Initial experience with a robotically operated video optical telescopic-microscope in cranial neurosurgery: feasibility, safety, and clinical applications

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OBJECTIVE The move toward better, more effective optical visualization in the field of neurosurgery has been a focus of technological innovation. In this study, the authors' objectives are to describe the feasibility and safety of a new robotic optical platform, namely, the robotically operated video optical telescopic-microscope (ROVOT-m), in cranial microsurgical applications.

METHODS A prospective database comprising patients who underwent a cranial procedure between April 2015 and September 2016 was queried, and the first 200 patients who met the inclusion criteria were selected as the cohort for a retrospective chart review. Only adults who underwent microsurgical procedures in which the ROVOT-m was used were considered for the study. Preoperative, intraoperative, and postoperative data were retrieved from electronic medical records. The authors address the feasibility and safety of the ROVOT-m by studying various intraoperative variables and by reporting perioperative morbidity and mortality, respectively. To assess the learning curve, cranial procedures were categorized into 6 progressively increasing complexity groups. The main categories of pathology were I) intracerebral hemorrhages (ICHs); II) intraaxial tumors involving noneloquent regions or noncomplex extraaxial tumors; III) intraaxial tumors involving eloquent regions; IV) skull base pathologies; V) intraventricular lesions; and VI) cerebrovascular lesions. In addition, the entire cohort was evenly divided into early and late cohorts.

RESULTS The patient cohort comprised 104 female (52%) and 96 male (48%) patients with a mean age of 56.7 years. The most common pathological entities encountered were neoplastic lesions (153, 76.5%), followed by ICH (20, 10%). The distribution of cases by complexity categories was 11.5%, 36.5%, 22%, 20%, 3.5%, and 6.5% for Categories I, II, III, IV, V, and VI, respectively. In all 200 cases, the surgical goal was achieved without the need for intraoperative conversion. Overall, the authors encountered 3 (1.5%) major neurological morbidities and 6 (3%) 30-day mortalities. Four of the 6 deaths were in the ICH group, resulting in a 1% mortality rate for the remainder of the cohort when excluding these patients. None of the intraoperative complications were considered to be attributable to the visualization provided by the ROVOT-m. When comparing the early and late cohorts, the authors noticed an increase in the proportion of higher-complexity surgeries (Categories IV–VI), from 23% in the early cohort, to 37% in the late cohort ($p = 0.030$). In addition, a significant reduction in operating room setup time was demonstrated ($p < 0.01$).

CONCLUSIONS The feasibility and safety of the ROVOT-m was demonstrated in a wide range of cranial microsurgical applications. The authors report a gradual increase in case complexity over time, representing an incremental acquisition of experience with this technology. A learning curve of both setup and execution phases should be anticipated by new adopters of the robot system. Further prospective studies are required to address the efficacy of ROVOT-m. This system may play a role in neurosurgery as an integrated platform that is applicable to a variety of cranial procedures.

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KEY WORDS robot; ROVOT-m; cranial microsurgery

ABBREVIATIONS AVM = arteriovenous malformation; EBL = estimated blood loss; ICH = intracerebral hemorrhage; MCA = middle cerebral artery; PCoA = posterior communicating artery; PICA = posterior inferior cerebellar artery; ROVOT-m = robotically operated video optical telescopic-microscope; RPS = relative positional sense; VS = vestibular schwannoma.

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TECHNOLOGICAL innovation is an important driver in the development of new medical procedures and surgical techniques. The concept of robotics and integration especially has been a recent topic of interest in the surgical realm, with an effort to create more efficient operative platforms.^{6,13}

The development of surgical robotic devices is founded on the principle of a human-machine interface, which is integral to the definition of a robot. By programming an integrated computer unit, this platform can be referred to as human-computer-machine interface. We consider surgical robotics in the following 3 broad classifications: 1) Detectors are robotic devices that enhance optical visualization, i.e., equivalent to the human eye. 2) Effectors are robotic devices that enhance dexterity, maneuverability, and scale motion, i.e., equivalent to the human hand. 3) Integrative/intelligent robotic devices capture information through iterative processes and are able to predict and define a series of steps, based on this “learned information,” i.e., equivalent to the human brain. Explicitly, detector, effector, and integrative systems may also be referred to as “robotic eyes,” “robotic hands,” and the “robotic mind,” respectively.

Historically, interest in surgical robotics has been primarily focused on effector robots for the purposes of enhanced dexterity and superior micromanipulation. Such devices have been recently introduced into other surgical subspecialties.^{7,10,11,21} However, as noted by Peter Jannetta, one of the first neurosurgeons to document and integrate the microscope into neurosurgery in 1968, “... the hand cannot perform if the eye cannot see...” (personal communication).²⁵ This may have been why the development of effector robots in neurosurgery has been profoundly limited; specifically, inadequate visualization has been a rate-limiting step. In other words, the enhanced maneuverability that might be achieved by effector robotic devices would only become valuable once the visualization scale demands it. Therefore, the first step toward a meaningful integration of robotics into neurosurgery should focus on the detector system, followed by the effector.

Enhanced visualization represents the very essence of microscopy (from the Ancient Greek: *mikros*, “small” and *skopein*, “to look”). This can occur with binocular visualization with conventional stereoscopic microscopes or other alternative systems.^{18,28} In this report, we present the application of a novel detector system, namely, the robotically operated video optical telescopic-microscope (ROVOT-m; BrightMatter Servo System, Synaptive Medical). Specifically, within this optical chain, 3 individual components were designed in an attempt to leverage the synergistic performance of the overall chain: 1) The payload: telescopic-microscope (BrightMatter Vision). This is an exoscope, distinct from existing stand-alone exoscopes, in that it is purpose-built for the ROVOT-m. 2) The navigation system: (BrightMatter Guide). This system creates an automated human-machine interface, tracking the relative position of the payload and a series of instruments within the operative field. 3) The positioning system: automated holding robotic arm (BrightMatter Drive). This system uses the computer-interfaced global positioning system to automatically and robotically position the payload.

