Robotic Ear Surgery

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KEYWORDS

• Surgical robots • Minimally invasive • Stapes • Cochlear implant

KEY POINTS

- Three classifications of surgical robots in ear surgery are discussed: collaborative (eg, passive parallel robot to guide drilling), teleoperated (eg, the daVinci surgical system), or autonomous (eg, bone-mounted robot performing mastoidectomy).
- Current clinical trials include minimally invasive drilling approaches to the cochlea with both collaborative guides and autonomous robots as well as stapes surgery and cochlear implant electrode array insertion using a teleoperated system.
- Within otology/neurotology, while autonomous robots may have the potential for higher impact (eg, drilling translabyrinthine approaches to the internal auditory canal), collaborative or teleoperated manipulators are likely to be clinically translated first, given less disruption to current surgical workflow and less rigorous regulatory criteria.
- Market forces will largely determine when adoption of robots as standard of clinical practice within otology will occur.

INTRODUCTION

Surgical robots are of considerable interest to clinicians and patients for their perceived benefit in more accurately targeting structures and more effectively accomplishing surgical tasks, often in a minimally invasive fashion while overcoming human limitations (eg, inherent tremor, limited tactile feedback, and technique variability). In this article aimed at covering the current state of the art regarding robotic ear surgery, the authors first begin by defining 3 classes of robotic devices in ear surgery to be used. These definitions are largely based on the surgeon-device-patient interaction with “end effector” defined as the surgical instrument that is contacting the patient.

- *Collaborative Robot/Guide*. The surgeon’s hands directly actuate the end effector. The robot/guide passively (eg,[1]) or actively (eg,[2]) constrains and potentially augments surgical motion.

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- *Teleoperated Robot.* The surgeon remotely controls the end effector during the surgery (ie, surgeon motions map to end effector motion with potential modification [ie, tremor reduction, scaling]; eg,[3]).
- *Autonomous Robot*. The end effector interacts with the patient independently, whereas the surgeon supervises (eg,[4]). Note, the surgeon initiates the interaction (perhaps with a button push/hold) and closely monitors progression with intervention, if necessary.

Also pertinent to understanding the current and future state of the art is some appreciation of regulatory oversight that may help to explain why autonomous robots—which are standard of care in most high-volume manufacturing facilities (eg, car assembly) where they are considered safer and more efficient than human operators—have yet to be widely introduced into our surgical armamentarium while teleoperated systems, such as Intuitive's da Vinci surgical system (Intuitive Surgical Inc., Sunnyvale, CA) have been introduced.

With respect to ear surgery, surgical robotic devices have the potential to give surgeons superhuman abilities by augmenting their existing training. One specific example of when this augmentation would be clinically useful is during cochlear implant (CI) electrode array insertion. Past studies[5,6] have demonstrated that human surgeon perception is on the same order of magnitude as severe intracochlear trauma. A logical extension of these findings is that subtle intracochlear trauma cannot be appreciated by human surgeons, yet CI companies instruct surgeons to stop electrode array insertion when increased force is perceived, which seems to not be humanly possible. Perhaps as important as development of robotic technology is recognition by surgeons that the technology is necessary. This example is but one of the broad potential applications in this field that is discussed in the following section. In this article, the authors focus on clinical applications of the devices defined in the classes mentioned earlier. Interested readers may also find further details on many of the technologies discussed later in the cited references as well as in other review articles on this topic.[7,8] For each defined class of surgical robot, the authors first describe the general landscape of that robot in ear surgery and then discuss known clinical implementations with regulatory approval.

APPLICATIONS

Collaborative Surgical Robot/Guides

The authors begin the discussion with perhaps the simplest approach to robotic assistance in ear surgery—the collaborative robot/guide. One example of this type of device is a template or frame that aligns a tool/implant to a patient-specific trajectory and the surgeon then carries out the remaining surgical tasks. Such technology has been in use in neurosurgery since the 1970s, first with rigid N-frames[9] and then articulated arm robots[10] and now includes 2 Food and Drug Administration (FDA)-cleared and clinically used models—the Neuromate (Renishaw, Inc.) and the Rosa (MedTech, Inc.)—which are used for minimally invasive intracranial biopsy, deep brain stimulator placement, and ablative therapy for intractable epilepsy. Extension of such collaborative guides to target the cochlea for minimally invasive access to the cochlea has been reported by numerous groups including setting the trajectory with a patient-customized microstereotactic frame[11] (details on clinical implementation discussed later) or setting the trajectory with a passive parallel robot.[1,12]

