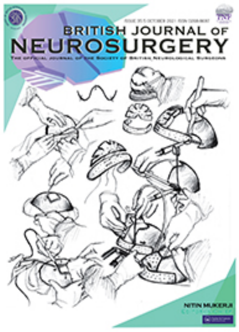

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REVIEW ARTICLE

Cranial neurosurgical robotics

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ABSTRACT

Object: The purpose of this review is to highlight the major factors limiting the progress of robotics development in the field of cranial neurosurgery.

Methods: A literature search was performed focused on published reports of any Neurosurgical technology developed for use in cranial neurosurgery. Technology was reviewed and assessed for strengths and weaknesses, use in patients and whether or not the project was active or closed.

Results: Published reports of 24 robots are discussed going back to 1985. In total, there were 9 robots used in patients (PUMA, Robot Hand, EXPERT, Neuromate, Evolution 1, ROSA, iSYS1, NeuroArm and NeuRobot) and only 2 active today (ROSA, NeuroArm). Of all clinically active systems, only three were used in more than 30 patients (ROSA, iSYS1 & NeuroArm). Projects were limited by cost, technology adoption, and clinical utility to actually improve workflow. The most common use of developed robots is for Stereotaxis.

Conclusions: There is a clear void in the area of cranial neurosurgery regarding robotics technology despite success in other fields of surgery. Significant factors such as cost, technology limitations, market size and regulatory pathway all contribute to a steep gradient for success.

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Image-guided intervention; minimally invasive surgery; robotic surgery; cranial robotics; cranial robot

Introduction

Robotics has seen tremendous growth in other fields such as general, gynecologic, urologic, and most recently head and neck surgery (TORS – TransOral Robotic Surgery) with the da Vinci Robot (Intuitive Surgical, Inc., Sunnyvale, CA). In 2015 alone, there were over 700,000 procedures performed using the da Vinci Robotic System.[1] The reason for the success of the da Vinci robotic system is due to its numerous clinical application and easy adaptability. The first robotic procedure in Neurosurgery was performed over 30 years ago using the PUMA 200 (Westinghouse Electric, Pittsburgh, PA) for needle placement in a CT-guided brain biopsy[2] but despite this early adoption progress has been slow. There is a demand for a cranial neurosurgical robotics with easy setup, accuracy, and reduction of hand tremor, especially during long procedures and in particular with deep lesions.[3,4] Major developmental constraints for Neurosurgery are cost, anatomical limitations, and minimal progress with visualization.[5] Robotics has not seen mainstream use within cranial surgery except for within the area of Stereotaxis. FDA-approved robots on the market used in Stereotactic procedures have been more aptly designated 'Co-Robots' or 'Cobots'.[5,6] Stereotactic procedures have become a major area of research interest. Robotic systems for these types of procedures could greatly improve its precision, while vastly increasing the capabilities of the surgeon.[7]

Robotics in surgery can be classified on the basis of working environment, manipulator design, targeted structure and methods or the level of autonomy.[8] The systems are then usually classified into passive and active systems.[9] *Passive Systems* or master-slave systemsis where a surgeon provides input to direct and maneuver the device.[10] *Active Systems* is where a robot functions autonomously receives information from its environment and carries out its task independently.[2,10] An intermediate form is the semi-active system with robotic guidance to the surgeon such as NeuroMate.[2,10] Even further, Active Systems can be classified into a: (1) supervisory-controlled system, (2) telesurgical system, and (3) shared-control system.[2,9,10] In a *supervisory-controlled* system, the robot automatically performs the task and is supervised by the surgeon. A *telesurgical system* is where the surgeon controls the robot in real-time via a haptic interface. In a *shared-control system* (combination of supervisory and telesurgical), the surgeon has full control of the procedure and the robot offers steady hand manipulation of the instrument.[2,9–11]

There have been a few comprehensive reviews of neurosurgical robots throughout years. For example in,12 they emphasized how the usage of robotics in neurosurgery shows much benefit but is limited by operational costs.[12] Another review by Karas and Chiocca stated that the future is adaptation of the surgeon's environment and creating enhancements like dexterity, sensory feedback and automation.[13] Neither of these reviews focus solely focus on cranial neurosurgical robots.

Since these reviews, what developments have been made? Have these developments been steady or impeded? If these developments are impeded then why?

We define a cranial neurosurgical robot, as a device that operates with some degree of autonomy in a procedure that involves the cranium. With this definition we conducted a review of the literature using PubMed and Google Scholar. The search terms used were 'Cranial Robotics', 'Robotic Surgery', and 'Cranial Robot'. A total of 58 articles were reviewed and included. This review excluded spinal-based systems and computer simulation studies. Rather it focuses on the development timeline, reasons

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for success or failure and then determines factors that need to be satisfied for success in clinical cranial surgery.

