximal force was 1.61 N. There were no complications related to the use of the modified curette.

Conclusions Forces to remove pituitary tumor are small and are similar between patients. The in vitro model presented here is adequate for further testing of a robotic skull base surgery system.

Keywords

- skull base
- endoscopic
- transnasal
- pituitary
- Cushing adenoma
- surgical robotics
- robot
- sensor
- force

Introduction

As medical technology advances, surgical approaches to the skull base have become less invasive. Where once large, painful, and disfiguring routes (bicoronal, transfacial, translabial, and transseptal incisions) with extensive mucosal dissection were required to reach these areas, the enhanced view provided by rigid endoscopes and high-definition cameras has allowed surgeons to access the skull base via endonasal approaches.[1–4] These approaches have improved visualization,[1,2,5–7] decreased surgical morbidity,[1,8] decreased operative time,[8–10] decreased intensive care unit and overall hospital length of stay,[1,5–7,9] decreased complications,[2,8–12] and lessened the patient discomfort[1,3,5–7,10,13] associated with skull base surgery while maintaining a similar degree of resection and equal endocrinologic and visual

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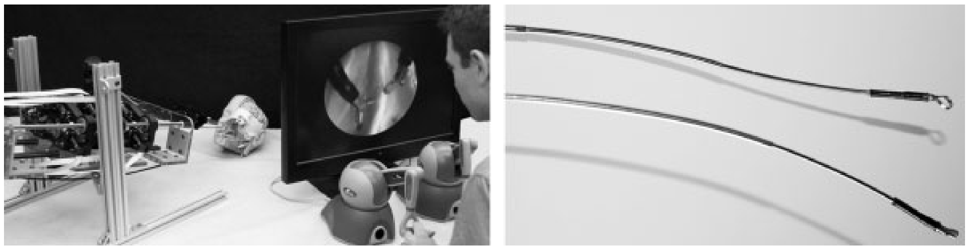

Fig. 1 A prototype robot is shown that comprises two concentric tube robots. Each robot is made of three concentric, precurved tubes that are grasped and actuated at their respective bases. A close-up view of the two robot arms is shown on the left, with a curette and gripper attached to the tips.

outcomes.[2,7,9,14] However, these transnasal endoscopic methods have their limitations. Traditional endoscopic skull base surgery instruments and endoscopes have straight or precurved rigid shafts with limited dexterity. Furthermore, there is limited workspace within the nasal cavity, which multiple implements must share without colliding and without obstructing one another. Finally, rigid endoscopes, though available with various angled lenses,[2,6,15] are still limited in their views and vantage points by their rigid and straight shafts.[16]

To improve surgical dexterity and endoscopic visualization while maintaining noninvasive access to the skull base, we are developing a robotic system for transnasal endoscopic skull base surgery. The robot comprises multiple precurved concentric tubes made from superelastic nitinol that are grasped at their respective bases and translated and rotated with respect to one another (►**Fig. 1**). This creates a tentacle-like motion of the robot arm, and also allows the manipulator to be in the 1-to-2-mm range. This novel surgical robot is described fully in Burgner, Swaney, Rucker, et al.[17]

This robot aims to provide increased dexterity and better visualization and to allow expansion of the role of transnasal endoscopic surgery to larger and more challenging lesions currently unresectable via a transnasal endoscopic route. Parasellar and suprasellar lesions are currently difficult to reach endoscopically[16] and may be more readily and safely reached with a dexterous and flexible robotic system. Previous work has been done using modified surgical tools to determine forces applied to endoscope shafts[18] and forces required to perform various sinusotomies during functional endoscopic sinus surgery[19] simulated in cadaver heads. No previously published study has looked at forces required to remove soft tissue at the skull base in vivo. The force data generated by this type of study are important for improving robot control, providing instrument–body interaction information to reduce or prevent harm caused by the robot, provide useful haptic feedback to the user of the robot, and help to characterize various tissue properties.[20]

Here we describe a novel modification to a standard surgical tool, which we have used to determine the forces applied in vivo at the skull base during transnasal endoscopic pituitary tumor excision surgery. We also present an accurate in vitro model for further study of transnasal surgical excision of pituitary lesions.

Methods

This study was approved by Vanderbilt University Institutional Review Board, IRB #121194 on September 20, 2012. The clinical trial was registered at the U.S. National Institutes of Health ClinicalTrials.gov (NCT01705821) on October 8, 2012. All patients undergoing transnasal endoscopic pituitary lesion excision at Vanderbilt University between the ages of 18 and 75 who were capable of giving informed consent were eligible for study enrollment. Data were collected between October 2012 and December 2012 during transnasal endoscopic pituitary lesion excision in a total of three patients. Patients gave their informed consent, and a copy of the signed informed consent was provided to them.

