Advancing neurosurgery with image-guided robotics

Technical note

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Robotic systems are being introduced into surgery to extend human ability. NeuroArm represents a potential change in the way surgery is performed; this is the first image-guided, MR-compatible surgical robot capable of both microsurgery and stereotaxy. This paper presents the first surgical application of neuroArm in an investigation of microsurgical performance, navigation accuracy, and Phase I clinical studies.

To evaluate microsurgical performance, 2 surgeons performed microsurgery (splenectomy, bilateral nephrectomy, and thymectomy) in a rodent model using neuroArm and conventional techniques. Two senior residents served as controls, using the conventional technique only (8 rats were used in each of the 3 treatment groups; the 2 surgeons each treated 4 rats from each group). Total surgery time, blood loss, thermal injury, vascular injury, and animal death due to surgical error were recorded and converted to an overall performance score. All values are reported as the mean ± SEM when normally distributed and as the median and interquartile range when not. Surgeons were slower using neuroArm (1047 ± 69 seconds) than with conventional microsurgical techniques (814 ± 54 seconds; p = 0.019), but overall performance was equal (neuroArm: 1110 ± 82 seconds; microsurgery: 1075 ± 136 seconds; p = 0.825). Using microsurgery, the surgeons had overall performance scores equal to those of the control resident surgeons (p = 0.141).

To evaluate navigation accuracy, the localization error of neuroArm was compared with an established system. Nanoparticles were implanted at predetermined bilateral targets in a cadaveric model (4 specimens) using image guidance. The mean localization error of neuroArm (4.35 ± 1.68 mm) proved equal to that of the conventional navigation system (10.4 ± 2.79 mm; p = 0.104). Using the conventional system, the surgeon was forced to retract the biopsy tool to correct the angle of entry in 2 of 4 trials.

To evaluate Phase I clinical integration, the role of neuroArm was progressively increased in 5 neurosurgical procedures. The impacts of neuroArm on operating room (OR) staff, hardware, software, and registration system performance were evaluated. NeuroArm was well received by OR staff and progressively integrated into patient cases, starting with draping in Case 1. In Case 2 and all subsequent cases, the robot was registered. It was used for tumor resection in Cases 3–5. Three incidents involving restrictive cable length, constrictive draping, and reregistration failure were resolved. In Case 5, the neuroArm safety system successfully mitigated a hardware failure.

NeuroArm performs as well and as accurately as conventional techniques, with demonstrated safety technology. Clinical integration was well received by OR staff, and successful tumor resection validates the surgical applicability of neuroArm. (DOI: 10.3171/2009.2.JNS081334)

Key Words • neuroArm • imaging-guided surgery • robotic surgery • clinical integration • stereotaxy • microsurgery • neurosurgery • rat

Contemporary neurosurgery requires accurate preoperative lesion localization for optimal biopsy, resection, or implantation. Neurosurgery, and indeed all of surgery, continues to evolve toward increasingly minimalist techniques.16,17 Minimally invasive approaches have proven beneficial, with faster recovery time and improved patient outcome.19,22 Hence, neurosurgeons are increasingly looking to push beyond the limits of their natural manual dexterity and spatial orientation.

In the 1980s, neurosurgical robots were introduced to enhance neurosurgery. Early designs offered better guidance but failed to meet safety requirements, preventing widespread clinical acceptance.7,15 Subsequent robots addressed other aspects of neurosurgery, such as surgical planning and stereotaxy;2 real-time image guidance;4 MR compatibility;5,21 and micromanipulation10,14,28.

In 2002, the development of a new robot, neuroArm,20,27 was initiated to take advantage of the MR environment25 and incorporate technological advances in haptic feedback, 3D image reconstruction, and hand-controller design. The design and manufacture of neuroArm were guided by health-care and regulatory requirements. The resulting robot is the first image-guided, MR-compatible25 robot capable of both microsurgery and stereotaxy.26 NeuroArm is telecapable and recreates the

Abbreviations used in this paper: IQR = interquartile range; OR = operating room.
rich sensory environment of the surgical site at a remote workstation. Patient safety is maximized by numerous software checks and redundant hardware sensors. Although previous publications have detailed the design, manufacture, and installation of neuroArm, no studies of surgical application have been published.