Robotic systems

Most of the systems developed as of the writing of this review should be classified as passive robotic systems. We classify passive systems (Table 1) into (1) Simple Robotic Adjuncts (2) Stereotactic Surgery Systems with Single Robotic Arms; and (3) Image-Guided Stereotactic Surgery Systems with Single Robotic Arms. Active robotic systems with a master-slave combinations can be found in Table 2. Table 3 categorizes robotic systems by neurosurgical subspecialty.

Simple robotic adjuncts

These tools consisted of surgical aids for CT-guided biopsy,[2,14] arm support,[14–16] and neurosurgical tools.[17,18] Only the PUMA (Figure 1),[2] Robot Hand,[15] and EXPERT[16] were used in patients; the others were used in a phantom model[16,17] or animal model.[18] None of these projects are active.

Stereotactic surgery systems with single robotic arms

Stereotactic procedures are among the most common interventions in neurosurgery.[19] Frameless procedures with navigation-guided mechanical positioning devices are routinely performed but with lower accuracy.[20] Robotic devices are implemented in these procedures in order to overcome the limitations of frame-based and frameless techniques in terms of inefficiency, accuracy and safety.[21] This group is discussed in Table 1.

Neuromate (1987)

The Neuromate Robot (Renishaw, New Mills, Wotton-under-Edge Gloucestershire, UK) is a commercially available neurosurgical robot used in many centers for stereotactic and endoscopic procedures. Neuromate was developed in 1987 and was the first neurosurgical robot device CE-marked in Europe for procedures in Stereotaxis.[22] It is a single robotic arm with 5 joints and 6 Degrees of Freedom (DOF). Accuracy of the robot has been validated in multiple studies.[4,23,24] Xia *et al.* further developed an image-guided robot system to provide mechanical assistance for skull base drilling consisting of a Stealth Station (Medtronic), Neuromate, and 3D Slicer visualization software. Experiments were performed on both foam skull and cadaver heads without further development.[25]

SurgiScope (1989)

The Surgiscope was developed by ISIS Robotics in 1989 and consisted of a ceiling-mounted robotic arm dedicated to endoscopy and biopsy procedures or neuronavigation application.[26] The SurgiScope proved to have such complexity that it required continual retraining of staff despite an accuracy of less than 2 mm.[27]

Evolution 1 (2002)

The Evolution 1 Robotic System (Universal Robot Systems, Schwerin, Germany) was designed for neurosurgical and endoscopic applications.[28,29] It comprised of different types of surgical instrumentation like endoscopes and high-speed drills. Control

Table 1. Passive cranial robots.

Class	Robot (year published)	Design	Procedures	Clinical application	Pros	Cons	Status
Simple robotic adjuncts	PUMA (1985)	CT Guidance	Stereotaxis	1 Patient[a]	Accuracy	Safety Concerns	Closed
	CT-Bot (2008)	CT Guidance	Stereotaxis	None	Accuracy	Poor design	Closed
	Robot Hand (2009)	Robot Hand	Reduce Tremor	23 Patients[a]	Accuracy	Lack of data	Closed
	Craniostar (2009)	Craniotome	Craniotomy	Animal	Accuracy	Miniaturization	Closed
	Robotic Instruments (2011)	Intelligent Suction	Microsurgery	Phantom model	Less tremor	Integration with sensors	Closed
	EXPERT (2013)	Arm Holder	Reduce Tremor	13 Patients[a]	Less tremor	Uncomfortable	Closed
Stereotactic surgery w/ single Robotic arms	Neuromate (1987)	Single Arm	Stereotaxis, Endoscopy	FDA approved[a]	Accuracy	Bulky and cost	Closed
	Surgiscope (1989)	Single Arm	Endoscopy	40 Units discontinued	Accuracy	Lack of mobility; Cost; complexity.	Closed
	Evolution 1 (2002)	Single Arm + Endoscope	Endoscopy	3 Patients[a]	Accuracy	Cost; lack of flexibility; Restricted workspace	Closed
Image Guided Stereotactic Surgery w/Single Robotic Arms.	PathFinder (2009)	Single Arm	Stereotaxis	Phantom trial	Accuracy	Registration and robot errors	Open[b]
	Robocast (2010)	Single Arm	Stereotaxis, Endoscopy	None	Accuracy	Complex algorithms	Closed
	VGR (2011)	Single Arm	Stereotaxis	Phantom & Animal trials	Easy to configure	Limited series	Closed
	MARS (2012)	Single Arm	Stereotaxis	Phantom trial	Frameless; Accuracy	Limited series	Closed
	ROSA (2012)	Single Arm + Haptics	Stereotaxis; Third Ventriculostomy	FDA approved [a]	Frameless; Accuracy	Bulky; Steep learning curve	Open[b]
	iSYS1 (2017)	Single Robotic Arm	Stereotaxis, Ventriculostomy	39 Patients[a]	Frameless; Accuracy	Limited series	Open[b]

Three classes of passive robots: simple robotic adjuncts, stereotactic surgery w/single robotic arms, and image guided stereotactic surgery w/single robotic arms. Each robot categorized by year first published, design, procedures, clinical application, pros, cons and status of project.