A standard Hardy transsphenoidal bayonet ring curette (P/N SP0007011, Codman) was obtained and transected at the junction of the grip and the shaft (see ►**Fig. 2a**). Two medical grade sterilizable polyetherimide (Ultem, Quantum Polymers Corp., Newark, Delaware, USA) disks were fabricated to join both ends of the transected curette to either side of a piezoelectric force sensor as well as electrically shielding the tool from the force sensor (Nano-17, ATI Industrial Automation, Inc., Apex, North Carolina, USA). These disks were secured to both ends of the surgical tool using medical grade polyacrylamide (Loctite 4011, Loctite Corporation, Rocky Hill, Connecticut, USA) and three medical grade stainless steel set screws (P/N 90778A022, McMaster Carr, Robbinsville, New Jersey, USA). The disks were then affixed to the

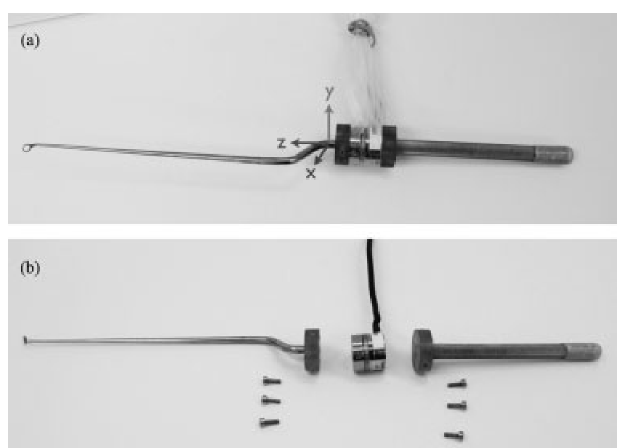

Fig. 2 The modified Hardy ringed pituitary curette is shown above. (a) The tool components disassembled, demonstrating the tip and handle attached to the Ultem disks, the Nano-17 force sensor, and the screws for assembly. The forces were measured using the coordinate frame shown here. (b) The tool assembled with force sensor sheathed in ultrasound probe bag for a sterile in vivo experiment.

parallel faces of the force sensor via a total of six stainless steel screws (P/N 92290A013, McMaster Carr), three for each side of the tool. For each experiment, the modified tool handle and tool tip were placed with an identical spatial orientation with respect to the axes of the force sensor to ensure consistency between trials (►**Fig. 2a**). When assembling the device sterilely for in vivo data collection, the force sensor was first placed into a standard ultrasound probe cover bag, as discussed in the in vivo testing section below (►**Fig. 2b**). The tool was cleaned and sterilized prior to each procedure, along with a stainless steel hex key for assembly of the tool intraoperatively (P/N 5020A21, McMaster Carr), using steam sterilization methods as per Vanderbilt University Operative Services.

In Vitro Testing

Prior to in vivo use during skull base surgery, the tool was tested and data were collected using a phantom consisting of a plastic skull with a defect in the roof of the sphenoid sinus. The sella was filled with a 5:1 mix of water to ballistic test material by weight (Sim-Test, Corbin Manufacturing & Supply, Inc., White City, Oregon, USA). This was then removed through a transnasal endoscopic fashion using the modified Hardy pituitary ringed curette while recording force data using the Nano17 interface provided by the manufacturer. Six datasets were collected.

In Vivo Testing

Intraoperatively, the two curette ends with the affixed Ultem disks, the hex key, and screws were opened onto the sterile field along with a sterile ultrasound probe cover. The Nano17 force sensor was cleaned using standard operating room (OR) surface cleaning wipes and attached to a computer running the manufacturer-provided software via the included cable. The Nano17 sensor was placed into the lumen of the ultrasound cover and the sterile cover was deployed over the wire leading to the computer. Once the bony roof of the sphenoid sinus and the dura were opened by the surgeon in a standard fashion, the curette was then placed into free space in the sphenoid sinus and the sensor was biased (zeroing out any confounding forces from tool tip weight) using the software interface. Force and torque data were then recorded by the data-acquisition system while the pituitary tumor was resected in a standard fashion. Three datasets were collected during each operation. Collisions with the bony skull base were noted. Once the tumor was adequately resected, the tool was handed off of the surgical field and was disassembled and washed for reprocessing. Data were collected during the surgeries of three patients.