System approval for neuroArm was obtained from the Canadian Standards Association in 2007. Institutional ethics approval and investigational testing approval were granted by the University of Calgary and Health Canada, respectively, in 2008. Although such approvals are necessary for clinical application, they do not ensure acceptance from the surgical team or neurosurgical community. For a technology to be embraced, it must be able to demonstrate proof of concept, reliable safety features, and successful clinical application. In the context of these requirements, this paper presents results of initial surgical applications of neuroArm in both preclinical and clinical studies.

Methods

A trial profile of the microsurgery performance, navigation system accuracy, and Phase I clinical integration studies is featured in Fig. 1.

All procedures are in compliance with University of Calgary Health Sciences Animal Care Committee; the University of Calgary Conjoint Health Research Ethics Board of the Faculties of Medicine, Nursing, and Kinesiology; and Health Canada guidelines. Testing was completed at the Seaman Family MR Research Centre and University of Calgary.

Microsurgery Performance Evaluation

To compare the microsurgical performance of neuroArm to conventional techniques, splenectomy, bilateral nephrectomy, and thymectomy were performed on 30 adult male Sprague-Dawley rats. Two experienced surgeons performed the procedures, first with the robot, and then with standard microsurgical technique. Because the surgeons were not blinded to the experimental design, 2 senior neurosurgery residents also performed conventional microsurgical technique to serve as controls. Each participant completed 4 trials, preceded by 1 practice trial for familiarization with the procedure and equipment. A senior neurosurgery resident served as the sole assistant for all surgeries.

In the robotic trials, the neuroArm bipolar forceps, based on ISOCOOL technology (Codman & Shurtleff, Inc.), were placed in the neuroArm right end effector, and the neuroArm tissue forceps were placed in the left. A Leica microscope (model M525 0H4; Leica Microsystems GmbH) provided magnification and illumination of the surgical site. The bipolar footswitch (Codman & Shurtleff, Inc.) was operated by C.S.A., who also used various microinstruments to assist with the procedure.

For conventional microsurgery, participants could operate the bipolar switch themselves. A standard selection of microinstruments was available to all participants. The ISOCOOL forceps were not used because the surgeons and residents felt more comfortable using a smaller, more graspable forceps (Codman 1.0 mm bipolar forceps; Codman & Shurtleff, Inc.), a Zeiss Universal S3 microscope (Carl Zeiss Meditec Vertriebsgesellschaft GmbH) enhanced visualization. The use of different microscopes between procedures was due to the availability of different surgical suites; however, both microscopes were approved by the common assistant prior to use.

Each rat was anesthetized using an intraperitoneal injection of 0.5 ml sodium pentobarbital (65 mg/100 ml). The spleen, kidneys, and thymus were exposed through midline abdominal and neck incisions. Postsurgery, the animals were killed by intracardiac injection of 1.0 ml of the sodium pentobarbital solution.

Surgical completion time, blood loss (measured as the weight difference of surgical gauze before and after surgery in the absence of irrigation), incidence of thermal and vascular injuries as reported by C.S.A., and the incidence of animal death due to surgeon error were recorded by 1 observer (S.P.) for all trials. These data were then combined into an overall performance score using the following formula: Performance (seconds) = Time (seconds) + 60 seconds per 0.5 g blood loss + 120 seconds if thermal injury present + 120 seconds if vascular injury present + 15 minutes in event of animal death due to surgical error.

This equation was derived prior to data analysis as a means of comparing many aspects of surgery. Uniform blood loss for each trial was not anticipated, and therefore a graded penalty for this variable was applied. A penalty of 60 seconds per 0.5 g of blood lost was thought to be reasonable in the context of anticipated surgery time. Because thermal and vascular injury are absolute indicators of technical error and are either present or absent, they were assigned a more severe, fixed penalty. Because death due to surgical error would represent a critical event, it was assigned the heaviest penalty, approximately equal to the anticipated average surgery time. Adverse events not related to surgical performance, such as death from anesthesia, were not included in the evaluation of performance. Data were compared between 1) the surgeon-neuroArm and surgeon-microsurgery groups, and 2) the surgeon-microsurgery and resident-microsurgery groups.