[a] Indicates which robots were FDA approved or used in patient studies.

[b] Indicates open projects.

Table 2. Active cranial robots.

Class	Robot (year published)	Design	Procedures	Clinical application	Pros	Cons	Status
Active with a master-slave robotic Combination	RAMS (2000)	Dual arm	Microsurgery	In vivo rat carotid arteriotomy	Manual dexterity	Task time; Lack of haptic feedback	Closed
	NeuroArm (2002)	Teleoperated, dual arm	Microsurgery	35 Patients[a]	Manual dexterity	Maintenance; Costs	Open[b]
	NeuRobot (2002)	Three arms + endoscope; 10-mm port	Deep Lesions, Microsurgery	5 Patients[a]	Manual dexterity	Limited Maneuvering; Workspace	Closed
	CRANIO Project (2010)	Robotic drilling arm	Microsurgery	None	Manual dexterity	Limited series	Closed
	Cobra 600 Robot (2011)	Single arm + camera	Bone Drilling, Endoscopy	None	Visual system	Lack of Illumination/ Visualization; Safety mechanism	Closed
	MRS (2013)	3D Hi-Def + dual arms	Microsurgery	None	Manual dexterity	Task time	Closed
	Da Vinci (2014)	3D Hi-Def + four robotic arms	Keyhole Craniotomy	Cadaver study	Manual dexterity	Limited tools; Size	Open[b]
	Endonasal Robot (2016)	Telemetric, dual arms	Transphenoidal Surgery	Phantom model	Telemetric operation	Initial development	Open[b]
	Active Cannula (2016)	Single steerable cannula	Hematoma Evacuation	Phantom model	Steerable catheter	Initial development	Open[b]

Active Robots with a Master-Slave Combination categorized by year first published, design, procedures, clinical application, pros, cons and status of project.

[a]Robots used on patient or received FDA approval.

[b]Open projects.

was by a touch screen and a master joystick device to control end-effector motion and speed, and the robot was integrated with planning software (VectorVision, BrainLab). Evolution 1 had limited flexibility and was restricted by the parallel actuator, which was large and caused restriction of the workspace.[28,29]

Image guided stereotactic surgery with single robotic arms

PathFinder (2009)

PathFinder (Prosurgics, Guildford, GBR) is a single robotic arm that integrates image-guidance to enhance frameless stereotaxy. Pathfinder was used in patients to test the accuracy of the frameless system with tool placement.[30] The device can position a stereotactic probe to an accuracy < 1 mm without the need of a head frame.[31,32]

Robocast (2010)

The ROBOCAST project was started in 2008 for the assistance of keyhole neurosurgery.[33,34] ROBOCAST was made up of three distinct robotic systems used in combination to create a kinematic chain: Prosurgics's PATHFINDER™ arm (United Kingdom), Mazor Robotics (Caesarea, Israel) Renaissance® Guidance System, and a custom-made insertion unit. The innovation of this project was in the intelligence of the system and flexible probe. One innovative concept of the technology was to help the surgeon driving the insertion of the probe through a haptic device adapted with an ergonomic stylus. Despite early progress, the project was closed in 2012.

VGR: Vision-Guided Robotic Arm (2011). Wei et al designed a vision-guided, hybrid robotic system consisting of a passive serial arm and an active parallel frame. The prototype system accomplished phantom and animal trials with satisfactory accuracy. The system could withdraw from the working area and restore the aiming posture freely.[35] No further studies were done.

MARS: Motor-Assisted Robotic Stereotaxy System (2012). The MARS system was developed by IBG Robotronic Gmbh (Goeke Technology Group, Neuenrade, Germany). The device was fixed directly onto the surgical table and connected via USB to a computer-controlled interface. It represented a compact and lightweight robotic system for stereotactic neurosurgery.[36] Mean errors were smaller than currently used mechanical systems and the results showed that the robot's accuracy is appropriate for stereotactic interventions. No further studies were completed.

The ROSA System (2012). The ROSA system (Figure 2) is an image-guided device with advanced navigation functions and haptic capabilities for both stereotactic and non-stereotactic approaches.[37] The surgeon can either supervise the robot performing autonomously or directly control and move the surgical instrument during the procedure. The ROSA system is composed of a compact robotic arm and a touch screen, mounted on a mobile trolley attached to the head holder. It combines human decision making with the accuracy of the robotic arm and the haptic ability of the surgeon. Studies showed the versatility of the device improving safety and feasibility while minimizing risks and surgical time[11,38] and improving accuracy.[39] Hoshide et al conducted a study of 9 pediatric patients undergoing Third Ventriculostomies. The study showed great success however exhibited a steep learning curve.[40]

Table 3. Neurosurgical robots by subspecialty.