Another type of collaborative robot is one that constrains surgical motion to establish so-called no-fly zones to prevent surgeons from damaging healthy tissue. This type of robot allows the surgeon to freely move the drill but uses active braking with motors[2] (Fig. 1) or passive braking[13] to enforce safety boundaries. Both the patient and robot are tracked using an infrared image guidance system (IGS). When a boundary is approached—boundaries are set during preoperative planning—the system sends an audible signal followed by braking to prevent the drill from violating the boundary. These types of robots could have utility during training and/or in complex cases where unusual anatomy may be encountered.

Several groups have worked on variations of collaborative “micromanipulators” modified for ear surgery to overcome inherent physiologic tremor and improve repeatable positioning. The Steady Hand Robot from Johns Hopkins University[14] is a robot designed to reduce hand tremor and has undergone preclinical testing for stapes surgery and is being commercialized by Galen Robotics, Inc. (Baltimore, MD). This robot has also been used for improved cochlear implant insertions with the implementation of no-fly zones.[15] The Micron is another micromanipulator modified for stapes footplate surgery, with past studies showing 50% reduction in hand tremor.[16]

Clinical implementation

Labadie and colleagues[11] reported in 9 patients the ability to use a customized microstereotactic frame to access the cochlea via a narrow tunnel drilled from the surface of the mastoid through the facial recess. Their initial cohort included a patient with a heat-induced facial nerve paresis, which resolved to a House-Brackmann II/VI. Because of regulatory changes at the United States FDA via the 2012 Safety and Innovation Act, their work was halted, whereas technological improvements and obtainment of an Investigational Device Exemption was sought. They reported reinitiation of clinical trials in a recent case report under review. The same group has also clinically used the customized microstereotactic frame approach to drain a petrous apex lesion via both the subacurate and infralabyrinthine approaches.[17]

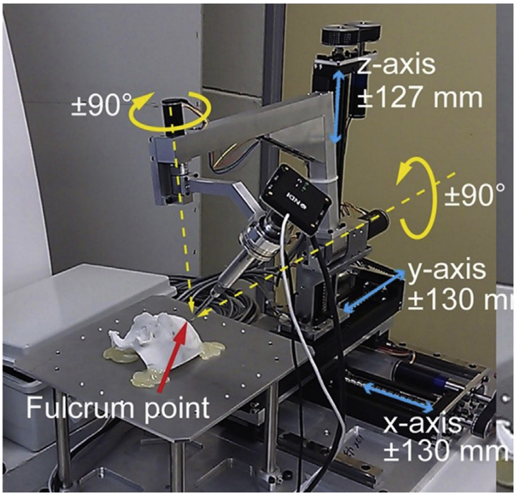

Fig. 1. Collaborative robot system allowing a drill to be freely moved by the surgeon within a specified workspace but restricted from violating preset boundaries (eg, tegmen, sigmoid sinus, facial nerve, labyrinthine, and external auditory canal). (*From* Auris Nasus Larynx, 43(2), Lim H, Matsumoto N, Cho B, et al. “Semi-manual mastoidectomy assisted by human-robot collaborative control - A temporal bone replica study”, pages 161-165, © (2015) Elsevier Ireland Ltd, with permission from Elsevier.)

Teleoperated Surgical Robots

Teleoperated surgical robots have relatively broad clinical use with Intuitive's da Vinci, perhaps the most recognized example. The da Vinci system has found widespread use in urology with more limited applications in otolaryngology where it has been used for tumor resection without the need to split the jaw for access.[3] The use of the da Vinci surgical system for ear surgery, while proposed and even demonstrated in cadaver models, does not seem to offer immediate cost-effective value or advantages over traditional techniques.[18] Although the da Vinci surgical system is not designed for ear surgery, the concept of a teleoperated robot for ear surgery has high yield, as many of the interventions ear surgeons perform are at or near the threshold of human abilities including stapes surgery, CI electrode array insertion, and cochleostomy drilling. Efforts describing teleoperated systems specifically designed for ear surgery include the system developed by Zhang and colleagues[19] for insertion of steerable CI electrode arrays. Yasin and colleagues[20] developed a teleoperated robot with a dexterous gripper demonstrating increased reachability and precision capabilities in the middle ear space. A teleoperated system that seems to be close to clinical implementation is from Technische Universität München and the Department of Otolaryngology from the University Hospital of Leipzig in Munich where they have built a teleoperated micromanipulator[21] that includes a 3 degree-of-freedom (DOF) manipulator controlled via a joystick similar to what is used in laboratories for control of micropipettes injecting into and/or extracting from individual cells. They have performed a clinical study showing decreased learning curve for stapedotomy.[22] The regulatory status of this project regarding clinical use is uncertain as of this writing.