Navigation System Assessment

This study compared the localization accuracy of the neuroArm navigation system software to an established frameless surgical navigation technology (VectorVision Sky Navigation System; BrainLAB) using 2 cadaveric heads. NeuroArm was used to localize the left globus pallidus and head of the left caudate in each trial, whereas VectorVision was used to localize these targets on the contralateral side. To identify its final position, each navigation system used a common biopsy tool to implant uncoated ferrous oxide nanoparticles developed in our lab for the purpose of tissue labeling (Fig. 2A).

First, bilateral frontal craniotomy was performed using a pneumatic drill (Midas Rex; Medtronic, Inc.). The exposed dura mater was opened in a cruciate manner, and preoperative MR images were taken to register the neuroArm navigation system. Guided by the registered image (Fig. 2C), neuroArm was used to implant the nanopar-
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ticles at the designated targets, and a screenshot depicting
the neuroArm-localized nanoparticles was taken (Fig.
2D). Following implantation with neuroArm, postproce-
dural MR images were taken to identify the true position
of the nanoparticles. These postprocedural images also
served as preprocedural MR images for VectorVision
registration. As before, a screenshot was taken following
implantation (Fig. 2B), and postprocedural MR images
identified the actual location of the nanoparticles.

The distance between the indicated and actual nano-
particle position was deemed the localization error. The
localization error for each implantation was determined
using Pythagorean theory, after identifying the slices
containing the indicated and actual nanoparticle loca-
tions. Out-of-plane displacement was calculated by multi-
plying the slice thickness by the number of slices between
the 2 locations. In-plane displacement was calculated by
superimposing the locations onto a common plane and
measuring using the ruler function in DicomWorks (ver-
sion 1.3.5).

All MR images (pre-, intra-, and postprocedural)
were acquired using a movable 1.5-T intraoperative MR
imaging system.11,24 Sequence parameters were set to
provide 110-slice axial volume T1-weighted scans with
2-mm thickness and no gap, but were adjusted to provide
optimal target visualization as necessary.

Phase I Clinical Integration

To demonstrate the clinical suitability of neuroArm,
the robot was integrated into 5 neurosurgical procedures
in a planned, stepwise fashion. Patients with CNS neo-
plasia were identified in the neurosurgical clinics at the
Foothills Medical Centre and provided informed consent
for the use of neuroArm during their procedure.

Patients were anesthetized and positioned for surgery,
and intraoperative MR images were obtained for surgical
planning. The OR staff, including the anesthetist, surgical
assistant, and scrub nurses, were consulted prior to the
introduction of neuroArm into the OR. NeuroArm was
increasingly involved in each procedure. In the first case,
neuroArm was draped and positioned as in Case 1. IMRI = intraoperative MR imaging.

Statistical Analysis

Statistical analysis was performed with SPSS ver-
sion 15.0 for Windows. Population distributions were
analyzed for normality by using the Shapiro-Wilks test.
If normal, populations were compared using independent
t-tests. Nonnormal distributions were analyzed using the
Mann-Whitney U test. Independent t-tests were further
subjected to the Levene test of equal variance, and prob-
ability values were determined accordingly. All probabil-
ity values reported are 2-tailed and were tested against an
α level of 0.05.

In performance studies, operating time, blood loss,
and performance data were compared between the sur-

Fig. 1. Chart showing trial profile. A: Overview of preclinical studies. B: Overview of Phase I clinical studies. Each Phase I
case incorporated the tasks of previous cases. For example, in addition to registration for surgical planning in Case 2, neuroArm
was also draped and positioned as in Case 1. IMRI = intraoperative MR imaging.

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**Results**

**Microsurgery Performance Evaluation**

These studies assessed the performance of neuroArm relative to conventional microsurgery. The mean total surgery time, blood loss, and overall performance scores for each group in the animal trials are presented in Table 1. The surgeons were faster in microsurgical trials (814 ± 54 seconds) compared with robotic trials (1047 ± 69 seconds; p = 0.019). The surgeons in the robotic trials incurred equal blood loss (0.525 ± 0.16 g) compared with surgeons in the microsurgery trials (1.43 g [IQR 0.45–2.72 g], p = 0.092). The data for total surgery time, blood loss, thermal injury, vascular injury, and surgery-induced death were factored into an overall performance score, which proved to be equal between surgeon-neuroArm (1110 ± 82 seconds) and surgeon-microsurgery (1075 ± 136 seconds) groups (p = 0.825).