Neurosurgical subspecialty	Robotic system or technology
Stereotaxis	PUMA, CT-Bot, MARS, VGR, Robocast, Pathfinder, Neuromate, iSYS1[b], ROSA[b]
Neuro-Endoscopy	Surgiscope, Evolution 1
Microneurosurgery	Robotic Instruments, EXPERT, Robot Hand, RAMS, NeuroArm[b], NeuRobot, Cranio, Microsurgical Robotic System, Da Vinci[a]
Craniotomy	Craniostar, Cobra, Active Cannula
Transphenoidal Surgery	Endonasal Robot[a]

Robotic system/technology grouped by neurosurgical subspecialty.

[a] Current open projects.

[b] Technologies currently used on patients.

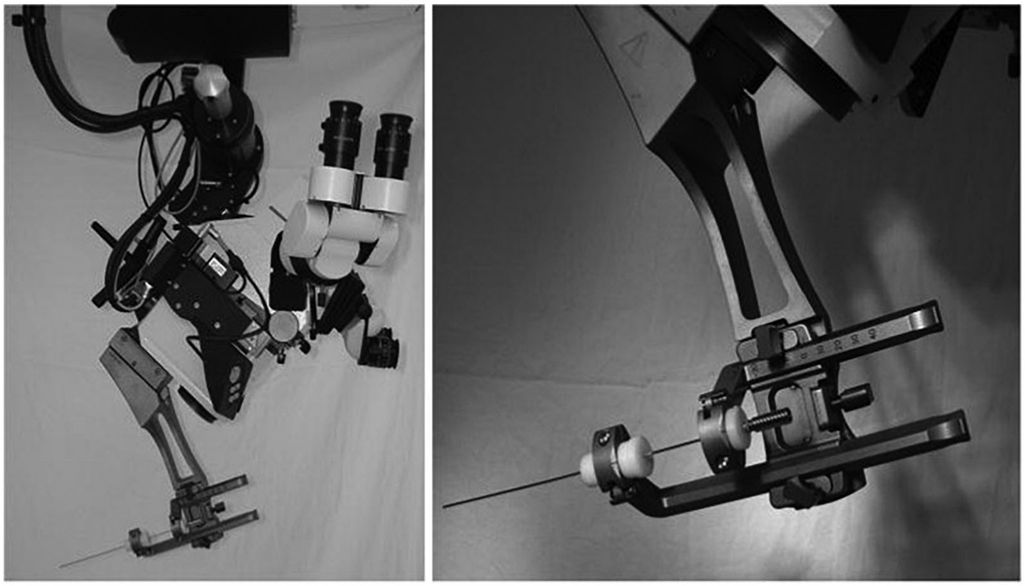

Figure 1. PUMA.

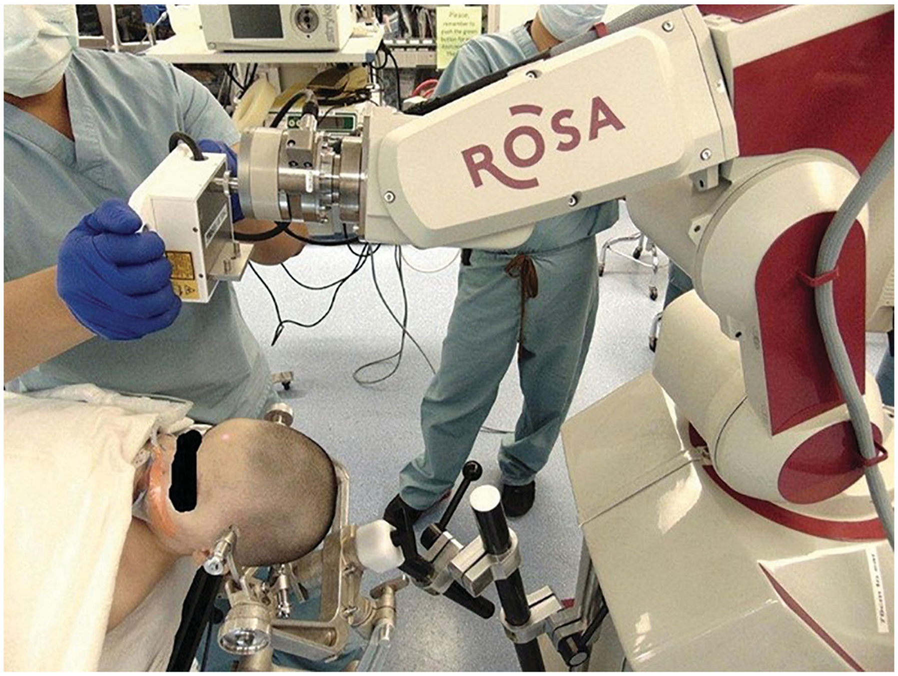

Figure 2. ROSA.