Clinical implementation

To the best knowledge of the authors, the only teleoperated robot approved by a regulatory body for ear surgery is the RobOtol developed at Pierre and Marie Curie University in Paris, France and now offered commercially within the European Union by Collin Ltd (Bagnuex, France) with CE mark approval.[23] RobOtol (**Fig. 2**) consists of a platform placed on the opposite side of the patient as the surgeon (eg, where a scrub technician would typically stand) and has up to two effector arms (eg, endoscope and/or surgical instrument) that may be positioned by the surgeon using either a mouse and/or stylet interface. Motions can be scaled to accomplish gross versus microscopic motions. Initial clinical familiarity on simple procedures (eg, myringotomy and tube placement), is recommended before undertaking more challenging cases (eg, stapes surgery). A paper describing initial clinical use as an endoscope holder or microinstrument holder is under review as of this writing. Another potential[24] application of the RobOtol would be pairing with a force feedback control drill end effector allowing drilling of a stapedotomy or cochleostomy with minimal trauma to internal endosteum. Such technology was developed at Birmingham University in the United Kingdom,[25] and efficacy was dramatically demonstrated by drilling a hole in an uncooked egg without violating the membranous lining.[26]

Autonomous Surgical Robots

Autonomous robots are the types of robots that most people envision when they think of robots. Many would be surprised to learn that these autonomous robots have been used in surgical interventions for decades with first reports dating back to the mid-1980s when a neurosurgeon used an articulated robot arm to biopsy intracranial lesions.[10]

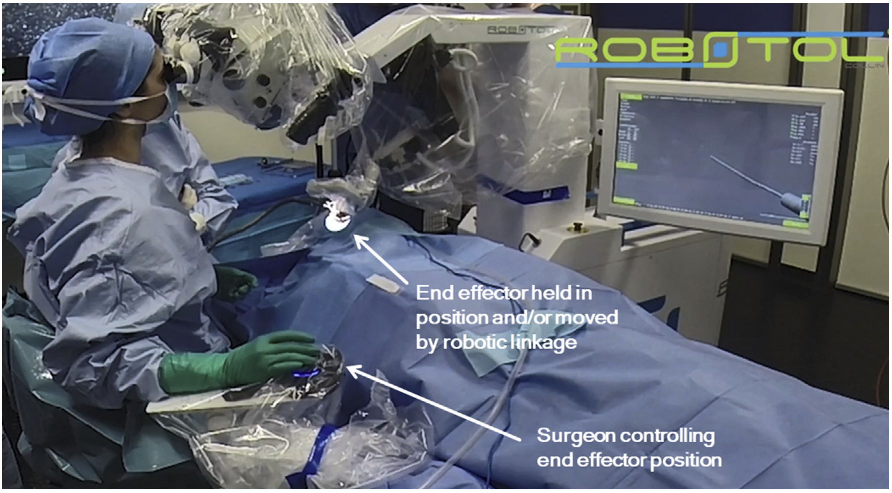

Fig. 2. Teleoperated RobOtol system. The surgeon sits opposite the robot that can hold an endoscope and/or an end effector, which is controlled via mouse and/or stylus. In this photograph, the surgeon is visualizing via the microscope and is moving an end effector (visible on the computer screen) with a mouse.