As a feasibility-only study, there are 3 objectives of this report: to describe an initial experience in cranial neurosurgery with the ROVOT-m, to assess the feasibility and safety of this system in cranial applications, and to describe the incremental experience needed to overcome the associated learning curve.

Methods

Patient Population

After receiving institutional review board approval, we queried a prospective database comprising patients who underwent cranial procedures between April 2015 and September 2016. The first 200 patients who met the inclusion criteria were selected as the cohort for a retrospective chart review. The inclusion criteria consisted of the following: an adult population (> 18 years), microsurgical cranial procedures, and use of a single integrated navigation and optics system, specifically the ROVOT-m, for the actual execution of the procedure.

Records of patient demographics, radiological and intraoperative findings, postoperative course, and pathology were retrieved from electronic medical records. Particularly, operative reports were reviewed for the general setup time, which was defined as the interval between the patient arrival time in the operating room to skin incision, type of anesthesia (awake surgery vs general anesthesia), use of any optical systems other than the ROVOT-m (conventional stereoscopic microscopes or an endoscope), use of a portal-access system (BrainPath, NICO Corp.), intraoperative complications, estimated blood loss, and procedure time (defined as the interval between skin incision and closure).

Given that the primary goal of this study was to evaluate the technical feasibility of the ROVOT-m for cranial applications and not its efficacy, detailed clinical outcomes, such as extent of resection and symptom relief, are not provided. Such evaluation requires a prospective subgroup analysis of a larger series and is beyond the scope of this study. In addition, long-term follow-up results were not queried, as this study was meant to demonstrate feasibility.

Classification of the Surgical Complexity Level

To provide incremental experience and describe the associated learning curve, we sought to categorize a heterogeneous cohort in an attempt to represent the breadth of cranial microsurgical procedures. Any case complexity classification scheme will be constructed based on the surgeon's unique experience. To provide some degree of objectivity, we considered objective elements of the pathology, e.g., the location. We then considered the technical skills required in performing the procedure. Eventually, we classified the level of complexity into 6 distinct and increasingly complex categories based on technical microsurgical skill requirements, pathology, and location (Table 1). Although somewhat arbitrary, we believe that this classification scheme does reflect an incremental surgical complexity level. While the nuances can be debated, the spirit of an increasing level of technical skills is needed, and the concept of a learning curve is expressed.

TABLE 1. Classification of microsurgical cranial procedures into 6 categories of incremental complexity level

Category	Corresponding Entities	Example	Considerations
I	1) ICH 2) Cerebral abscess		All ICH & abscesses were evacuated using microsurgical technique, & therefore considered part of this study.
II	1) Intraaxial lesions in noneloquent areas 2) Extraaxial lesions w/o skull base or venous sinuses involvement	1) Resection of right frontal premotor metastasis 2) Resection of convexity meningioma	The location and microsurgical skills that are required to perform Category II procedures would be greater than those for an ICH.
III	1) Intraaxial lesions in eloquent areas 2) MVD surgery	1) Resection of glioma involving the left frontal operculum 2) MVD for trigeminal neuralgia	The microsurgical skills of resecting a glioma in the left frontal operculum (Category III) would be the same as the right (Category II), but the eloquent location of the former results in a higher complexity.
IV	1) Skull base pathologies 2) Extraaxial lesions w/ venous sinuses involvement	1) Resection of vestibular schwannoma 2) Resection of parasagittal meningioma	The increased complexity of this category is a function of creating surgical access. In addition, the microsurgical skills required to manage the cerebral vasculature including the venous drainage systems would need to be considered.
V	Intraventricular lesions	Resection of a colloid cyst	Based on the findings of Cikla et al, the 3rd ventricle & its associated regions represent a single, unforgiving anatomical region w/ devastating potential consequences if not properly handled. Although accessing this region might be considered less complicated than accessing the skull base, the microsurgical skills required for working on the target represent an additional layer of complexity. In addition, the rarity of these lesions precludes repeated routine experience, adding to the complexity level.
VI	Cerebrovascular lesions	Resection of arteriovenous malformation	The combination of the required microsurgical skills & its associated risks elevate cerebrovascular procedures to this category.

MVD = microvascular decompression.

Category I consists of spontaneous intracerebral hemorrhages (ICHs) and cerebral abscesses. We used a transsulcal corridor exclusively, primarily a portal-access corridor, for the evacuation of ICHs following a previously reported technique.^{8,20} Category II consists of intraaxial lesions, either primary or secondary, not involving eloquent brain areas, and extraaxial lesions that do not involve either the skull base or major venous sinuses. In line with current acceptance, eloquent brain areas were defined as areas in the cerebral hemisphere required for carrying out basic neurological functions (sensorimotor cortex, language cortex, and subcortical structures such as the internal capsule and basal ganglia).³ Category III consists of resection of intraaxial lesions that involve eloquent brain (note that we consider the posterior fossa as eloquent), and microvascular decompression for cranial neuropathy. Category IV consists of skull base lesions and other extraaxial lesions that involve major venous sinuses. Category V consists of procedures for resection of intraventricular lesions. Category VI consists of cerebrovascular procedures.