Because the surgeons were not blinded to the study design, it is possible that this introduced a bias. To determine whether this was the case, the surgeon-microsurgery group was compared with a resident-microsurgery control group. Within the microsurgical trials, the residents (591 ± 50 seconds) were significantly faster than the surgeons (814 ± 54 seconds; p = 0.009). However, blood loss between the surgeon (1.43 g [IQR 0.45–2.72 g]) and resident-microsurgery (1.1 g [IQR 0.37–1.82 g]) groups was equal (p = 0.401). The resident group also incurred 1 animal death due to vascular injury. Including this rat, overall surgical performance was equal between the surgeon-microsurgery (1075 ± 136 seconds) and resident-microsurgery groups (781 seconds [IQR 665–878 seconds]; p = 0.141).

**Navigation System Assessment**

The cadaveric navigation trials compared the accuracy of neuroArm to the VectorVision navigation system. All intraoperative MR studies were captured at the original parameters of 110-slice T1-weighted images with 2-mm thickness and no gap. In 3 cases, slice thickness was increased to 4 mm to provide better target visualization. One of these 3 scans was visualized in a coronal orientation while all other parameters were kept constant.

The localization error of each system, defined as the difference in the indicated and actual nanoparticle posi-
Phase I Clinical Integration

NeuroArm involvement in clinical cases is depicted in Fig. 3. Details of patient diagnoses, the role of neuroArm, and occurrence of adverse events are summarized in Table 2.

Initial clinical studies were undertaken to integrate neuroArm into the neurosurgical suite. The safety features and ease of clinical integration of neuroArm were reported over the course of treatment in 5 patients. In Case 1, a right occipital metastatic carcinoma was resected using conventional techniques. NeuroArm was subsequently draped for sterility, brought into the surgical field, and positioned as the primary surgeon. When neuroArm was positioned, the surgeon was able to continue with hemostasis in the position of the assistant. The location of the robot did not impede surgeon and nurse interactions, although neuroArm positioning was restricted by cable length. This issue was resolved in later cases by reconfiguring the cable position.

In Case 2, neuroArm was registered to intraoperative MR imaging to allow the surgeon to target the intracranial pathological entity (Fig. 3) and plan the craniotomy. NeuroArm was then removed from the surgical field for draping and placement of sterile instruments into the end effectors. Following a small right paracentral craniotomy, the tumor was resected using conventional techniques. NeuroArm was then returned to the operative site and the surgeon manipulated the instruments within the surgical corridor from the workstation. In this case, the assistant was positioned at the neuroArm workstation in a room adjacent to the OR. The location of the robot did not impede surgeon and nurse interactions, although neuroArm positioning was restricted by cable length. This issue was resolved in later cases by reconfiguring the cable position.

In Case 3, neuroArm was registered to intraoperative MR imaging to allow the surgeon to target the intracranial pathological entity (Fig. 3) and plan the craniotomy. NeuroArm was then removed from the surgical field for draping and placement of sterile instruments into the end effectors. Following a small right paracentral craniotomy, the tumor was resected using conventional techniques. NeuroArm was then returned to the operative site and the surgeon manipulated the instruments within the surgical corridor from the workstation. In this case, the assistant was positioned at the neuroArm workstation in a room adjacent to the OR. The location of the robot did not impede surgeon and nurse interactions, although neuroArm positioning was restricted by cable length. This issue was resolved in later cases by reconfiguring the cable position.

In Case 3, a patient presenting with focal seizures and progressive right lower-extremity weakness was found to have a large, left posterior parafalcal lesion consistent with meningioma. As in the previous case, neuroArm was registered, draped, and used for surgical planning. For this case, a bipolar forceps was placed into each manipulator, optimizing hemostasis during tumor resection. The first assistant surgeon operated a Cavitron ultrasonic surgical aspiration system (Valleylab) for tumor decompression.