Benedictis et al reported the largest series of pediatric neurosurgical cases using the ROSA robotic system. The system assisted in 128 surgical procedures performed in 116 children, including implantation of SEEG electrodes, neuroendoscopy, tumor biopsy, functional procedures (DBS and pallidotomy), and other stereotactic approaches. The overall surgical success

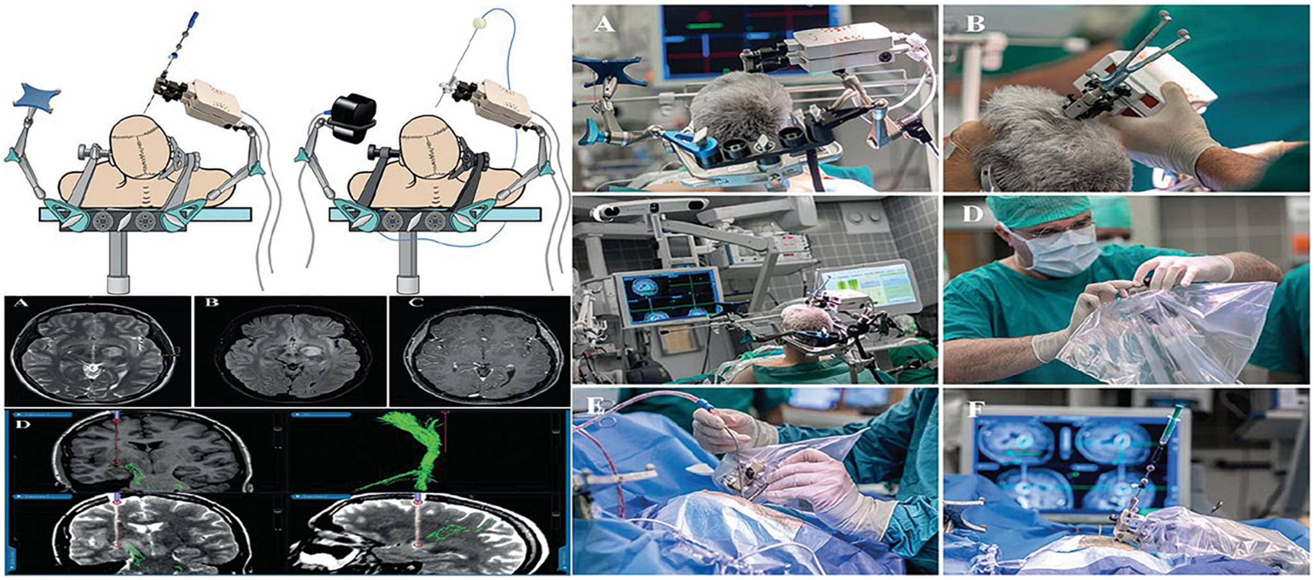

Figure 3. iSYS1.

rate was 97.7%, with a 3.9% rate of early clinical transient complications.[41]

iSYS1 (2017). Originally designed for needle guidance in interventional radiology, the iSYS1 (Figure 3) is a miniature robotic guidance device for aligning a surgical tool along a predefined trajectory based on rigid fixation and image guidance.[42] Feasibility and accuracy were assessed in 25 consecutive cases of tumor biopsies and intracranial catheter placements.[43] Clinical results showed the application of the iSYS1 robotic guidance device was feasible in all but 1 case. A follow-up study with 39 patients recently published[44] supported the accuracy of the frameless system with optical neuronavigation. Due to the limited number of patients, the preliminary series did not draw significant conclusions.

Active robotic systems with a master-slave combination

RAMS: Robot-Assisted Microsurgery System (2000)

The Robot-Assisted Microsurgery System consisted of a 6 DOF, Master-Slave telemanipulator with programmable controls including a task-frame referenced manual force feedback and textural feedback. Roux et al used the device to repair carotid arteriotomies in 10 rats. Although the system completed the surgical task, operative times were long and lack of haptic feedback made it more difficult.[45] No further studies were published.

Neuroarm (2002)

NeuroArm (Figure 4) is a teleoperated surgical robotic system (http://www.neuroarm.org/) to allow operating with real-time intraoperative magnetic resonance imaging (MRI).[46,47] NeuroArm was successfully manufactured and installed into intraoperative MRI room and was used in 35 cases.[3] The device is MRI-compatible and image-guided made of two PEEK (poly-ether-ether-ketone) robotic arms capable of manipulating microsurgical tools such as a bipolar and special grabbing device. At the workstation, a human-device interface provides both MRI data and real-time high definition 3D images of the surgical site. Haptic feedback is relayed to the surgeon through the hand controls. In the most recent publication, the group attempted to correlate tissue pathology in brain tumors to force exerted on the NeuroArm robotic arms without success.[48]

NeuRobot (2002)

The NeuRobot™ (Figure 5), also known as the 'HUMAN' system, had the first successful clinical test in August 2002; four more successful surgeries between 2002 and 2008; and telesurgical usage proved feasible in 2009. There have been no further reports since 2009. NeuRobot was a multi-arm robot used through a single 10-mm port. Three miniature surgical manipulators (3-mm diameter) and a single miniature endoscope (4 mm), with a camera and light source, were placed through a 10-mm diameter tube. In addition to the manipulators and endoscope, the system also contained miniaturized ports for suction/irrigation and bipolar cautery. Each manipulator had 3 DOF and allowed surgeons to automatically change tools. The system was designed to be disassembled and assembled by medical staff, and with complete sterilization capability.