Statistical Analysis

Data were collected using Excel 2010 (Microsoft Corp.). The patient demographics and intraoperative variables were analyzed using descriptive statistics and are expressed as the mean and SD for continuous variables and frequency distribution for categorical variables. For categorical variables, a chi-square or Fisher exact test,

wherever appropriate, was used to compare the groups. For continuous variables, a t-test for independent samples was used to compare 2 groups. To assess the impact of incremental experience, additional analyses were performed after the entire cohort was evenly divided into 2 groups of patients. The early cohort consisted of the first half of the cases (Cases 1–100), and the late cohort comprised the second half of cases (Cases 101–200). These 2 cohorts were examined for distribution of the predefined variables based on case complexity. Probability values < 0.05 indicated significant differences. All statistical analyses were performed using SAS software (version 9.4, SAS Institute).

Results

Patient Population

The cohort of 200 cases consisted of 104 women (52%) and 96 men (48%), with a mean age of 56.7 years.

Distribution of Cases by Pathology

Table 2 summarizes the cohort based on cranial entities and pathology. The most common entities were neoplastic lesions representing 153 cases (76.5%), followed by spontaneous ICH (10%) and other vascular lesions (6.5%). Of the 153 neoplasms encountered, glioma was the most common pathology (36.6% of all neoplasms), accounting for 44 cases of high-grade gliomas and 12 of low-grade gliomas. The most common benign tumors were meninge-

TABLE 2. Cranial entities encountered in the initial 200 patients who underwent neurosurgical procedures using the ROVOT-m

Variable	No. of Patients (%)
Cranial entity	
Neoplastic lesions	153 (76.5)
Intracerebral hematoma	20 (10)
Vascular lesions	13 (6.5)
Cranial neuropathy	8 (4)
Infection	3 (1.5)
Congenital malformations	3 (1.5)
Total	200 (100)
Pathology	
Astrocytoma	56 (36.6)
Meningioma	40 (26.1)
Metastasis	33 (21.5)
Other primary	5 (3.2)
Schwannoma	5 (3.2)
Colloid cyst	4 (2.6)
Epidermoid/dermoid cyst	3 (1.9)
Paraganglioma	2 (1.3)
Craniopharyngioma	1 (0.6)
Pituitary adenoma	1 (0.6)
Miscellaneous	3 (1.8)
Total	153 (100)

The pathologies encountered in the 153 patients with neoplastic lesion are also presented.

omas, representing 40 cases (26.1%); 33 were WHO Grade I and 7 were WHO Grade II meningiomas. Metastatic tumors were grouped together, representing 21.5% of the oncological cases. The most common metastatic tumor was non-small cell lung cancer (42.4% of all metastases), followed by breast carcinoma (21.2%). There were a few different rare pathologies, each representing 0.6%; these were collectively placed into the miscellaneous category.

Thirteen vascular lesions were included, of which 7 were anterior circulation aneurysms, 5 were arteriovenous malformations (AVMs), and 1 was a dural arteriovenous fistula in the anterior cranial base. Eight cranial neuropathies represented 4% of all cases, consisting of 7 cases of trigeminal neuralgia and 1 case of hemifacial spasm. Finally, 2 arachnoid cysts and a case of Chiari I malformation were grouped together as congenital malformations (1.5% of the cases).

Distribution of Cases by Complexity Categories

Figure 1 illustrates the distribution of the incremental surgical level of complexity for our 200 patients. Most patients were in Categories II–IV, which, per definition, include the majority of oncological cases. Specifically, surgeries of Category II lesions were the most common (36.5%), followed by Category III lesions (22%).

Category I consisted predominantly of evacuation of spontaneous ICH (87%). Table 3 provides a summary of the distribution of the cases in Categories II, III, and IV. Category II consisted predominantly of supratentorial intraaxial tumors (78%) in noneloquent regions, either primary or

FIG. 1. Distribution of the first 200 patients regarding the complexity category of the case. DAVF = dural arteriovenous fistula; IT = infratentorial; ST = supratentorial.

secondary, with the remaining tumors being convexity meningiomas without venous sinus involvement. Category III consisted predominantly of supratentorial tumors (63.6%) in eloquent regions. Skull base pathologies were the largest component (75%) of Category IV. These tumors primarily consisted of sphenoid ridge and cerebellopontine angle tumors, each representing 23.3% of all skull base surgeries. Category V (intraventricular) and Category VI (vascular) collectively represented 10% of the cohort.

Perioperative Complications

In total, there were 3 (1.5%) major perioperative neurological complications and 6 (3%) 30-day mortalities.

Major Neurological Morbidity

Case 28. A 70-year-old man experienced immediate accumulation of a postoperative hematoma following resection of a left frontal glioblastoma (complexity Category II). The patient underwent uneventful cytoreductive surgery under awake conditions. Shortly after the surgery, the patient developed rapidly progressive expressive aphasia and right hemiparesis; a CT scan demonstrated a hemorrhage within the resection bed. The patient underwent immediate evacuation of the hematoma and gradually recovered motor (Grade 4/5) and language functions. However, at the time of discharge he was still experiencing mild aphasia.

Case 44. A 45-year-old man presented with a vestibular schwannoma (VS) (maximum diameter 3 cm) with encasement of a branch of the posterior inferior cerebellar artery (PICA) and sustained an intraoperative laceration of this vessel (complexity Category IV). The bleeding was controlled and the branch was sacrificed, leading to an infarction of the territory supplied by this branch. The patient experienced a complicated and prolonged postoperative course, experiencing dysphagia, dysarthria, and ataxia. Over a period of time, he gradually regained most of his preoperative functions in regard to gait, swallowing, and facial functions.

Case 49. A 68-year-old woman experienced postoperative infarction in the territory of the M₂ segment of the middle cerebral artery (MCA) territory following clipping of an unruptured calcified MCA aneurysm (maximum diameter 6 mm, complexity Category VI). Intraoperatively, the patient experienced an M₂ embolism with temporary loss of motor responses that recovered shortly after the embolus was “milked” along the artery. However, the patient developed aphasia and right hemiparesis due to the M₂ infarction. These deficits gradually improved over a 1-year period, but mild hemiparesis (Grade 4/5) and mild aphasia persisted.