The data were analyzed and graphics were created using both Matlab (MathWorks, Natick, Massachusetts, USA) and Excel (Microsoft, Redmond, Washington, USA). Periods of known soft tissue and bony collisions were noted as shown in ►**Fig. 3**, and this data were analyzed to determine the mean, maximum, and standard deviation of force during both soft tissue and bony collisions for each case and between cases.

Results

Results were obtained during six phantom pituitary lesion resections using 5:1 water to ballistic test material and during three operative procedures in patients.

Raw force data were collected over time for both the in vitro and in vivo experiments. A representative dataset from the third surgical patient is displayed in ►**Fig. 3**. In this example dataset, spikes in the z-axis force are attributed to collisions of the tool tip with bony structures at the sella. The average x-, y-, and z-axis forces from each of the patients (Patients 1, 2, and 3) and phantom systems (in vitro test) are

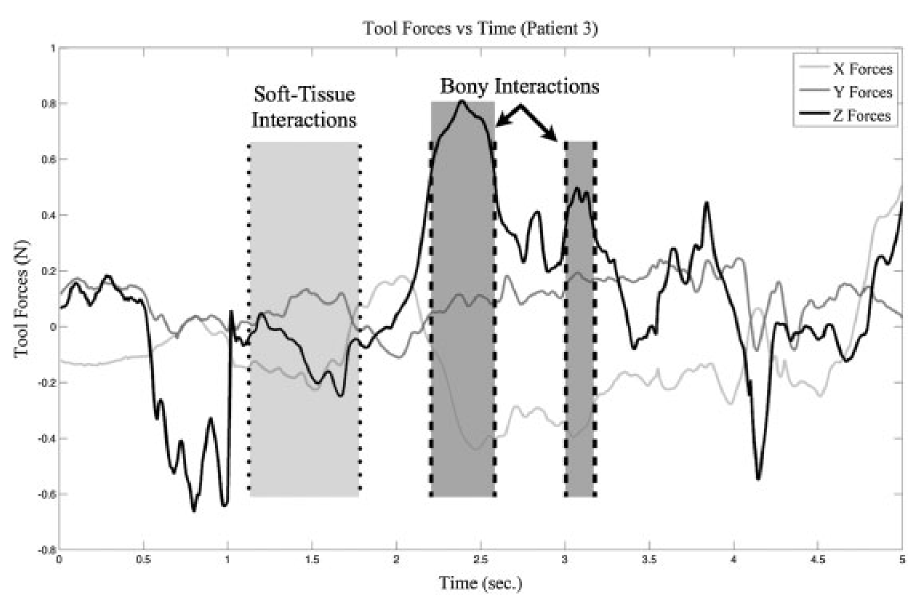

Fig. 3 The tool tip forces collected in the operating room for a 5-second data collection are shown. Note the soft tissue and bony collisions delineated above.

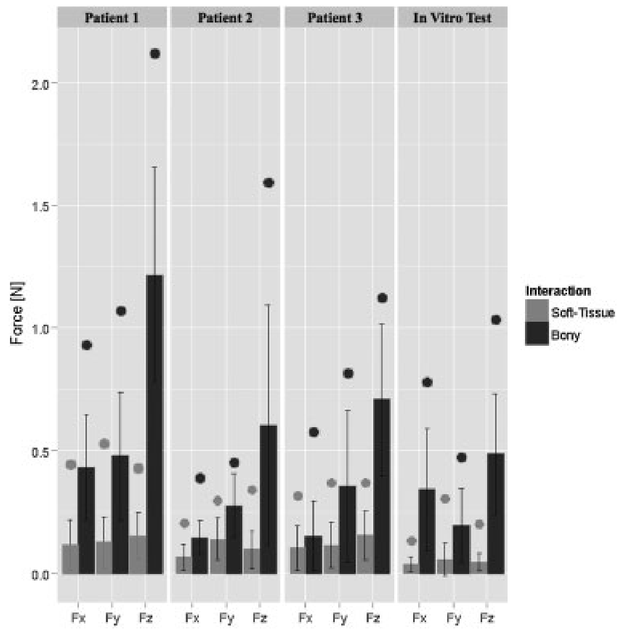

Fig. 4 The average x, y, and z forces for both soft tissue and bony interactions are shown for each patient as the height of the bars. The error bars display the standard deviation of each set, and the maximum value of each force set is indicated by the dot above the bar.

shown in ►**Fig. 4**. Maximal forces for each case are also displayed. All maximal forces were encountered along the z axis. The mean forces are quite small in all cases, with mean forces between 0.1 and 0.5 N in all three axes. ►**Table 1** displays the average force data and standard deviation after pooling all the data from the three in vivo experiments. The maximal force encountered during testing was 2.12 N during surgery on Patient 1. The average maximal force between in vivo datasets was 1.61 N. These maximal forces did not result in any violation of the bony skull base or dura. Maximal forces occurred with collisions of the tool tip with bony structures at the sella. There were no intraoperative or postoperative cerebrospinal fluid leaks identified. There were no adverse events associated with the use of this modified ring curette in vivo during surgery.