CRANIO project (2010)

The CRANIO project was an active robotic system developed to automate bone drilling.[49,50] Preoperative CT scans were evaluated with image software to define the bony surgical volume for resection and a fiducial-based ultrasound system was used to assess bone thickness in real time. A high-speed drill was integrated into the system utilizing a robot. The entire system was controlled through a master-slave mechanism that allowed automated robotic control with the ability for the surgeon to relieve robot control at anytime. Although the results were promising with a true Master-Slave set-up, the project was limited to experimental studies only.

Cobra 600 robot (2011)

Awang et al created the Adept Cobra 600 robot (Adept Technology Inc., San Jose, CA). It is a selective compliant assembly robot arm (SCARA) robot with 4 joints and a 25mm lens mounted camera. The study was used to assess function in basic neurosurgical procedures such as bone drilling and endoscopic procedures. A total of 10 selected burr holes were used to assess

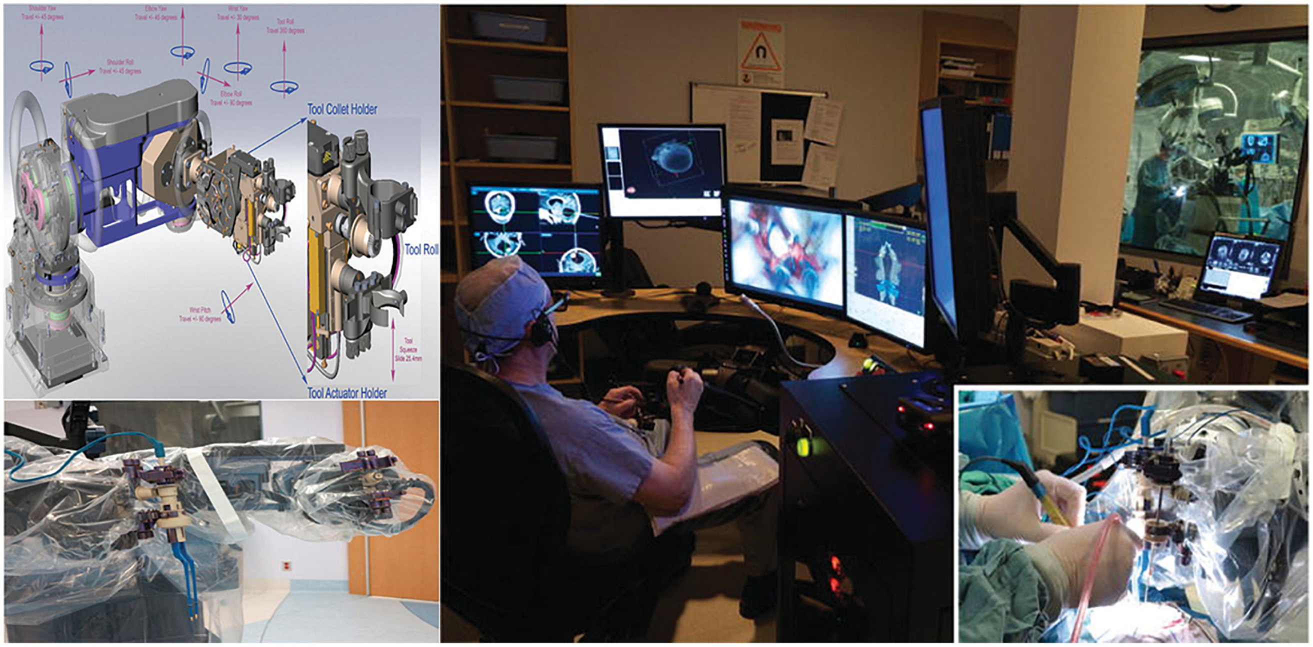

Figure 4. NeuroArm.