Thirty-Day Deaths

Four of the 6 deaths occurred in elderly patients (> 70 years) who underwent evacuation of ICH and died within 30 days (postoperative Days 8–17). In all of these cases, the evacuation was uneventful. Apart from these cases, there were 2 other deaths as detailed below.

Case 198. A 56-year-old man underwent clipping of a

TABLE 3. Summary of the distribution of the lesions encountered in Categories II, III, and IV

Complexity Category	Lesion Distribution	No. of Patients (%)
II	Location	
	Frontal	25 (44)
	Occipital	12 (21)
	Parietal	10 (17.5)
	Temporal	10 (17.5)
	Total	57 (100)
	Laterality	
	Right	38 (66.6%)
III	Left	19 (33.3%)
	Location	
	Frontal	9 (32.1)
	Temporal	9 (32.1)
	Frontoparietal	6 (21.4)
	Insular	2 (7.1)
	Frontotemporal	1 (3.6)
	Parietal	1 (3.6)
	Total	28 (100)
	Laterality	
	Right	10 (35.7)
	Left	18 (64.3)
IV	Eloquence	
	Language areas	12 (42.9)
	Sensorimotor areas	11 (39.3)
	Deep structures	5 (17.9)
	Location	
	Sphenoid ridge	7 (23.3)
	CPA	7 (23.3)
	Anterior skull base	5 (16.7)
	Sphenoorbital	5 (16.7)
	Sellar & suprasellar	2 (6.7)
	Jugular foramen	2 (6.7)
	Middle fossa	1 (3.3)
	Foramen magnum	1 (3.3)
	Total	30 (100)

CPA = cerebellopontine angle.

The table presents the following: 1) location and laterality of the 57 noneloquent supratentorial intraaxial tumors in Category II, 2) location, laterality, and involved eloquent areas of the 28 supratentorial intraaxial tumors in Category III, and 3) location of the 30 skull base pathologies.

ruptured posterior communicating artery (PCoA) aneurysm (complexity Category VI). The patient presented in extremis (Glasgow Coma Scale Score 4, Hunt and Hess Grade V) with a diffuse SAH and intraventricular extension (Fisher Grade 4). Angiography revealed a large (maximum diameter 15 mm) wide-neck right PCoA aneurysm with a fetal configuration. Despite the high-grade presentation and given the patient's age, a decision to protect against rehemorrhage and afford the patient an opportunity for recovery was made. After a review by a multidisciplinary team and based on the morphology of the aneurysm, microsurgical reconstruction was selected. Intraoperatively, it was noted that the supraclinoid internal carotid artery was dysplastic and the base of the aneurysm circumferentially incorporated its wall, extending from the intradural origin through the bifurcation. To obliterate

TABLE 4. Intraoperative consideration by complexity category

Complexity Category	No. of Patients	Mean Procedure Time (mins)	Mean Blood Loss (ml)	No of Reops (%)	No. Awake (%)	No. w/ Port (%)
I	23	185 ± 88	108 ± 81	0	7 (30.4)	18 (78.2)
II	73	254 ± 111	151 ± 166	7 (9)	53 (72.6)	22 (30)
III	44	265 ± 107	167 ± 217	3 (6.8)	24 (54.5)	22 (50)
IV	40	472 ± 190	384 ± 398	4 (10)	3 (7.5)	0
V	7	323 ± 222	229 ± 135	1 (14.3)	4 (57)	5 (71.5)
VI	13	358 ± 146	219 ± 140	0	2 (15)	0

this dysmorphic aneurysm, a series of clips were applied, requiring the sacrifice of the fetal PCoA. The patient did not recover despite aggressive medical treatment and a decompressive craniectomy for refractory intracranial pressure; the patient died several days later.

Case 109. A 61-year-old woman underwent resection of anterior cranial base meningioma (6 cm, complexity Category IV). The patient also had an intracranial aneurysm that had recently been treated with coiling and needed antiplatelet therapy; she also had significant cardiopulmonary comorbidities. She rapidly developed progressive cognitive dysfunction and an altered level of consciousness due to increasing edema with no response to high-dose corticosteroids. Despite significant comorbidities, cytoreductive surgery to reduce the mass effect was undertaken. The surgery was uneventful. However, postoperatively the patient developed significant multifocal ischemia in remote regions that was presumed to be of an embolic origin from withdrawing her antiplatelet therapy. Postoperatively, the patient developed further significant cardiac dysfunction, eventually leading to her death.

Intraoperative Considerations

All 200 procedures were successfully performed using the ROVOT-m exclusively, with no need to convert to a conventional stereoscopic microscope in any of the cases. In 1 case of a dural arteriovenous fistula in the anterior cranial base (Case 190), a concomitant expanded endonasal approach was used to augment the transcranial approach and ligate the feeding ethmoidal arteries; however, it should be noted that the transcranial approach was performed using the ROVOT-m exclusively.

Table 4 presents the intraoperative findings; specifically, procedure time, EBL, primary surgery versus reoperation, type of anesthesia (general vs awake), and the use of a port were categorized by case complexity. For all categories, the procedure time and EBL varied directly with case complexity, with the exception of Category IV, which consisted predominantly of skull base procedures that, as expected, had the longest mean procedure time (472 minutes) and the greatest mean EBL (384 ml). The majority of Category II and III intraaxial tumors were performed with the patient awake; importantly, the intraventricular lesions (Category V) were also primarily performed with the patient awake. On the contrary, surgeries in the remaining categories were primarily performed with the patient under general anesthesia.