One area of otologic surgery where autonomous robots may bring value includes those robots that, in a semi- or fully automated fashion, drill the mastoid. Different groups have demonstrated drilling a minimally invasive tunnel to the cochlea with an autonomous robot either using an industrial arm robot with image guidance[27,28] or using a custom-built image-guided robotic system[4] (more later on clinical implementation of this robot). Autonomous robots can also be used to drill more of the mastoid than just a tunnel to the cochlea—they can perform a full mastoidectomy independently. For robotic mastoidectomy, the position of the robotically positioned drill tip relative to the patient's anatomy must be known. Position feedback can be provided by image guidance (eg, infrared tracking) or by rigidly linking the robot to the skull, creating a single rigid body from which drill tip calculations relative to anatomy can be made. First demonstration of image-guided, autonomous robotic mastoidectomy drilling was reported by Danilchenko and colleagues.[29] They modified an industrial-grade robot arm to hold a high-speed surgical drill. The robot, drill, and skull were tracked using an infrared image-guidance system. Although the system accomplished the task at hand, the need for line of sight of the tracked fiducial markers was made more difficult by the bone dust and irrigation that accumulated on the infrared markers. Another tracking system that does not require line of site is an electromagnetic tracking system, but this option does not currently support a level of tracking accuracy sufficient for this task. The need for line of sight tracking can be avoided by rigidly linking a robot to a patient's skull, and at least 2 groups have pursued this technique. Dillon and colleagues[30] developed a lightweight, 5 DOF (x, y, z, and rotation about 2 of these axes) robot (**Fig. 3**), which they used to drill translabyrinthine approaches to the internal auditory canal (IAC) in cadavers. The hypothesized advantage of this robot is that it performs the tedious bulk dissection of bone leaving a rim of bone over vital structures (eg, facial nerve, opening to the IAC) to be manually removed by a highly skilled, human surgeon. Similar work was done by Couldwell and colleagues[31] using a 5 DOF computer numeric control machine rigidly affixed to a cadaver by means of a Mayfield head holder.

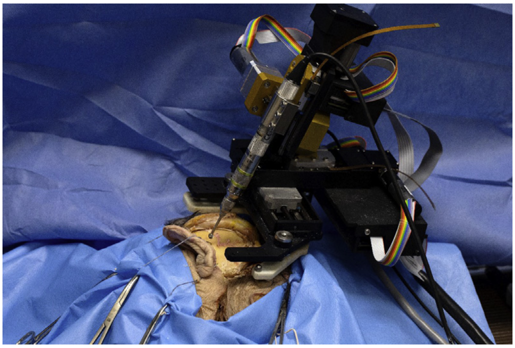

Fig. 3. Bone-affixed 5 DOF autonomous robot drilling translabyrinthine approach to IAC.

Autonomous robots also have great potential in insertion of CI electrode arrays. If a CI trajectory is specified, electrode array insertion can be largely reduced to linear advancement of the array along that trajectory especially for straight (a.k.a., lateral-wall) arrays. Such placement occurs at the limits of human perception with intracochlear trauma during insertion—including tip fold-over and translocation from scala tympani to scala vestibuli—occurring relatively frequently. For precurved (a.k.a., perimodiolar) electrode arrays, a second motion is necessary to stop stylet motion during insertion. These insertion motions can be automated by highly precise actuators such as those described[32] that consists of a linear advancement coupled with a stylet stop. Comparison of a modified version of this tool to manual, human insertion showed that although a human—at their best—may outperform the robot, the robotic insertion tool consistently and repeatably achieved very low insertion forces[33] likely to be associated with less intracochlear trauma and improved audiological outcomes[34] as compared with the human operator. The latest automated insertion tool from the RobOtol developers can be coupled to the RobOtol and has demonstrated smoother insertion force profiles compared with manual insertions.[37] Another automated linear tool that is nonmagnetic has been developed to be incorporated into a magnetic steering system meant to provide atraumatic insertion of magnet-tipped CI arrays.[36] Building on the aforementioned work of Zhang and colleagues[19] have developed a multi-DOF automated insertion solution using a parallel robot design that can be teleoperated or autonomous. This robot was initially designed and tested[35] and was the first robot to incorporate control feedback during CI insertion.[38] Perhaps the most unique of the CI electrode array insertion robots is one proposed to be surgically implanted in the mastoid, allowing slow insertion over hours or days and/or advancement of a hybrid CI electrode array if, over time, the patient's hearing were to further degrade.[39]

