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Endonasal endoscopic transsphenoidal approach robot prototype: A cadaveric trial

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ABSTRACT

Background: The Endonasal Endoscopic Transsphenoidal Surgery (EETS) is a minimally invasive procedure to approach and remove pituitary tumors and other sellar lesions. The process causes less pain, faster recovery, and provides further minimal invasive access in critical cases. However, a slight deviation of tools from the target area can be fatal to the patients. The aim of this study is to design and develop a prototype robot to demonstrate neurosurgical robot-assisted EET approach.

Methods: The effectiveness of a prototype robot in executing a minimally invasive EET surgery was studied in 6 cadavers. The robot was associated with a multi-information integrated technique for surgery including QR code tracking. The robot was controlled and driven by the neurosurgeon.

Results: The standard procedure of EET was followed and the robot carried out the first stage of EET under the supervision of neurosurgeon. Finally, the sellar was reached by the neurosurgeon. The result was determined by qualitative analysis and was confirmed by the neurosurgeon. The time for the entire EET surgical procedure showed marked reduction compared to the traditional EET approach.

Conclusion: The robot design was found to be technically feasible and hence can be used for assisting the EET procedure. The robot used was able to assist the neurosurgeon correctly to approach the sinus.

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1. Introduction

Pituitary adenoma is a slow-growing benign tumor in the pituitary gland, which is a small, oval-shaped gland located in the sella turcica of the brain, just behind the bridge of the nose.¹ According to National Institute of Health (NIH), USA, approximately 1 in 10,000 people develop pituitary tumor.² Pituitary adenoma is curable normally and the surgical resection is the most common choice to remove the tumors >1 cm in diameter.^{2,3} Traditional craniotomy or transcranial surgery is one method to remove pituitary tumors and other skull base tumors. However, this surgical approach requires a large opening to be made in the skull or cranium of the patient to access the brain leading to the risk of

postoperative brain swelling or blood clot as well as a long healing time.^{2,3} The advancement in modern neurosurgical techniques emphasizes utilizing minimally invasive procedures for the management of sellar and parasellar lesions since they are less traumatic and result in faster recovery.^{2,4} The Endonasal Endoscopic Transsphenoidal Surgery (ETSS) is a novel minimally invasive technique that is being widely used by the neurosurgeons nowadays for the treatment of pituitary adenoma and other intersellar lesions.⁵

In 1963, Guiot first proposed the use of an endoscope to overview the contents of the sella turcica in the course of conventional transsphenoidal approach.⁶ Later, Jho et al described 'pure' endoscopic endonasal transsphenoidal surgery using endoscope as a stand-alone visualizing instrument to envision the surgical route and the target region of the surgery.^{6,7} The EETS does not require brain retraction and is the least traumatic route to the sella turcica with minimum post-surgical complication rate.^{7,8} EETS provides a widened field of visualization of the pituitary gland and associated

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intersellar lesions,⁸ thus allows temporal and spatial surgical manipulations. EETS is a quite complicated surgery requiring experienced and skillful neurosurgeons with in-depth anatomical knowledge. There are two processes involved in EETS; the first one is the sphenoid sinus approaching process and the second one is the tumor removal process.^{1–5} The first process of EETS has three phases:

- i) The *nasal phase*-when the endoscope and surgical tools are introduced through the selected nostril then passed through the nasal cavity and finally progressed to the sphenoethmoid process
- ii) The *transsphenoidal phase*-involves the dissociation of the nasal septum from the sphenoid rostrum and removal of sphenoid septa
- iii) The *sellar phase*-The sella is present at the back wall of the sphenoid sinus. The vomer bone is opened to expose the sella turcica present at the sellar floor. As the sellar floor is opened the lesion or tumor can be reached (Fig. 1).⁷

Represented from: Chumnanvej et al, 2019[5].