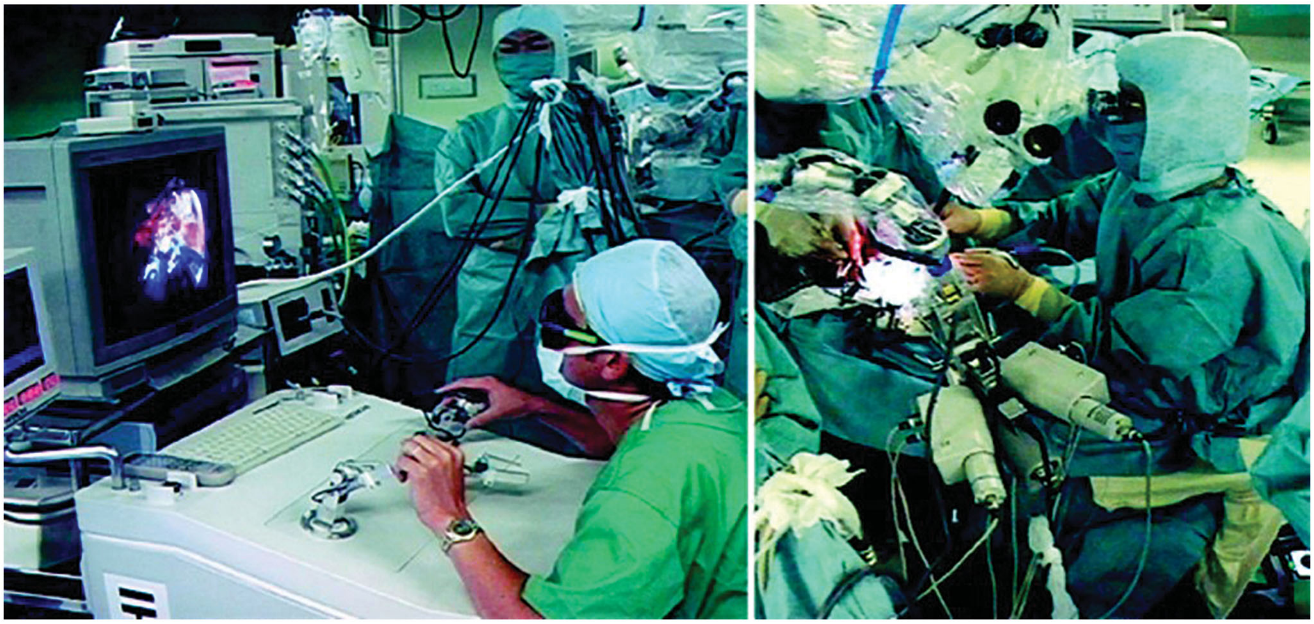

Figure 5. Neurobot.

the capability of the robot to insert an endoscope. The robotic system was accurate and able to perform the surgical tasks however, further study was needed to refine the robotic system, including the safety mechanisms.[51]

MRS: Microsurgical robotic system (2013)

Mitsuishi et al created a master-slave robotic system for microsurgical arterial anastomoses. The platform was equipped with a 3D stereomicroscope, manipulators, and computer software. Performance of the robot was validated by conducting end-to-end anastomoses (0.3 mm artificial vessel) and side-to-end anastomoses (0.5 mm artificial vessel). Although the experiments demonstrated that the robotic system had sufficient accuracy and dexterity, the task completion time was much longer than for manual operation.[52]

Da Vinci robot (2014)

The Da Vinci robot uses 3D high-definition cameras and four integrated arms. Marcus et al performed a cadaver study to evaluate the feasibility and safety of a da Vinci robot-assisted keyhole neurosurgery procedure.[53] The instrument arms could not be placed in parallel through the keyhole craniotomy and, therefore, could not be advanced to the deep cisterns without significant clashing. Also, the lack of haptic feedback was a notable limitation. Chauvet et al evaluated the feasibility of TransOral Robotic Surgery (TORS) to the sella turcica in cadavers ($n = 4$). They could open the sella in all cadavers with a minimally invasive approach, although the instruments still proved too bulky.[54]

Endonasal robot (2016)

Burgner et al developed a dual-arm robotic assistant with concentric tubes providing benefits such as telesurgery.[55] Wirz et al. described the system used by the Burgner system to perform a phantom pituitary tumor resection done in Nashville, Tennessee, where a surgeon 800 km away in Chapel Hill, North Carolina controlled it remotely. A phantom pituitary tumor removal experiment was conducted twice, once locally and once remotely, with the robotic system. There was no loss of control or response due to latency over the long distance.[56] No further studies reported.

Active Cannula: robotic aspiration of intracranial hemorrhage (2016)

The Active Cannula system is based on a less invasive needle-based approach in which the clot is debulked from within using a superelastic, precurved aspiration cannula controlled by a robotic arm and image guidance.[57] The system includes a robotic drive that controls a steerable needle with a series of concentric tubes. The outer tube ('the needle') is a straight, stiff tube made of stainless steel. The inner aspiration cannula is a tube that is precurved and made of superelastic nitinol. As it passes through the outer tube, it is straightened, but it returns to its pre-curved shape when it exits the tip of the outer tube. The actuation unit controls insertion and retraction of both tubes, and axial rotation of the inner tube. The innermost tube is coupled to a suction pump used to evacuate blood. Experiments demonstrate that the system can effectively and safely evacuate 83–92 percent of a hemorrhage volume. Ultrasonic tips, spatulas and other end effectors are under development.

Discussion

This review has discussed 24 cranial-related robotic projects since 1985 with 9 devices used in patients (PUMA, Robot Hand, EXPERT, Neuromate, Evolution 1, ROSA, iSYS1, NeuroArm and NeuRobot) and with only 2 still active today (ROSA, NeuroArm). Overall, NeuRobot was the closest device that provided the most versatility in terms of (1) multiple ports, (2) adequate viewing through an associated endoscope, (3) instrument interchangeability, (4) miniaturization, and (5) a clinical history. Unfortunately, this project was closed for unknown reasons.