Clinical implementation

Caversaccio and colleagues[4] have clinical trials underway for their HEARO robot (**Fig. 4**), which has certification mark (CE) approval being offered by Cascination AG (Bern, Switzerland). Their approach uses a custom-built multiarticulated arm robot with image guidance to guide drilling from the surface of the mastoid through the facial recess during which the drill functions as a facial nerve stimulator with concurrent monitoring. Initially performed at University Hospital in Bern, Switzerland, they have now extended their study to Antwerp University in Belgium. The modularity of the

Fig. 4. HEARO system showing the IGS system (*white box* houses infrared tracking cameras) monitoring the robotic arm relative to the patient. The human hand is holding suction-irrigation clearing away debris so that humans can visualize the interaction between the end effector and the patient. (*From* PLoS One. 2019; 14(8): e0220543. Published online 2019 Aug 2. https://doi.org/10.1371/journal.pone.0220543.)

system allows for future expansion to include force-feedback drilling preserving endosteum (eg,[25]) and robotic CI electrode array insertion.

DISCUSSION

From an engineering standpoint, robotic interventions are obvious solutions to interventions that require high precision and border on the limits of human abilities. In the world of industrial manufacturing (eg, car assembly), robots are *preferred* over human operators, given the improved accuracy and reliability (ie, although robots occasionally need servicing, they can work 24 hours a day, 7 days a week, and do not have to deal with human stresses that can degrade operation). Why, then, have robots not been equally embraced within surgical realms, especially otology, where their utility doing high-precision work seems obvious? The answer to this question is complex but involves both inertia of existing behavior and uncertainty regarding regulatory approval processes.

Regarding inertia of existing behavior, ear surgery requires high manual dexterity skill levels that are acquired during lengthy training. Entry into the field is relatively exclusive with compensation and status commensurate with the training involved. This exclusivity may lead to conscious and/or unconscious bias in adopting technology that could lessen the exclusivity of these skill sets and allow less-experienced surgeons to be able to perform complex procedures without the need for lengthy, income-delaying training. This resistance to adoption of technology has been seen in other labor markets (eg, elevator operators who were obviated by the development of the automated elevator) and is typically overcome by economic incentives.

Regarding regulatory approval in the United States, highly automated systems, for example, autonomous surgical robots, are heavily regulated by the FDA. Although autonomous surgical robots have the potential for high impact in otology, such robots are highly disruptive to current surgical techniques and workflow, which can lead to delayed clinical adoption. A further barrier to their clinical implementation is stringent regulatory controls that are often prohibitively expensive to pursue especially by academic research teams. FDA compliance is achieved either by Premarket Notification 510(k) process in which a manufacturer can claim substantial equivalence to a device on the market before 1976 to be FDA-cleared or Premarket Approval (PMA) to be FDA approved. The 510(k) process is a much quicker and cheaper pathway for medical devices to reach clinical realization, and—not surprisingly—the pathway most often pursued especially in high-risk devices.[40] In contrast, the PMA pathway is much more costly, primarily due to the need for clinical testing. Relevant to surgical robots, the prototypical teleoperated manipulator, the da Vinci surgical system, was FDA cleared via the 510(k) pathway with a predicate device difficult to trace but likely either a manual retractor and/or and endoscope holder.[41] It is likely that autonomous otologic robots will require the much more costly PMA.

SUMMARY

Ultimately, as with most new behaviors within health care, innovations are adopted either because they have dramatic improvement in outcomes and/or because they provide similar results at a much-reduced cost compared with the current standard. Regarding robots for otologic interventions, otology is a relatively small field with good clinical outcomes. Clinical adoption of an otologic robot will require extensive investment by industry to obtain regulatory approval, intensive marketing to hospital administrators regarding increased through-put and/or decreased cost, and buy-in from highly trained otologists/neurotologists who may resist adoption of the technology. However, as is typical in capitalist economies such as the United States, over time, market forces largely dictate behaviors and are driven by often unforeseen occurrences (eg, the introduction of the Internet and electronic medical records). As of this writing, the world is dealing with the COVID19 pandemic that may push the adoption of otologic robots, allowing human surgeons to stay safely afar from potentially infectious debris.

CLINICS CARE POINTS

- Surgical robots have exciting potential in ear surgery but are not yet the standard of care.
- Most promising initial applications include cochlear implant and stapes surgery.
- Robots will only become standard of care if most of the ear surgeons deem them useful and/or necessary and if substantial regulatory hurdles are overcome.

DISCLOSURE

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