The sphenoid sinus approaching process is quite time consuming; takes more than an hour and has a higher risk of causing damage to the nasal mucosa even with a slight deflection.^{1–5} Tumor removal is a lengthy procedure that takes about 2–4 h and accurate movement of surgical tools is mandatory during this process.^{1–5} Since the entire procedure is taking place inside the brain, and important vascular and neurological structures, such as cavernous sinuses, cranial nerves, optic nerves, and carotid arteries are adjacent to the sella turcica (Fig. 1)², a slight deviation from the EETS pathway can lead to serious post-operative complications including intrasellar, nasal, and endocrine system complications.^{1,2,5} The limitations of the traditional EETS can be circumvented by application of surgical-assisting robot. The robot can provide enhanced precision to hit the exact target area, increased surgical dexterity, reduced surgical time and technical complexity of the procedure,^{1,3} thereby allowing the surgeons to concentrate properly on the surgery.² Additionally, the robot allows single insertions instead of multiple insertions, which lowers the risk of damaging nasal mucosa.⁵ Therefore, robot-assisted EETS would increase patient safety and improve patient outcomes following surgery.^{2,9} Although different specialties such as urology, gynecology, and colorectal surgery make use of the advantages of this robotic assistance, the neurosurgeons and skull base surgeons have not much exploited the surgical robotic system and there remains paucity of literature about robot-assisted EET case report and cadaveric studies.¹⁰

The overall goal of the present study was to demonstrate the neurosurgical robot-assisted EET approach. The main focus was to design a robot that would maintain a stable and steady trajectory and reach the target along with the surgical tools, keeping in mind

the technical feasibility. The fluoroscopy was used to monitor the EET pathway and the fluoroscope images were obtained through the connected computer systems. And also, this robot would be clinically available with Quick Response (QR) code tracking (Open Source Computer Vision Library). The multi-information integrated tactics for surgery (MINITS) is proposed for this robotic tracking system. The robot would be operated and controlled by the neurosurgeon, thereby lowering the risk factors related to the non-guided machine. The indication is the dominant approach to the sellar area particularly pituitary adenomas.^{11,12} This study is intended to decrease the risk factors and constraints of the traditional EETS approach.

2. Methods

2.1. Importance of surgical robot for EET approach

Even though many robotic systems have been developed for natural orifice surgery and intravascular interventions, only a few systems are involved in endonasal surgery.³ This is mainly because the dimension of the nose is much smaller than natural orifices (throat, abdominal port, etc.) and the tool diameters of the conventional surgical robots are quite large. Hence, it is challenging to coordinate multiple tools with wide diameters in the narrow area of the nasal cavity.¹ The objective of prototype robot systems (non-commercial, non-FDA approved) designed for EET approach were to provide patient safety, facilitate endoscope manipulation, and control via MINITS system,¹³ thus decreasing the technical barriers to reach the sphenoid sinus.¹

2.2. Design and development of EET-guiding robot

In order to investigate the feasibility and advantages of a prototype robotic system in performing EETS, experiments in this study were conducted on cadavers following standard EET procedure. The components of the robot-aided system included pre-operative planning system, a robotic system to assist in holding and carrying the surgical dissector along the surgical trajectory, and the control station (Fig. 2). The robot can be controlled by the neurosurgeon via a computer and a controller. Technological advancements facilitate the use of computer integrated surgery (CIS) in modern surgical system (2). Accordingly, the designing of the prototype robot in this study was based on the surgical computer-aided design (CAD) and computer-aided manufacturing (CAM) systems to allow it to work together with pre-operation and intra-operation systems.¹ The dimension and orientation of EETS pathway required for the intraoperative system were obtained from medical images of the patient in the preoperative system and then the computer assisted the surgeon in planning relevant intervention.^{2,14} The neurosurgeon performed the surgical procedure under the guidance of the computer utilizing robotics.¹⁴



Fig. 1. Location of pituitary gland; Pathway of Endonasal endoscopic transsphenoidal surgery Represented from: Chumnanvej et al, 2019[5].

