Image-Guided Mastoidectomy with a Cooperatively Controlled ENT Microsurgery Robot

Christopher R. Razavi, MD,1 Paul R. Wilkening, MS,2 Rui Yin,2 Samuel R. Barber, MD3, Russell H. Taylor, PhD,2 John P. Carey, MD,1 and Francis X. Creighton, MD1

Sponsorships or competing interests that may be relevant to content are disclosed at the end of this article.

Abstract
Mastoidectomy is a common surgical procedure within otology. Despite being inherently well suited for implementation of robotic assistance, there are no commercially available robotic systems that have demonstrated utility in aiding with this procedure. This article describes a robotic technique for image-guided mastoidectomy with an experimental cooperatively controlled robotic system developed for use within otolaryngology–head and neck surgery. It has the ability to facilitate enhanced operative precision with dampening of tremor in simulated surgical tasks. Its kinematic design is such that the location of the attached surgical instrument is known with a high degree of fidelity at all times. This facilitates image registration and subsequent definition of virtual fixtures, which demarcate surgical workspace boundaries and prevent motion into undesired areas. In this preliminary feasibility study, we demonstrate the clinical utility of this system to facilitate performance of a cortical mastoidectomy by a novice surgeon in 5 identical temporal bone models with a mean time of 221 ± 35 seconds.

Keywords
robotic surgery, robotic mastoidectomy, otology, image guidance

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Robotic surgical systems have been cited as having the potential to reduce complications and morbidity given their ability to perform accurate and repeatable motions with the elimination of tremor.1,2 Mastoidectomy is a procedure that would seem to lend itself to robotic assistance; the operative field consists of rigid bone in a fixed orientation that facilitates image guidance.3 Despite this, no commercially available robotic technology has demonstrated clinical utility in this procedure.

Although there are feasibility studies describing the use of novel robots in performing mastoidectomy, many of these have autonomous designs.4-10 As autonomous robotic systems operate independently, they require knowledge of burr selection and of the appropriate force required to safely perform various portions of the procedure.10 Due to variability in mastoid aeration, there is a subsequent patient and spatially dependent variation in bone density.11 Accordingly, these systems require patient-specific force/path modeling to maximize operative efficiency and safety. Conversely, cooperatively controlled robots, in which the user and robot manipulate the surgical drill together, obviate the above requirements. The user can make determinations regarding burr selection and drill angle/force in the typical fashion, while still appreciating benefits of tremor elimination, enhanced precision, and image guidance that the robot may facilitate.

We have developed an experimental cooperatively controlled robot for ear, nose, and throat (ENT) microsurgery and have demonstrated its use in simulated microlaryngeal, microvascular, and otologic surgical tasks due to its ability to eliminate tremor, enhance precision, and have accurate knowledge of tool position in 3-dimensional space.12-15 Here we describe its capability to incorporate image-based virtual fixtures facilitating cortical mastoidectomy by a novice surgeon.

Methods
The robotic platform used in this study is a cooperative-control robot consisting of a gantry arm with 5 actuated
degrees of freedom (Figure 1). Conventional surgical instruments can be fit with adaptors to articulate with the device. For this study, a Midas Rex Legend drill (Medtronic, Minneapolis, Minnesota) with a 4-mm cutting burr was used. The iteration of the technology used was an updated prototype of the robotic platform that we have previously described at length.\textsuperscript{12,13,16-19} In summary, its design allows for the user to manipulate the attached instrument with dampening of tremor and heightened precision. The position of the gantry arm and, therefore, attached instrument, is known with a high degree of fidelity. Therefore, after image registration, boundaries of allowable motion (virtual fixtures) can be enforced. When these virtual fixtures are activated, the instrument affixed to the robot is adherent to spatial motion constraints, where it is permitted to move freely within the described volume, but motion outside is forbidden.\textsuperscript{20}

A right temporal bone model (Phacon, Leipzig, Germany) was used as the surgical phantom and registered to the robot using accompanying imaging. Using 3D Slicer (open source, https://www.slicer.org),\textsuperscript{21} 3 intersecting planes were created within the imaging so that the resultant geometry approximated the volume of bone removed during a cortical mastoidectomy (Figure 2). After registration and virtual fixture activation, a software engineer was instructed to drill away material within the allowable working space. He received no intraprocedural coaching, while indicating procedure completion when the drill could no longer reach areas of intact phantom material. This task was repeated 5 times (see the supplemental video in the online version of the article). Outcomes included time to completion and procedural success, which was defined as entrance into the antrum with preservation of the incus, horizontal canal, facial nerve, tegmen, sigmoid sinus, posterior fossa dura, and external auditory canal. Procedural success was evaluated via specimen review by a fellowship-trained neurotologist (J.P.C.) who was not present during the time of drilling. Johns Hopkins University Institutional Review Board Approval was obtained.

**Results**

Procedural success was 100% (5/5), with entrance into the antrum and protection of the aforementioned structures in all cases (Figure 3). The task was completed in an average of 221 ± 35 seconds. There was a trend toward more expeditious completion of the procedure with sequential trial times of 267, 249, 225, 177, and 185 seconds.

**Discussion**

The robot facilitated cortical mastoidectomy safely in 100% of cases in this proof-of-concept study. Given the excellent
expected outcomes and low complication rate with mastoid surgery, robotic systems in this space must be safe but also provide additional benefits in our value-based health care system.\(^3\) One such potential avenue is in reducing operative time. The 221-second mean procedure time in our series is in stark contrast to reported drilling times of 5400 seconds for a similar task by an autonomously operated robotic mastoidectomy system.\(^2\) These preliminary results suggest that the cooperative control design of the robot may reduce procedure time in comparison to autonomous systems and, potentially, freehand techniques.

Prior literature describing robotic mastoidectomy has noted that these devices still require the same level of neurotologic expertise as the open approach to safely and effectively function.\(^8\) This is despite the autonomous design of many of these platforms. In contrast, we demonstrated that robot-assisted mastoidectomy could be safely performed by a novice surgeon. Although this was in a simulated surgical task and required expertise in operative planning, this suggests the robot may provide value to the less experienced surgeon. Further studies are needed to elucidate this and to examine whether experienced neurotologists may derive utility when performing more complex surgical tasks.

**Conclusions**

The robot safely facilitated cortical mastoidectomy by an engineer with no prior surgical experience. The cooperative-control design provides many potential benefits over previously described autonomous devices. These include decreased drill time and utility to less experienced surgeons. Future cadaveric studies evaluating performance with more complex dissections are needed to delineate its ultimate clinical utility.

**Author Contributions**

Christopher R. Razavi, conception/design, data acquisition, data analysis, manuscript drafting, final approval; Paul R. Wilkening, conception/design, data acquisition, manuscript drafting, final approval; Rui Yin, conception/design, data acquisition, manuscript drafting, final approval; Samuel R. Barber, conception/design, data acquisition, manuscript drafting, final approval; John P. Carey, conception/design, data acquisition, manuscript drafting, final approval; Francis X. Creighton, conception/design, data acquisition, manuscript drafting, final approval.

**Disclosures**

Competing interests: Paul R. Wilkening, employee of Galen Robotics; Rui Yin, intern at Galen Robotics; Russell H. Taylor, consultant at Galen Robotics and equity holder in Galen Robotics.

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**Supplemental Material**

Additional supporting information is available in the online version of the article.

**References**