Comparison Between Early and Late Cohorts

In an effort to evaluate our learning curve with the ROVOT-m, the entire cohort was evenly divided into 2 groups, as follows: The early cohort includes the first 100 cranial cases (Cases 1–100), and the late cohort includes Cases 101–200. Both age and sex were found to be independent variables, with no significant difference between the cohorts. The mean ages of the early and late cohorts were 55.4 and 58 years, respectively ($p > 0.05$); 48% of the early cohort and 56% of the late cohort were females ($p > 0.05$). Three quantitative parameters were considered relevant in evaluating the learning curve and incremental progression: distribution of cases based on complexity, setup time, and overall procedure time.

Case Complexity

First, we compared the early and late cohorts with respect to the distribution of case complexity and noted a trend of incremental complexity over time. Explicitly, the number of cases performed in each of the 3 higher complexity categories (i.e., Categories IV–VI) progressively increased; however, it failed to reach statistical significance (Table 5).

When pooling all lower-complexity categories (I–III), essentially consisting of intraxial lesions, and comparing to pooled higher-complexity categories (Categories IV–VI), consisting of skull base, vascular, and intraventricular lesions, a statistically significant difference was noted between the early and late cohorts in terms of case complexity; specifically, given the dilution effect of subgroup analysis within a relatively small sample size, the analysis revealed that the late cohort (Cases 101–200) comprised incrementally more complex surgeries. Moreover, when Category I (ICH and abscess) was excluded from these

TABLE 5. Comparison of the distribution of all surgeries with regard to complexity categories between early and late cohorts

Complexity Category	Early Cohort	Late Cohort	p Value
I	6	17	>0.05
II	46	27	>0.05
III	25	19	>0.05
IV	16	24	>0.05
V	1	6	>0.05
VI	6	7	>0.05
Total	100	100	

FIG. 2. Operating room setup time (in minutes, y-axis) in the first 200 cases of ROVOT-m implementation, divided into quartiles. Three groups were separately analyzed. The all-cases group (solid line) represents all cases in the early cohort versus all cases in the late cohort, regardless of the type of anesthesia. The general anesthesia group (dotted line) represents all patients who received general anesthesia in the early cohort versus all patients who received general anesthesia in the late cohort. The awake group (dashed line) represents all awake patients in the early cohort versus all awake patients in the late cohort. A statistically significant reduction of the setup time between the early and late cohorts was demonstrated in all 3 groups (all cases, from 99.8 ± 57.2 to 71.1 ± 15.7 minutes when comparing the first and last quartiles of patients [$p < 0.001$]; general anesthesia group, from 90.8 ± 26.7 to 72 ± 20.2 minutes [$p = 0.025$]; and awake group, from 108.8 ± 76.1 to 70.2 ± 9.8 minutes [$p = 0.009$]).

cohorts, the difference proved to be even more profound. Explicitly, the proportion of the high-complexity surgeries increased from 23% in the early cohort to 37% in the late cohort ($p = 0.030$) when we included all 6 complexity categories and from 24.5% to 44.6% ($p < 0.01$) after excluding Category I surgeries (see *Discussion* for implications).

Setup Time

Second, we compared the 2 cohorts with respect to operating room setup time, defined as the interval between a patient's arrival in the room and the skin incision. Assuming that all other components associated with setup (such as anesthesia, patient positioning, and instruments) should not significantly vary over time and should be equivalently distributed between the early and late cohorts, a significant difference would be the result of ROVOT-m use.

The other key variable that will significantly impact setup time is the type of anesthesia (awake or general); therefore, we performed the setup time analysis in 3 groups separately. In the all-cases group, all patients in the early cohort (Cases 1–100) versus all patients in the late cohort (Cases 101–200) were compared, regardless of the type of anesthesia. In the general anesthesia group, all patients who received general anesthesia in the early cohort versus all patients who received general anesthesia in the late cohort were compared. In the awake group, all patients in the early cohort versus all patients in the late cohort were compared.

We noted a statistically significant reduction in setup times for all 3 groups (Fig. 2). Furthermore, a consistent reduction in setup time was also demonstrated when the entire study population was further divided into quartiles (50 cases in each), and the 3 groups were compared; once again, the reduction was statistically significant in all 3 groups.

Overall Procedure Time

Finally, we compared the mean procedure time for the early and late cohorts, which revealed a mean increase from 277.8 ± 142.7 minutes in the early cohort to 324.7 ± 178.3 minutes in the late cohort. However, this difference did not reach statistical significance ($p > 0.05$); of note, there was also a correlative increase in case complexity between the early and late cohorts.

Illustrative Cases

Figure 3–8 and Videos 1–6 present illustrative cases of patients who were surgically treated with the aid of the ROVOT-m, detailing a case from each complexity category.

VIDEO 1. Complexity I. Evacuation of an ICH. Copyright Aurora Neuroscience Innovation Institute. Published with permission. [Click here to view.](#)

VIDEO 2. Complexity II. Resection of a right parietal glioblastoma. Copyright Aurora Neuroscience Innovation Institute. Published with permission. [Click here to view.](#)

VIDEO 3. Complexity III. Microvascular decompression for hemifacial spasm. Copyright Aurora Neuroscience Innovation Institute. Published with permission. [Click here to view.](#)

VIDEO 4. Complexity IV. Resection of a medial sphenoid wing meningioma. Copyright Aurora Neuroscience Innovation Institute. Published with permission. [Click here to view.](#)

VIDEO 5. Complexity V. Resection of a recurrent colloid cyst. Copyright Aurora Neuroscience Innovation Institute. Published with permission. [Click here to view.](#)

VIDEO 6. Complexity VI. Resection of an arteriovenous malformation. Copyright Aurora Neuroscience Innovation Institute. Published with permission. [Click here to view.](#)