In the in vitro experiments, the average forces required to remove tissue were slightly lower as compared with the in vivo experiments. Force values were in the 0.10 to 0.15 N range in the x, y, and z axes (►**Fig. 4**). The maximal force was similar to the in vivo experiments and was associated with bony collisions.

Table 1 Pooled average force and variance data

	X axis	Y axis	Z axis
Soft tissue interaction			
Average force (N)	0.097	0.12	0.13
Standard deviation (N)	0.088	0.096	0.094
Bony interaction			
Average force (N)	0.23	0.36	0.82
Standard deviation (N)	0.19	0.26	0.48

Discussion

Transnasal endoscopic resection is rapidly becoming the preferred approach for treatment of pituitary lesions. This method has been shown to be less invasive and less painful along, and to significantly decrease the duration of hospital stay. The degree of surgical resection and endocrinologic results of the transnasal approach have been shown to be similar to more invasive methods. Despite these benefits, there are still limitations to this technique related to surgical instrumentation, limited work space, and visualization. Also, there are only a handful of centers able to provide this treatment option due to the specialized training and equipment required to perform this type of surgery. We aim to develop a dexterous concentric tube robotic system that can operate at the skull base with improved visualization. With this robot we aim to expand the capabilities and precision of the transnasal endoscopic skull base surgeon, allowing the delicate removal of tissues in all areas of the skull base and nasal cavity.

To optimize this robot for pituitary lesion excision, the mechanics of this procedure must be understood. Here we determine the typical forces through the use of a novel force-sensing Hardy pituitary curette in vivo during transnasal endoscopic transsphenoidal hypophysectomy. To our knowledge, these are the first published data using a force sensing tool during pituitary lesion excision in vivo. With this information, the engineers on our team are able to optimize the tube diameter and wall thickness of the concentric tubes. The aim is to minimize the size of these arms as much as possible so as many as four robotic arms can be present in the endonasal workspace at any given time without colliding with one another while ensuring that they are rigid enough to successfully remove the desired tissue. Knowing the typical forces required to remove pituitary tumor tissue provides a starting point to build safety algorithms that prevent the robot from exerting dangerous forces that may damage surrounding structures such as the optic nerve and carotid artery and prevent unwanted penetration of the instrument through bone, dura, or other anatomical barriers at the skull base. Based on the results presented here, average forces during soft tissue excision of pituitary lesions are in the 0.1 to 0.5 N range in the x, y, and z directions. Maximal forces tended to occur in the z direction, especially with bony collisions and peak at 2.12 N in the in vivo experiments. In our patients, at the specific locations in the sella where these values were obtained, there were no adverse events due to these peak forces. Bone thickness and strength varies throughout different regions of the skull base and expansile masses in the skull base may lead to abnormally thin areas. In the future, in a robot equipped with force sensing, the maximal force applied on the bone by the robot could potentially be limited automatically by feedback control, preventing it from exceeding a specific threshold.

Here we also examine the use of ballistic test material in the sella of a preserved or plastic skull in a test model for further evaluation of this robot. Based on comparison of in vivo and in vitro force data, we find that 5:1 water to ballistic test material reasonably approximates the in vivo situation. The average forces required to remove the test material are at the low end of the range for the in vivo data. We also note that the ballistic test material can be made with increasing stiffness depending on the quantity of water introduced.

The surgeon found the sensorized tool to feel and behave like a standard Hardy pituitary curette and did not find the bagged sensor and wire leading from the surgical field to be bothersome or inhibit dexterity or mobility of the tool. The surgeon felt that other surgical tools used during this and other surgeries could be similarly modified and used to gather data without significantly altering the ability to use the tools in a standard fashion.

Future work using a force sensor that is more distally located on the curette tip may give more accurate force data and remove nasal sidewall interactions; however, there is not currently a commercially available sterilizable force sensor that is small enough to place at the curette tip. Also, further work investigating forces required to violate vital structures in cadaver skulls (dura, skull base, carotid artery, and optic nerve) may prove beneficial in determining safety parameters for robotic transnasal endoscopic skull base surgery.

Conclusion

We believe that the use of sensorized standard surgical tools is a useful method for aiding in the design of surgical robots. Here we determine average forces during excision of pituitary tumor resection. This method enables the safe and effective application of this emerging technology to advancing the treatment of surgical patients.

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