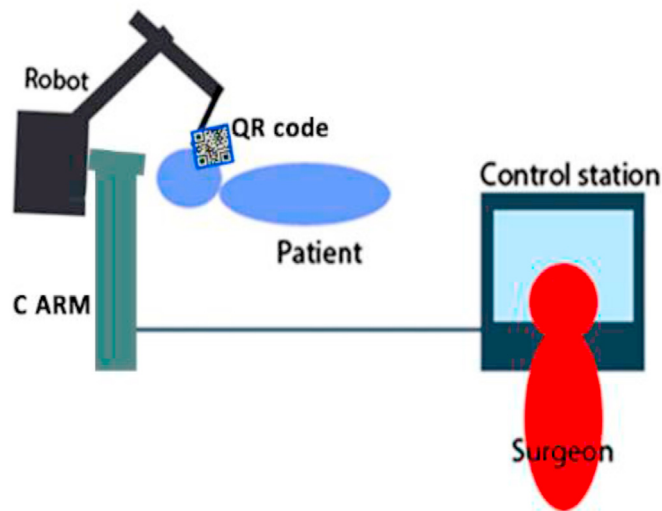


Fig. 2. The components of robot aiding system for endoscopic transsphenoidal surgery. Represented from: Suratriyanont and Suthakorn, 2013^[14].

2.3. Pre-operative 3D model of workspace

The pre-operative model of workspace, which gives the overall picture of the anatomical structure is important for planning the surgery.¹⁵ The ‘workspace’ is the area where the neurosurgeon operates safely and the workspace is designed according to the neurosurgeon’s knowledge on clinical anatomy and also after the performance of simulation or cadaveric study under the image guidance techniques (CT and MRI scan images) during the pre-operative stage. The bone structure of the workspace can be visualized by the CT images whereas soft tissue and vein can be observed in MRI images. A 3D model of the anatomical structure is crucial for the surgeon to warranty patient safety during robot-assisted surgery.¹⁵ In this study, a 3D model of the surgical workspace was created by using a set of CT images in order to plan and navigate the robot’s path. Then a robotic software system was used to calculate the distance to be traveled and trajectory-to-target workspace within the brain and also to guide whether to reach the sella turcica or around the anterior cranial fossa. The path of surgery is a straight line consisting of the entry point of a nostril, nasal septum, vomer, and sphenoid sinus (Fig. 1).¹⁵ ‘Virtual fixtures’ were employed to constrain the motion of the medical tools so that they remain within the safe zone as defined in a preoperative CT scan. The navigation system with MINITS and the robot together confer stability along the surgical trajectory and also prevent the surgical instruments from going beyond the safe area.¹⁵ The pre-operative planning is, therefore, the principle aspect of the robot-assisted surgery.

2.4. Mechanism of the prototype robot

The robot used to guide EET surgery in this study was based on a remote center of motion (RCM). The concept of RCM has been developed to improve dexterity and to prevent potential damage to the body tissue by the robot thereby directly linked with patient safety.^{16,17} Hence, RCM generation is prerequisite for the robots used in minimally invasive surgery.¹⁷ The robot must provide RCM at the entrance of the nostril, which is the mechanical constraint of the surgery.¹⁸ Accordingly, the robot in the current study was RCM based to allow pitching and yawing movements around the incision port. The cone-shaped workspace had a maximum angle of 90°

with 10–12 cm space for the insertion. The robot also contained tool adaptor, in order to facilitate the changing of multiple tools during the surgical procedure. The robot was based on a parallel-gram mechanism. The degree of freedom and the range of motion are the two limiting factors for designing the prototype robot. Generally, DOFs of surgical robots comprise of two parts: i) setting up of initial position and ii) movement during operation.² Usually, a guided robot with parallel mechanism has 4 degrees of freedom (DOF); 2 DOFs for translation motion and 2 DOFs for rotation motion. This is because of small workspace and increased precision and accuracy in EETS.¹ Consequently, the EET guiding robot in this study comprised of 2 movement parts; the first is 3 active-DOFs; 2 DOFs are for translations and 1 DOF for surgical tool insertion. The second part is 1-passive DOF responsible for rotations around the tool axis. Fig. 3 shows the robot design. The RCM based robot design in this study with 4 DOFs is advantageous for ETSS as it provides rigidity, precision, and accuracy. EPOS 24/2 from Maxon Motor™ was used as the control system of the prototype robot. The neurosurgeon was controlling the robot using the joystick with teleoperated mode (Figs. 2, 4 and 7). During the operation, the neurosurgeon; the first author (SC) was driving the joystick as sagittal and coronal plane visualized under the Multi-Information Integrated Tactics for Surgery or MINITS. MINITS is the tactics to acknowledge not only the imaging but also the other information that role the surgical achievement and coupling of much information to target during surgery. In this present study, MINITS is