Table 1: Results of microsurgical performance studies in rats

<table>
<thead>
<tr>
<th>Factor</th>
<th>Internal Control: Surgeons</th>
<th>External Control: Residents</th>
<th>Tx Group: Surgeons</th>
</tr>
</thead>
<tbody>
<tr>
<td>total time (sec)</td>
<td>814 ± 54</td>
<td>591 ± 50†</td>
<td>1047 ± 69†</td>
</tr>
<tr>
<td>blood loss (g)‡</td>
<td>1.43 (0.45–2.72)</td>
<td>1.1 (0.37–1.82)</td>
<td>0.525 ± 0.16</td>
</tr>
<tr>
<td>performance (sec)</td>
<td>1075 ± 136</td>
<td>781 (665–878)</td>
<td>1110 ± 82</td>
</tr>
</tbody>
</table>

* Results from external control and treatment group surgeries were compared with data from the internal control group. All values are reported as the mean ± SEM when normally distributed, and as the median (with IQR in parentheses) when not.
† Significant difference (p = 0.009 for external vs internal control, and p = 0.019 for treatment group vs internal control).
‡ Measured as the weight difference of surgical gauze before and after surgery in the absence of irrigation.

Fig. 3. Intraoperative photographs showing neuroArm application in clinical cases. A: Surgical tools inserted in the neuroArm end effectors (inset) and the robot draped for surgery. B: Screenshot of the neuroArm biopsy tool-tip superimposed on the intraoperative MR image acquired for surgical planning. The resulting biopsy tool trajectory is confined to a single axis by the Zlock feature of the system (inset). C and D: NeuroArm takes the place of the chief surgeon in the surgical suite, while the position of assistant surgeon and scrub nurse remain the same. E: NeuroArm bipolar (left) and suction (right) tools are maneuvered within the surgical corridor. F: The chief surgeon is positioned at the neuroArm workstation in a room adjacent to the OR. From left to right, the monitors display the surgical site as viewed by the microscope, tool-tip overlay, system status, and field camera. An additional monitor above the rightmost screen displays the surgical site in high definition. (Panel F reprinted with permission from Dr. Sutherland; it appears on the neuroArm website [http://www.neuroarm.org].)
and the second operated a suction catheter. NeuroArm was sited between the 2 assistants, permitting all personnel to perform their respective roles without interference or discomfort (Fig. 4). Using the tool overlay, a portion of the brain–tumor interface was established using neuroArm. Although a portion of the tumor-brain interface was dissected using neuroArm, the majority of this dissection was completed using conventional techniques, as planned.

Eight weeks prior to surgery, neurofibromatosis Type 2 associated with multiple intracranial tumors was diagnosed in the patient in Case 4. At that time, a left convexity meningioma was resected using conventional techniques. Postrecovery, the decision was made to remove a right olfactory groove lesion consistent with meningioma using neuroArm. As in Case 3, neuroArm was registered to intraoperative MR images and used for surgical planning. Following a left frontal craniotomy, neuroArm was draped. A bipolar forceps was inserted into the right manipulator, and a suction catheter into the left. The instruments were used for hemostasis and tumor aspiration. The assistant surgeon supplemented the dissection with microscissors and a second suction aspirator, as planned. The tumor-pia-arachnoid interface was defined, and feeding/draining vessels were coagulated using neuroArm. The vessels were divided by the assistant surgeon, who also inserted cotton strips into the dissection plane. As planned, a conventional technique was used to dissect the contralateral olfactory nerve and tumor-brain interface.

In the patient in Case 5, a cystic right cerebellopontine angle lesion was diagnosed, which was consistent with recurrent epidermoid tumor, 20 years after initial surgery. The lesion was exposed via a translabyrinthine operative approach. The manipulators were draped, a bipolar forceps inserted into the right arm, and a suction catheter inserted into the left. NeuroArm was used to coagulate and open the tumor capsule. The tumor was very soft and therefore readily aspirated. At the completion of tumor removal, neuroArm was removed from the surgical field for acquisition of updated intraoperative MR images. Unlike previous cases, reregistration was not successful in this instance. NeuroArm was returned to the operative field for additional tumor removal. Surgery proceeded using microscopic guidance without image-guided tool overlay. The remaining tumor was readily aspirated by the surgeon at the workstation. Only a portion of the tu-

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**TABLE 2: Summary of Phase I clinical studies of neuroArm in 5 patients who underwent neurosurgical procedures**