Why is there a tremendous technology gap in the most advanced field in medicine & surgery? The benefits of a neurosurgical robot that would satisfy the following are obvious: (1) reduce fatigue and tremor, (2) allow deep access, (3) improve accuracy, and (4) automate simple tasks. Over time, appropriate development should then lead to shorter operative times with hopefully better patient outcomes. Coupled to these benefits are the major limitations to development such as: (1) cost, (2) technology constraints, (3) market size, (4) regulatory concerns, and (5) risk.

Cost

The overwhelmingly important factor in developing a Neurosurgical Robot is cost. The project would require multiple disciplines working together over a long period of time or a significant business effort lead by Venture Capital. The senior author has some background in product development. In a hypothetical situation, a developer would have to invest at least $10 million in capital over the span of 3–5 years to develop a successful working prototype. This prototype would have gone through vigorous testing and evaluation by the means of: animal studies, clinical trials, and patent applications. Subsequently this device would require additional capital for FDA approval and subsequent clinical use. Venture Capitalist or VC are reluctant to invest in any technology that is (1) not protected Intellectual Property, (2) a Class III Device that requires PreMarket Approval by the means of costly clinical trial, and (3) insufficient market size ($100 Million or greater) to warrant development.

Operational Cost also poses a significant obstacle from the viewpoint of the consumer. Most consumers when looking at cost effectiveness, refer to the cost versus charge ratio. In an average operating room it would cost $20 per minute to conduct a procedure.[58] Utilizing robots that require lengthy assembly and disassembly, this would further inflate the cost of procedure. Robotic systems that are integrated into the operating room and require limited assembly should be the objective of developers.

Technology constraints

In developing a robot, if similar to the NeuRobot or Da Vinci, the size of the arm and accompanying camera pose a key problem in fitting the necessary robot into a small enough opening. The success of the da Vinci system is partly because there is enough volume to manipulate instruments within an insufflated abdomen. *Visualization* is a requirement in that the Neurosurgeon operator needs proper viewing at all times; current endoscopes would not suffice to satisfy said specifications. Furthermore, in the example of the NeuroArm, the requirement of having an intraoperative MRI (iMRI) has potentially slowed the incorporation of this robotic system. The slow adoption of the Neuroarm could be directly related to a slow adoption of the iMRI.

Haptic feedback is an absolute requirement because of retraction of brain parenchyma. In the 2007 review article by Karas and Chiocca also emphasized further development in feedback mechanisms.[13] Since this review, there has only been a few studies in the progression of the feedback systems. One study, by Lorenzo et al, aimed at estimating the resistance to a standard probe for brain biopsies by using a master-slave driver with direct feedback on the mechanical characteristics of the tissue, and showed better performance using the control-based method.[59] Time to development is also a limiting factor. Academic-based projects that rely on grant funding take a much longer time when compared to private funded ventures; grants lapse, funding becomes scarce, and investigators leave. Extended development time can lead to obsolete prototypes by competing technology. Above all, the technology must achieve the primary goal of making cranial surgery better for the neurosurgeon and patient.

Market size

Venture Capitalists are only interested in markets that exceed hundreds of millions to billions of dollars. The market size for craniotomy in the United States is difficult to estimate, but data from 2007 shows approximately 150,000 or more procedures per year.[60] Assume a new robotic device would cost $750,000 to purchase + $50,000 yearly service contract + $2,500 per case in disposables; a 1% market share (assume 15 hospitals at 100 procedures per year). This model would yield a yearly expense of:

15 installations @ $750,000 = $11,250,000

15 Service Contracts @ $50,000 = $750,000

1,500 cases w/disposables @ $2,500 = $3,750,000

Total Expense (Year 1) = $15,750,000

It would be no easy task for a start-up to break even with these numbers as management, development and a sales force would require additional funding of at least another $10–$20 million (in addition to the initial $10 million seed capital) to get to this particular sales cycle. In the end, it would cost approximately $30 million or more in VC funding to approach the above sales scenario. Depending on the business model for the robot, any company that develops it will have to compete for hospital capital with other expensive items such as image-guidance systems, intraoperative CT & MRI Units, spinal robots, and stereoscopic imaging systems. In addition to the initial cost of the robot, the disposable items needed for the machine delivers additional expenses and revenues.

Conclusion: the ideal cranial robot

After the review, it is our estimation that the first iteration of a cranial robot should include the following: (1) access through the skull in a port no larger than 25 mm; (2) at least 3 to 4 robotic arms with each tool having a diameter of 10 mm; (3) a robotic camera with at least 6 DOF to access anywhere within a cavity; (4) interchangeable tools such that the surgeon can change between dissector, microscissors, etc.; and (5) integrated to image guidance. The second iteration would incorporate artificial intelligence such that the robotic system would be programmed to complete a task such as the resection of a tumor or hematoma with the surgeon supervising the treatment plan.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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