Discussion

In the current study, we have demonstrated the feasi-

FIG. 3. Evacuation of an ICH (Category I; corresponds to Video 1). **A and B:** Preoperative sagittal (A) and axial (B) CT images showing a right frontal ICH. **C and F:** Intraoperative photographs obtained before (C) and after (F) the evacuation was completed. **D and E:** Postoperative sagittal (D) and axial (E) CT images demonstrating satisfactory evacuation of the hematoma with preservation of the frontal cortex superior to the hematoma.

bility and safety of the ROVOT-m as a detector system in broad cranial applications; specifically, we report the following findings: 1) No intraoperative conversions from ROVOT-m to a conventional stereoscopic microscope were encountered. 2) No intraoperative complications occurred that were attributable to the visualization provided by the ROVOT-m, and major perioperative neurological morbidity and mortality rates (1.5% and 1.0%, respectively) were well within the accepted rates for the respective case complexity. 3) An incremental case complexity over time was noted, suggesting incremental acquisition of skills and comfort of the surgical team with this emerging technology.

ROVOT-m Technical Feasibility and Cranial Applications

The feasibility of the ROVOT-m in a wide range of cranial microsurgical applications was demonstrated. The intended surgical goal was achieved in all 200 cases without the need for intraoperative conversion. This study demonstrates the broad application of the ROVOT-m for performing various cranial neurosurgical procedures, including the evacuation of 20 ICHs, resection of 153 tumors extending across the neurooncological continuum (intra- and extraaxial, eloquent and noneloquent, benign and malignant), and 13 vascular lesions. Additionally, location was not a prohibitive barrier, as lesions within every intracranial compartment (supra- and infratentorial, skull base, and intraventricular) were accessible (Tables 2 and 3). Taken altogether, our study indicates a direct application and feasibility of the ROVOT-m for transcranial microsurgical procedures, independent of the case complexity. Notably, the type of anesthesia did not affect the use of the ROVOT-m, as surgeries under awake conditions and general anesthesia were equally feasible with the system.

While individual components of the system (e.g., navigation and exoscopes) have been previously described, to our knowledge, the use of a purpose-built integrated single system has not been reported. Specifically, several studies have reported the neurosurgical applications of exoscopes, which, in contrast to endoscopes, are positioned in extracavitary regions. In particular, Mamelak et al. have described a high-definition exoscopic payload for use in cranial and spinal neurosurgery.^{22,23} However, this particular exoscope is attached to a static holder that requires repeated manual repositioning to achieve each new viewing angle and is not specifically designed based on the performance of the other 4 components of the optical chain. The ROVOT-m, on the other hand, comprises an exoscopic (telescopic) payload that is coupled to an automated robotic arm, which dynamically repositions it through a global positioning navigation system using a computer-machine interface that creates a fully integrated system, wherein each component is designed to enhance the overall performance of the collective elements of the optical chain.

Importantly, the stereoscopic view (binocular 3D perception) that is provided by a conventional stereoscopic microscope is not available with the ROVOT-m. Previous studies in which the manual-holder exoscope was used have mentioned that the lack of binocular stereopsis is a significant limitation for approaching deep-seated cranial lesions, which is in part due to the limitations of the scope holder that require continuous repetitive manual movement to create a coaxial direct line-of-sight, resulting in optimal visualization.^{22,23} However, we found that the dynamic movement of the robotic arm within the surgical corridor, in both its axial and in particular the rotational planes, provided an important means to compensate for the inherent lack of binocular stereoscopic vision through

FIG. 4. Resection of a right parietal glioblastoma (Category II; corresponds to Video 2). **A:** Preoperative axial Gd-enhanced T1-weighted MR image showing a right parietal glioblastoma with vasogenic edema. **B and C:** Intraoperative photographs showing the trajectory of the port (B), which was designed preoperatively to avoid violating neural tracts in the vicinity of the lesion, and the portal view (C) while executing the resection. **D:** Postoperative axial Gd-enhanced T1-weighted MR image demonstrating satisfactory cytoreduction.

motion and parallax. This is in keeping with the previous experience that we have described, suggesting that dynamic movement represents a critical compensation for 2D image generated by neuroendoscopic surgery.^{15,16,30}

In this series, despite undertaking progressively more complex cases over time, ranging from tubular port surgery, through complex intraventricular and skull base surgery and to cerebrovascular surgery, we were not inhibited by the lack of binocular stereoscopic 3D perception. Explicitly, the spectrum of transcranial microsurgical procedures was feasible and safely performed without limitation using the ROVOT-m; this was the case for surgeons with 3 different levels of experience with video-based surgery, i.e., a novice surgeon, a midcareer surgeon, and a surgeon with 20 years of video-endoscopy surgery.

To better understand the generation of the 3D view, we first have to define what 3D perception represents. Three-dimensional perception is defined as the relative position of 2 objects with respect to one another within a fixed volume; we have coined this as relative positional sense (RPS).

RPS can be achieved through a multitude of mechanisms, not the least of which is proprioception, dynamic movement resulting cues from shadowing and parallax.^{1,2,5,12} However, perhaps the most important requirement of RPS is an a priori understanding of the anatomical relationships, e.g., if one knows the position of the MCA relative to the carotid artery, the RPS becomes infinitely easier.

Anatomical knowledge can be significantly enhanced by the use of real-time neuronavigation, i.e., if the dynamic movement can be tracked using a global positioning system to provide real-time RPS, the 3D perception is profoundly enhanced. In the performance of higher-complexity surgeries (Categories IV–VI), we have found that simultaneous views with one monitor displaying the optics and the second showing the integrated navigation view are effective. We consider this to be “stereoscopic” 3D visualization, although each monitor provides different input, optics, and navigation. While beyond the scope of this report, there are other critical optical metrics that are vital in generating various forms of 3D perception.