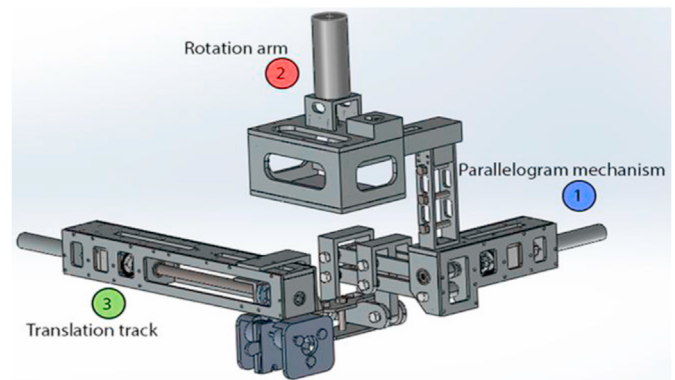


Fig. 3. EET-guided robot operating on parallelogram mechanism. The parallelogram mechanism is shown in blue (labelled 1), rotation arm is shown in red (labelled 2), and translation track is shown in green (labelled 3).

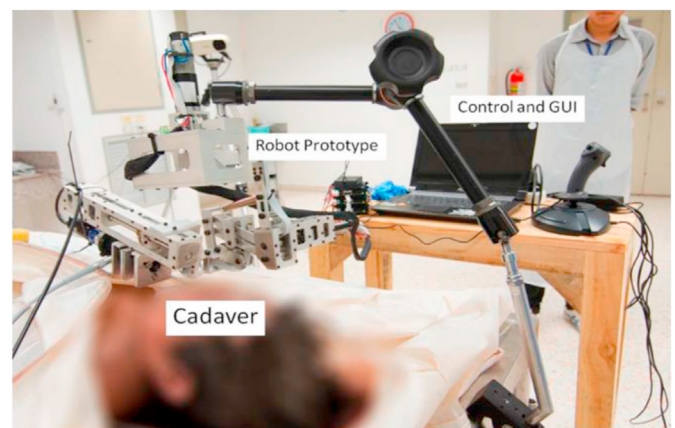
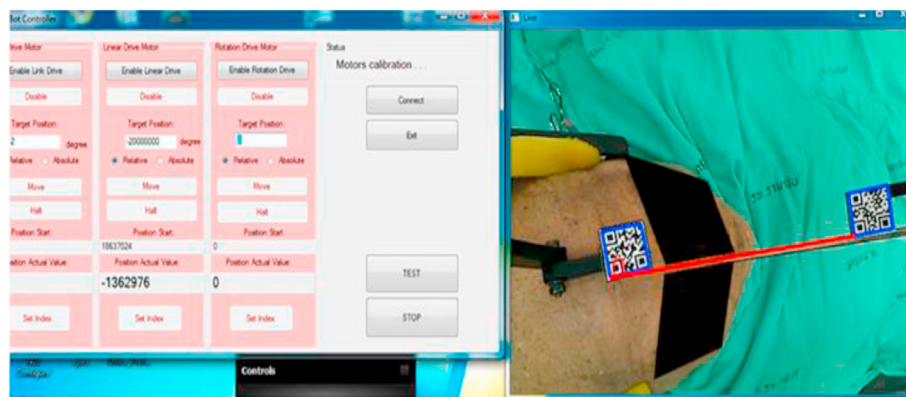


Fig. 4. The position of the cadaver and the orientation of the robot prototype.