<table>
<thead>
<tr>
<th>Case No.</th>
<th>Diagnosis</th>
<th>Role of NeuroArm</th>
<th>Incident Occurrence &amp; Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>rt occipital metastatic carcinoma from lung primary</td>
<td>draping &amp; positioning of robot in surgical field</td>
<td>neuroArm mobility restricted by length of power cables, which were repositioned in subsequent cases</td>
</tr>
<tr>
<td>2</td>
<td>rt paracentral interaxial malignant astrocytoma</td>
<td>draping, positioning, &amp; registration of robot</td>
<td>neuroArm force feedback abnormal due to overly constrictive draping, which was revised for subsequent cases</td>
</tr>
<tr>
<td>3</td>
<td>lt posterior parafalk meningioma</td>
<td>draping, positioning, registration, &amp; establishment of brain-tumor interface</td>
<td>no incidents observed during surgery</td>
</tr>
<tr>
<td>4</td>
<td>lt olfactory groove meningioma associated w/ neurofibromatosis Type 2</td>
<td>draping, positioning, registration, &amp; 50% tumor resection</td>
<td>no incidents observed during surgery</td>
</tr>
<tr>
<td>5</td>
<td>rt cerebellopontine angle recurrent epidermoid</td>
<td>draping, positioning, registration, &amp; near-complete tumor resection</td>
<td>reregistration unsuccessful &amp; surgery proceeded w/o image-guided tool overlay; following the procedure, failure of the lt elbow yaw motor amplifier disengaged power to lt arm</td>
</tr>
</tbody>
</table>

* NeuroArm was increasingly integrated into 5 tumor resection procedures, starting with draping. Once identified, adverse events were rectified.

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**Fig. 4.** Intraoperative photograph showing neuroArm positioning in clinical Case 4. NeuroArm, with a bipolar forceps in each manipulator, is positioned between 2 assistant surgeons. The assistant on the left holds a Cavitron ultrasonic surgical aspirator for tumor decompression, while the assistant on the right operates a suction catheter. In this position, each member of the surgical team performs his or her respective roles without interference or discomfort, while communicating through wireless headsets.
response following his first surgery, which consisted solely of aspiration of the cyst contents. Following completion of tumor removal, the suction tool came into contact with the scalp retractor and the left elbow yaw motor amplifier unexpectedly failed. This activated a safety feature in the software, disengaging power to the left arm. The manipulator was manually removed from the surgical field. The wound was closed using conventional techniques.

**Discussion**

**NeuroArm** performed as well and as accurately as conventional methods in initial surgical application. The technology was successfully used for increasing degrees of planned tumor resection in a series of clinical cases, and its safety mechanisms successfully mitigated hardware failure. The introduction of neuroArm was well received by OR staff.

Results from animal studies showed that surgeons using neuroArm performed microsurgery as well as surgeons using conventional microsurgical techniques. Although robotic trials took significantly longer to complete than microsurgical trials, these results are not surprising because new technologies are often accompanied by increased OR time, but this is ultimately justified by improved patient outcome. In the present study, no animal deaths occurred in the neuroArm trials, whereas the microsurgery trials incurred 1 death due to vascular injury.

A few limitations have been identified in this study design. Although surgeons in these studies may have biased the results in favor of neuroArm, the surgeon-microsurgery group demonstrated no significant differences in either blood loss or performance compared with the resident-microsurgery group. Although the residents proved faster than the surgeons in the microsurgery trials, surgeons in the neuroArm group were slower than either group, making surgeon bias unlikely.

Surgery completion time for surgeons using neuroArm may have been increased by an additional factor. To activate the bipolar tool, surgeons in this group had to issue a verbal on/off command to the assistant surgeon, who would operate the bipolar footswitch accordingly. Surgeons and residents in the microsurgery trials could choose to operate the footswitch themselves. However, this procedural difference probably did not skew results, because it introduced delays on the order of seconds, whereas surgeries were completed on the order of minutes.

Other potentially confounding variables include the use of different microscopes in the robotic and microsurgical trials. This is not believed to have impacted study results because both were approved by the common assistant (C.S.A.) prior to use. Similarly, different bipolar forceps were used in the robotic and microsurgical trials due to availability and budgetary constraints, but blood loss was not significantly different between the systems. Last, although large sample sizes may have been beneficial, samples were limited to 4 per treatment group per surgeon (8 rats total per treatment group) to minimize animal use.