FIG. 5. Microvascular decompression for hemifacial spasm (Category III; corresponds to Video 3). **A:** Preoperative T2-weighted MR image showing a conflict between a branch of the right vertebral artery and the facial nerve (circle). **B and C:** Intraoperative photographs showing the exposure of the neurovascular structures in this retrosigmoid approach (B), the exit of the facial nerve (VII) that was hidden under the offending artery (C), and the same region of the facial nerve exit (*) now protected by a Teflon roll (D). CP = choroid plexus; IX, X = cranial nerves IX, X.

FIG. 6. Resection of a left medial sphenoid meningioma (Category IV; corresponds to Video 4). **A and B:** Preoperative coronal (A) and axial (B) Gd-enhanced T1-weighted MR images showing a left medial sphenoid wing meningioma. **C and F:** Intraoperative photographs showing the dissection of the tumor off the MCA (C), and the panoramic view of the resection bed at the end of the resection (F). **D and E:** Postoperative coronal (D) and axial (E) Gd-enhanced T1-weighted MR images demonstrating gross-total resection of the tumor. A1, M1 = A1, M1 segments of ICA; Ant. Chor. = anterior chorioid artery; Ant. Temp. = anterior temporal artery; ICA = internal carotid artery; LM = Liliequist membrane; Pcom = posterior communicating artery; SCA = superior cerebellar artery; III = cranial nerve III.

FIG. 7. Resection of a recurrent colloid cyst (Category V; corresponds with Video 5). **A and B:** Preoperative sagittal (A) and coronal (B) Gd-enhanced T1-weighted MR images showing the recurrent colloid cyst. **C and F:** Intraoperative photographs showing the sharp opening of the cyst (C), and the opened foramen of Monro (FM) at the end of the resection (F). **D and E:** Postoperative sagittal (D) and coronal (E) Gd-enhanced T1-weighted MR images demonstrating complete resection of the colloid cyst. Fx = fornix.

ROVOT-m Safety

Due to its retrospective nature, this study focused only on major perioperative neurovascular complications that were reliably extracted through a chart review. Of our entire cohort of 200 cases of various complexities, we encountered 3 (1.5%) major neurological morbidities and 6 (3%) 30-day deaths, leading to a combined complication rate of 4.5%. We believe that the 4 deaths in the ICH group, which represented 20% of all ICH cases in our cohort, is consistent with those in previous studies, demonstrating a 30-day mortality after ICH ranging from 28.3% to 46% in large series.^{29,31}

After excluding the 4 ICH-related mortalities, our combined complication rate was 2.5% (5 of the remaining 196 cases). Of these 5 cases, 4 (80%) occurred following high-complexity surgeries (Categories IV and VI). The 2 non-ICH-related deaths were not considered to be directly related to either intraoperative complications or technical limitations, but were rather a function of either the underlying disease or the patient's comorbidities. Specifically, one death was the result of a devastating ruptured aneurysm with a high-grade clinical presentation, and the other was related to significant cardiopulmonary comorbidities and discontinuation of antiplatelet aggregation therapy.

The 3 cases of major neurovascular morbidity were a postoperative hematoma following resection of a glioblastoma and 2 vascular events; the first was the laceration of an encased branch of the PICA during the resection of a VS, and the second was an embolic event during the clipping of an M_2 calcified aneurysm. We believe that these morbidities are within the range of accepted rates for these procedures; according to published surgical series, clinically significant postoperative hematomas occur in 1%–4% of patients following glioma surgery,^{9,27} postoper-

ative vascular injury occur in 2%–3% of patients following resection of VS,²⁶ and early postoperative cerebral infarction associated with aneurysm clipping occur in 11% of the cases of rupture aneurysms.¹⁹

Taken into entirety, these complications were attributed

FIG. 8. Resection of a posterior fossa AVM (Category VI; corresponds with Video 6). **A:** Preoperative sagittal CT angiogram showing the posterior fossa AVM fed from the vertebral artery. **B and D:** Intraoperative photographs showing a temporary clip applied on the vertebral artery (V) for proximal control (B) and the coagulation of the nidus of the AVM (D). **C:** Postoperative sagittal CT angiogram demonstrating complete obliteration of the malformation.

to the complexity of the cases and the patient's comorbidities, rather than the optical performance of the ROVOT-m. Notably, the PICA artery laceration that was experienced while resecting a VS was, despite the significant bleeding, effectively controlled with the ROVOT-m exclusively and without the need for intraoperative conversion to CS-m.

Clinical Learning Curve of the ROVOT-m

There is a learning curve in robotic surgery, as is the case with any new technology. It necessitates techniques, assessment of the required skills, and the translation of experimental results to the operating room.^{11,17} However, assessing a learning curve during actual surgeries can be challenging, given the inherent diversity of surgical scenarios that are the result of patient-, anatomical-, pathology-, and surgeon-related variability.^{17,24} In keeping with previous learning curve assessments in neurosurgical series, we used case complexity to evaluate the pace of translation of learned skills.¹⁴

In our series of 200 cranial procedures using the ROVOT-m, when comparing the early and late cohorts, we noticed a statistically significant increase in terms of complexity level of the cases (from 23% to 37%, $p = 0.030$). Of note, as a result of changing referral patterns, there were proportionally more Category I surgeries in the early cohort than in the late cohort (17 and 6 cases, respectively). When excluding Category I cases (mainly evacuation of ICHs) to provide a more balanced comparison, the difference between the proportions of the lower-complexity surgeries (Categories II and III) versus higher-complexity surgeries (Categories IV–VI), an even greater difference was noted; explicitly, the incidence of higher-complexity surgeries in the early versus late cohort was 24.5% and 44.6%, respectively ($p < 0.01$). These results suggest an incremental learning and translation of acquired microsurgical experience over time. These factors are important to note in safely developing, adopting, and scaling new technologies. As such, we have demonstrated the same philosophical adoption strategy as we did in describing the scaling of expanded endonasal approaches.¹⁴