QR Code Tracking from Monitor Display View

Fig. 5. QR code tracking system (Open Source Computer Vision Library). The system is associated with the robot guiding EETS. The QR code is displayed on the monitor.

including x-ray imaging laterally and QR code in coronal plane. As a result, an information data set is exercised and renders all data. The reliability of the extraction process largely determines the utility of the resultant information to target safely and precisely.

2.5. EET cadaveric trial set up

To verify the feasibility of using a prototyped robot in assisting EETS, a preliminary trial was conducted on six human cadavers without any previous history of head trauma or craniofacial surgery. The cadavers were dissected with the approval from the Ethics Committee. Each cadaver was used for one experiment; thus 6 experiments were performed. The 6 cadavers were operated using robotic-assisted EET approach following the standard technique. After the cadaver was positioned supine, the nostril was identified, and the cylindrical robotic arm was inserted through the nostril via automatic mode (Fig. 4).

2.6. QR code tracking system

The QR code tracking system (Open Source Computer Vision Library) is the open source. In addition, it was placed on the shaft of the trocar, which was then attached to the base of the robot. This

helped to navigate the anteroposterior axis of the skull and to keep the robotic arm in the midline. The QR code tracking system (Open Source Computer Vision Library) was used only in the initial set-up process and the data was obtained from the Monitor Display view (Figs. 5 and 6). To obtain the lateral view of the robotic arm reaching the target (the sphenoid sinus) C-arm was kept laterally (Fig. 7). The workflow of this QR code processing is including 1) the region of interest is detected for 2 QR codes in the acquired images under video camera guidance. 2) Afterward, each detected QR code is decoded. 3) The extracted QR code will be an input for the estimated position. 4) Then, the code structures will be computed as corresponding points. 5) The position and coordination are predictable. As a result, this will display on the monitor for the neurosurgeon to drive the robotic arm (Figs. 5 and 6).

2.7. Determination of the accuracy and precision of the robotic system

The insertion speed, which is the speed with which the robot inserted the trocar through the nostril to reach the target, was maintained at a constant rate of 64.3 mm/min. Thereafter a motor was used with a strong force to maintain the direction of the surgical tool. The tool was introduced from the nasal columella to the



QR Code Tracking from Monitor Display View

Fig. 6. QR code tracking system (Open Source Computer Vision Library) associated with the robot guiding EETS. QR code tracking from monitor display view.



Fig. 7. The EETS experiment on cadaver. a) The prototype Robotic system assisting the neurosurgeon in the EET approach; b) The overview of the operating room with the position of the whole team consisting of neurosurgeon, assistant1, assistant 2, biomedical engineer and the orientation of the cadaver and robotic system during EETS robotic approach.

sphenoid sinus base. The neurosurgeon controlled and monitored the entire robot-driven process (Fig. 7). All 6 cadavers were checked to detect whether the robot reached the target; sphenoid sinus, accurately and precisely. This is a qualitative evaluation by the neurosurgeon (SC) under endoscopic guidance (Fig. 8). With the endoscope, the neurosurgeon confirmed that the robot had reached the target accurately. As a result, the sellar was reached by the neurosurgeon with the guidance of the robotic system. This was followed by the closure of the surgical wound.

3. Results

To detect the performance of the developed robot in EETS, 6 cadaveric trials were set up. The time for the initial set up process,

the duration of operation, and duration of fluoroscopy for each experiment were shown in Table 1. The time for setting up process and docking the robotic arm was quite long (>180 min) in experiment 1; however, the time for initial set up decreased significantly in subsequent experiments. In experiment 2, the initial set up process took 180 min, which progressively reduced to 40 min, 30 min, and less than 30 min in experiments 3, 4, 5, and 6 respectively. In experiment 1, duration of operation was 30 min. Nonetheless, the operation time reduced in experiments 2 through 6; in experiments 4 and 5 the duration of surgery was only 1.10 and 1.31 min respectively. In experiment 1, more than 20 times fluoroscopy was performed with the duration of fluoroscopy being 0.59 min (or 35.4 s). In later experiments, the fluoroscopy was performed for lesser number of times (15 times in experiments 2