Studies performed using cadaveric heads showed that the neuroArm navigation system was as accurate as a conventional frameless navigation system. Surgeons also reported that the trajectory-planning features of neuroArm made it easier to use than the VectorVision system. With neuroArm, a Z-lock feature could restrict tool movement to its longitudinal axis, and tool position could be verified by overlay on updated 2D and 3D intraoperative MR images. In contrast, the VectorVision system does not restrict tool motion to 1 axis, and surgeons were limited to 2D cross-sections only. In addition to offering greater convenience, the Z-lock feature and 3D imaging of neuroArm could increase patient safety. For example, in half of the VectorVision trials, the experienced surgeon was forced to retract the biopsy tool and reenter the surgical site at a revised angle to reach the target correctly. In the clinical setting, this could lead to increased tissue injury. Although previous studies have shown the localization error of VectorVision to range between 0.5 and 4.05 mm, those values reflect the more typical use of VectorVision for surface navigation. The higher localization error values in this study (10.4 ± 2.79 mm) reflect the use of VectorVision for deep brain biopsy. VectorVision was used in this capacity to compare 2 frameless navigation systems.

Results from initial clinical application are promising: neuroArm was well received by OR staff and successfully used for tumor resection. Importantly, the neuroArm safety system promptly responded to hardware failure by disengaging power to the system.

Stepwise integration of the robot over the course of 5 tumor resection cases may have facilitated clinical application. Initial consultation, followed by progressive integration, allowed the anesthetist, surgical assistant, and nurses to gain familiarity with the new technology prior to its use for surgical dissection. As in surgical resident education, stepwise integration permitted the surgeon operating neuroArm to become increasingly confident with use of the robot. Progressive integration also allowed for the identification and management of logistical incidents, 1 at a time, as they arose. For example, in the second clinical case, ergonomics proved to be an issue for the assistant surgeon (Fig. 3C). This resulted in a less than ideal head-body position when looking through the microscope binoculars, which was improved in subsequent cases (Fig. 4). Stepwise integration permitted technical issues to be managed in turn: the originally restrictive length of the power cable was fixed, neuroArm draping was adjusted following abnormal force feedback messages, and the yaw motor amplifier was repaired. Being able quickly to address such issues improves acceptance of novel technologies; they can otherwise be discarded should clinical integration prove disruptive.

For all cases, the stereoscopic display at the workstation was less than that provided through the operating microscope. At the time of manufacture, high-definition miniature monitors were not available. This may have, in part, limited the use of neuroArm in establishing and dissecting the tumor-brain interface. It should be noted, however, that incomplete tumor removal in each case was planned, and that for each case the operating surgeon...
gained increasing confidence. To eliminate the former problem, the stereoscopic display is in the process of being upgraded to high-definition technology.

As a final note, both localization accuracy tests and clinical studies may have benefitted from additional trials to match sample sizes and demonstrate complete tumor resection, respectively. Ultimately, this was not possible because the neurosurgical suite was shut down to upgrade the intraoperative MR imaging system from 1.5 to 3.0 T.

Conclusions

Apart from identifying potential issues, the results demonstrate the successful initial application of neuroArm to neurosurgery. These studies suggest that the system is ready to progress to the next phase of clinical integration studies, which will incorporate new system upgrades and expanded case series. Ultimately, through clinical trials, the benefits of neuroArm will be established, allowing widespread clinical acceptance.

Disclosure

The study sponsors had no role in the study design, data collection, data analysis, data interpretation, or the writing of this report. The corresponding author (Dr. Sutherland) had full access to all data and had the final responsibility for the decision to submit for publication. Drs. Sutherland and Latour and Mr. Greer are active in the development of a Calgary-based company, neuroArm Surgical Ltd., created for the ongoing development, manufacture, and distribution of neuroArm. All 3 hold shares in this company. The remaining authors declare that they have no conflicts of interest.

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Author Contributions

Dr. Sutherland designed the study and performed rat surgeries with microsurgical and robotic techniques. Dr. Serrano-Almeida assisted at all rat surgery trials, selected navigation targets, and performed VectorVision navigation trials. Mr. Greer was responsible for neuroArm set-up, performed robotic navigation trials, and assisted with intraoperative MR image acquisition. Ms. Pandya recorded data while Dr. Motkoski assisted in all cases. Dr. Sutherland operated neuroArm in all clinical cases. Ms. Pandya and Mr. Motkoski performed all data analysis and prepared the manuscript. Dr. Sutherland supervised the writing process. Dr. Latour assisted with nanoparticle preparation for navigation trials and with editing of the manuscript.

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