We also measured the overall procedure time and EBL and compared the early and late cohorts. We demonstrated a general correlation between procedure time and EBL to the complexity level (Table 4), with the exception of Category IV procedures, which had the highest procedure time and EBL. Given that the majority of Category IV procedures were resections of skull base tumors, this finding was fairly predictable. Importantly, we do not consider procedure time and EBL to be reliable variables for evaluating complexity levels. The complexity level of a procedure was intended to reflect the level of microsurgical skills that were required for its safe execution, given the anatomical location of the lesion. With regard to learning curve assessment, the use of procedure time as a surrogate, although common, is considered largely inaccurate, particularly in such a heterogeneous cohort.¹⁷ Indeed, the procedure time was longer in the late cohort than in the early cohort (324.7 ± 178.3 and 277.8 ± 142.7 minutes, respectively). This correlation might be considered consistent with the incremental advancement in case complex-

ity demonstrated in the late cohort, but we believe such interpretation is problematic. The wide standard deviation is also consistent with the great heterogeneity in the study population as well as outlier cases that represent anomalies (i.e., a few particularly long cases).

Integration of ROVOT-m in Operative Workflow

In our series, we demonstrated a significant reduction in setup time over time, regardless of type of anesthesia (Fig. 2). The setup of the ROVOT-m and its components within the operative workspace took several iterations before the entire process became streamlined. As with other optical systems, proper, strategic positioning of all components is important for enhancing surgical workflow. Figure 9 illustrates the practical lessons learned over time with respect to our operating room setup with the ROVOT-m. Of note, while these considerations may vary from institution to institution, they seem to work well for our environment.

Study Limitations

While there are several limitations of this study, the reader should be particularly aware of retrospective data collection and interpretation, which can negatively impact the accuracy of the study because of factors of inherent biases; heterogeneous pathologies and surgical procedures (specifically, the grouping of heterogeneous subgroups may disproportionately affect the results according to which pathologies constitute the predominant subgroup); small sample size and dilutional effects of any subgroup analysis, particularly of the higher-complexity categories (i.e., the limited number of cases in complexity Categories V and VI—intraventricular and vascular, respectively); and as a feasibility study, this report does not include analysis of long-term outcome. Therefore, no statements relative to the efficacy of the ROVOT-m can be made; further prospective studies are required to address this aspect. Similarly, this study was not designed to provide a direct comparison against the visualization optical platform offered by conventional stereoscopic microscopy.

Conclusions

To the best of our knowledge, the current study is the first clinical report documenting the feasibility of the ROVOT-m for transcranial surgery. The results of this study support the feasibility of ROVOT-m as a safe detector system in a wide variety of cranial neurosurgical applications. An incremental learning curve is associated with the implementation of ROVOT-m in the surgical workflow, both during the setup and execution phases, and should be anticipated by new adopters.

The intent of this study was to demonstrate the safety and feasibility of the ROVOT-m platform, not to evaluate its efficacy. While there are theoretical advantages of optical power provided by this technology, these advantages will likely be the subject of larger prospective efficacy studies and ongoing work. Nevertheless, the wide variety of surgeries completed using this integrated system and its potential advantages suggest that this technology may add to the armamentarium of the neurosurgeon. However, it should be noted that the evolution of visualization from loupes to mi-

FIG. 9. The operating room setup for the ROVOT-m. As shown, the 5 optical chain components include the optical payload (1), light source (2), camera (3), holder (4), and display monitor (5). In this specific case, the setup was designed for a right-sided lesion. The general setup principles are applied, and include the following: 1) The position of both the robotic arm and its base depends on the location of the pathology and the resultant patient positions. In our experience, the robotic arm is typically positioned on the ipsilateral side of the lesion, with its base placed at the patient's hip level. 2) All joint angles are initially placed at 90° to allow for maximum unencumbered movement without creating singularity (i.e., locking the joints). 3) The operating room setup must provide the surgeon and assistants with an unobstructed view of the monitors that display the surgical view. We use at least 2 high-definition display monitors that, as a default, are positioned on the opposite side of the robotic arm unit: one monitor directly in front of the surgeon and the other at a slight angle to allow for "stereoscopic" input with optics and navigation. 4) The image navigation guide system is positioned on the contralateral side of the robotic arm to allow for visualization.

croscopes and endoscopy, and now to the ROVOT-m, simply represents the use of tools that rely on the judgment of the operator to determine their use.

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Disclosures

Dr. Kassam reports that he is a consultant for Synaptive Medical and KLS Martin Medical, and is on the medical advisory board of Medtronic Medical.

Author Contributions

Conception and design: Kassam, Gonen, Chakravarthi. Acquisition of data: Gonen, Chakravarthi. Analysis and interpretation of data: Kassam, Gonen, Chakravarthi. Drafting the article: Gonen, Chakravarthi. Critically revising the article: Kassam, Gonen, Chakravarthi. Reviewed submitted version of manuscript: all authors. Approved the final version of the manuscript on behalf of all authors: Kassam. Statistical analysis: Gonen, Chakravarthi. Administrative/technical/material support: Kassam. Study supervision: Kassam, Gonen, Chakravarthi.

Supplemental Information

Videos

- Video 1. <https://vimeo.com/208525320>.
Video 2. <https://vimeo.com/208525391>.
Video 3. <https://vimeo.com/208525474>.
Video 4. <https://vimeo.com/208525563>.
Video 5. <https://vimeo.com/208525827>.
Video 6. <https://vimeo.com/208525940>.

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