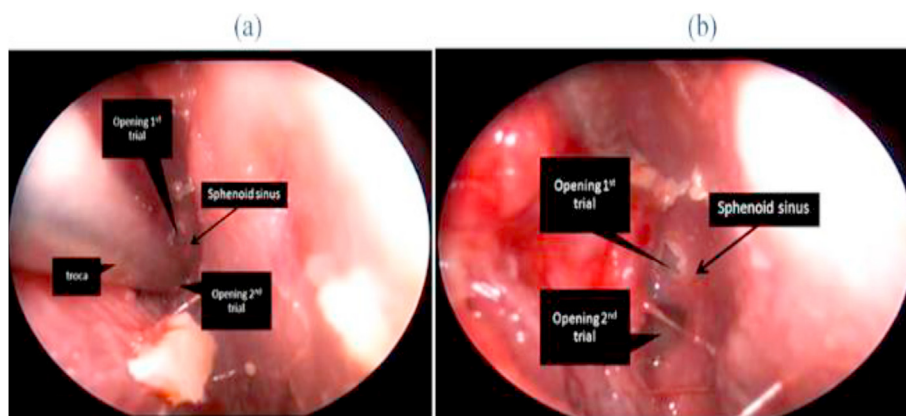


Fig. 8. a) The trocar was inserted and reached sphenoid sinus under the robotic assistance; b) The sphenoid sinus was opened on the first and second trial.

Table 1
Results of the cadaveric trials using prototype robot to assist Endoscopic Endonasal Surgery.

Experiment	Setup Process	Operation			
	Time (min.)	Duration of operation (min.)	Fluoroscopy Time (times)	Duration of fluoroscopy (min.)	Distance (mm.)
1	>180	30	>20	0.59	85.31
2	180	4.06	15	0.47	84.26
3	40	4	15	0.41	80.22
4	30	3.07	10	0.23	73.97
5	<30	1.10	4	0.20	59.05
6	<30	1.31	4	0.20	66.46

'Distance' refers to the distance between nasal columella and the sphenoid sinus.

and 3, 10 in experiment 4, and only 4 times in experiments 5 and 6) along with reduction in duration of fluoroscopy (0.47 min in experiment 2 and only 0.20 min in experiments 5 and 6). The distance between the nasal columella and the sphenoid sinus (the target) was measured for each experiment by determining from the encoder of Maxon Motortm and was shown in Table 1.

The accuracy and precision of the robotic system were determined qualitatively. The robot arm was found to reach the target accurately in all cadavers (Fig. 8) and this information had been confirmed by the neurosurgeon.

4. Discussion

The endoscopic endonasal transsphenoidal approach is a safe, efficacious, and minimally invasive technique for the treatment of intrasellar lesions and pituitary adenomas.¹⁸ The transsphenoidal midline route is the shortest pathway to reach the intrastellar region of the brain and also offers a reasonable workspace with lower complications and mortality rate.¹⁹ The endoscope provides enhanced illumination and panoramic wide-angled view of the suprasellar and parasellar portions of the pituitary lesion and allows looking “around the corner”.¹⁹ Even though during the initial introduction of this technique, insertion of an endoscope in the intrasellar region was a major challenge to the surgeon, with the current progress in medical technology, the endoscope introduction is no longer challenging.⁵ The development of surgical techniques and improvement of instruments made EETS a promising approach; however surgical difficulties and instrument dexterity are some of the practical limitations of this procedure.¹⁶ The surgeons have to be extremely proficient since they operate on a narrow working area. Additionally, they must be able to reach the exact target area during the operation, as the pituitary gland remains surrounded by important vascular and neural structures a slight deviation of tools can lead to adverse consequences.² This indicates the necessity for new instruments and modalities to assist the neurosurgeons.¹⁸

Robotic technology is now considered to be a vital modality for EETS.¹⁶ Nonetheless, the routine use of robots has not been observed for endoscopic sinus and skull base surgery. Some of the preclinical research teams are working at present to develop prototype robots; however, the design of these proposed robots are not entirely satisfactory to be used routinely. For designing a robot to guide EETS, following important points should be considered: i) the robot must be useful; the automation of the task must save time for the surgeon and enhances the surgeon's competence, ii) the robot must be reliable i.e. must have in-depth knowledge of workspace and types of interactions occurring between the instruments it holds and the tissues, and iii) the robot must be very small in size, which allows easy installation of the robot in the operating room and also can be maneuvered easily by the surgeon.²⁰ Keeping these points in mind, the present study aimed to design a prototype robot to guide the neurosurgeon in the EET procedure using cadavers.

This is probably the first cadaveric trial to research on sphenoid sinus, which is located in the sphenoid bone near the optic nerve and the pituitary gland. The results of all 6 experiments showed a significant reduction in the initial setup process and the time of operation compared to conventional EET approach. Experiment 1 took a long time for setup as well as operation. From Experiment 2 to 6 the total time for EETS was lowered most probably due to getting better experienced in MINITS. Duration and number of X-ray shots and radiation exposure were also diminished as obtained from fluoroscopy data. The reduction of the time period of EET using EET guided robot in this study is quite significant indicating the efficiency of the robot in saving the time of neurosurgery.

Moreover, reduced exposure to X-rays is beneficial as this would prevent the patient from the harmful effects of radiation. Normally, while performing traditional EETS, the neurosurgeon should be aware of the intrasellar anatomical variations along with the surgical workspace and the target region and it is very difficult to detect the sphenoid sinus base accurately from the endoscopic view.⁵

The distance between the nasal columella and the anterior wall of the sphenoid sinus is considered as a surgical landmark to explore the sellar floor.²¹ The base of the nasal columella is fixed and the distance from the base of the columella to the anterior wall of the sphenoid sinus provides the specific distance to be traveled by the robot to reach the sphenoid sinus aperture, which is the primary entry point to the sphenoid sinus during surgery.²² Different studies showed that the distance between columella root and inferior wall of the sphenoid sinus to be approximately ranging between 64 mm and 77 mm.^{21–23} This study detected the distance of columella to the sphenoid sinus and the values obtained in most of the experiments were within the range of the previously detected values.

Another key finding of this study is that the prototype robot with the surgical instruments was able to reach the sphenoid sinus accurately and precisely in all 6 cadavers. This is immensely important as this would provide the surgeon convenient and efficient workspace and a stable pathway to perform surgery accurately and ensure patient safety. The main limitation of this study is the small sample size; only 6 cadavers were used, and this small number of specimens may result in variation between the experiments. Another limitation is that soft cadavers, preserved below 0 °C without formalin were used. The workspace in this type of cadaver is slightly broader compared to the living person as the soft tissue shrinks. Hence, some differences would definitely exist between the robot-assisted EET in cadaveric trials and real-time surgeries.

5. Conclusion

The present study describes a new neurosurgical approach using a robot prototype. The study demonstrated designing a robot capable of guiding the neurosurgeon in executing a minimally invasive EET surgery on cadavers. The technical feasibility of robot-assisted EET approach was examined. The robot would be clinically available with the multi-information integrated tactics for surgery (MINITS) as the robotic tracking system. The robot was completely controlled by the neurosurgeon. The most remarkable finding of this study was the ability of the robot arm to reach the sphenoid sinus (the target area) accurately and precisely in all 6 cadavers via a single time insertion. The total time of EET, including initial set up process and duration of operation, was significantly lower (except in experiment 1 and 2) compared to the usual EETS. The robot used was able to assist the neurosurgeon correctly to approach the sinus. The prototype robot in this study can be considered to be a unique modality for EET approach and is beneficial for both the neurosurgeons and the patients. Future research needs to be directed towards designing next-generation robots most appropriate for EETS.

Ethical approval

Cadaveric based experiments were conducted and an Ethical approval statement is enclosed as an electronic supplementary material.

Declaration of competing interest

The authors declare that they have no known competing

financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.asjsur.2020.08.011>.

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