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Applied Force during Piston Prosthesis Placement in a 3D-Printed Model: Freehand vs Robot-Assisted Techniques

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Abstract

Objectives.—To describe a 3D-printed middle ear model that quantifies the force applied to the modeled incus. To compare the forces applied during placement and crimping of a stapes prosthesis between the Robotic ENT Microsurgery System (*REMS*) and the freehand technique in this model.

Study Design.—Prospective feasibility study.

Setting.—Robotics laboratory.

Subjects and Methods.—A middle ear model was designed and 3D printed to facilitate placement and crimping of a piston prosthesis. The modeled incus was mounted to a 6-degree of freedom force sensor to measure forces/torques applied on the incus. Six participants—1 fellowship-trained neurotologist, 2 neurotology fellows, and 3 otolaryngology-head and neck surgery residents—placed and crimped a piston prosthesis in this model, 3 times freehand and 3 times *REMS* assisted. Maximum force applied to the incus was then calculated for prosthesis

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Author Contributions

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Author Note

The technology described herein is currently under a license agreement between Galen Robotics, Inc, and the Johns Hopkins University. Dr Taylor is entitled to royalty distributions on the aforementioned technology. Dr Taylor is a paid consultant to and owns equity in Galen Robotics, Inc. Paul Wilkening is a paid employee of Galen Robotics, Inc. These arrangements have been reviewed and approved by the Johns Hopkins University in accordance with its conflict-of-interest policies. A portion of this work was also funded by a National Institutes of Health T32 training grant and the Rubenstein Hearing Center at Johns Hopkins.

Disclosures

Competing interests: Paul R. Wilkening, employee—Galen Robotics; Rui Yin, intern—Galen Robotics; Nicolas Lamaison, intern—Galen Robotics; Russell H. Taylor, consultant and equity holder—Galen Robotics.

Supplemental Material

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

placement and crimping from force/torque sensor readings for each trial. Robotic and freehand outcomes were compared with a linear regression model.

Results.—Mean maximum magnitude of force during prosthesis placement was 126.4 ± 73.6 mN and 105.0 ± 69.4 mN for the freehand and robotic techniques, respectively ($P = .404$). For prosthesis crimping, the mean maximum magnitude of force was 469.3 ± 225.2 mN for the freehand technique and 272.7 ± 97.4 mN for the robotic technique ($P = .049$).

Conclusions.—Preliminary data demonstrate that *REMS*-assisted stapes prosthesis placement and crimping are feasible with a significant reduction in maximum force applied to the incus during crimping with the *REMS* in comparison with freehand.

Keywords

robotic surgery; otosclerosis; stapes; otology; 3D printing

Middle ear microsurgery, particularly surgical management of otosclerosis, is a demanding procedure due to its technical difficulty and excellent expected patient outcomes. Surgeons are required to make fine movements under the guide of microscopy, with expected closure of the air-bone gap to <10 dB among $>90\%$ of patients in experienced hands.^{1,2} Furthermore, despite the high overall rate of positive outcomes, there remains a risk for complications, including total irreversible sensorineural hearing loss.^{3,4} As such, stapes surgery is one of the most litigated procedures within neurotology, with successful claims resulting in the second-highest mean payment per claim within the subspecialty at \$2,733,000.⁵ Complicating matters further is the decreasing volume of these procedures and the limited availability of high-fidelity, low-cost models to adequately facilitate resident/fellow training.⁶⁻¹⁰

As a result, many technical modifications to stapes surgery have been made in attempts to decrease the degree of difficulty of the procedure. These include performing stapedotomy as opposed to stapedectomy, performing laser-assisted instead of mechanical stapedotomy, as well as refinements in the design of prostheses to allow both maximum visualization of the stapes footplate and non-mechanical crimping of the prosthesis.¹¹⁻¹⁵ Despite these adjustments, inferior results continue to be seen among trainees and those with less-experienced hands in comparison with experts.¹⁶⁻¹⁸ Many postulate that this is a result of difficulties manipulating the prosthesis itself, with studies demonstrating that experienced neurotologists apply less force to the ossicular chain than their novice counterparts when performing prosthesis placement and crimping.^{9,17} As such, a mechanism that facilitates enhanced microsurgical precision and decreased force transmitted to the ossicular chain could lead to improved outcomes in surgical management of otosclerosis.

The Robotic ENT Microsurgery System (*REMS*; Galen Robotics Inc, Baltimore, Maryland) is a novel robotic system developed at the Johns Hopkins Laboratory for Computational Sensing and Robotics specifically for use within otolaryngology—head and neck surgery. Previously we have demonstrated enhanced precision and tremor elimination in simulated microvascular and microlaryngeal tasks with use of this device.¹⁹⁻²² As such, we sought to

evaluate the feasibility and potential utility of the technology in performing stapes prosthesis placement and crimping in a 3D-printed model.

Methods

The REMS

The *REMS* is a 6-degree of freedom cooperative control robot developed at the Johns Hopkins Laboratory for Computational Sensing and Robotics for use within otolaryngology-head and neck surgery. The technical description of the platform and its subsequent capabilities were previously described within the otolaryngology-head and neck surgery and robotics literature.²⁰⁻²⁴ In brief, the system consists of a base—the delta stage—that allows for manipulation of a gantry arm in the x , y , and z planes. Rotational movements about the x and y axes are provided by the roll and tilt stages, respectively. Conventional surgical instrumentation can be fit with custom-built adaptors to articulate with the distal end of the gantry arm, where rotation about the z axis of the unactuated tool provides the sixth degree of freedom of motion. A force sensor in this instrument exchange unit senses forces and torques exerted on the attached instrument, resulting in movement of the gantry arm in compliance. The responsiveness of the robot to these forces/torques is proportional to the amount of depression of an admittance gain foot pedal—full depression allowing for faster motion. Via this cooperative control mechanism, the surgeon and robot manipulate the articulated instrument together, with a high degree of precision and dampening of tremor. For the purposes of this study, we used a next-generation research version of the original *REMS* system produced by Galen Robotics, which has a redesigned delta stage that increased the available working space of the system by 1.8-fold (Figure 1).

3D-Printed Middle Ear Model

A middle ear phantom was modeled with the computer-aided design tool SolidWorks (Dassault Systemes SolidWorks Corp, Waltham, Massachusetts) for the purpose of 3D printing. The incus was modeled in a similar fashion to that of Ngyuen et al⁹ to facilitate mounting to a 6-degree of freedom force/torque sensor (resolution, 3 mN; ATI Nano 17, Apex, North Carolina), while the stapedotomy and distance between the stapedial footplate and incus were designed to facilitate placement of a 0.5- to 0.6-mm-diameter piston prosthesis with a length between 4.50 and 4.75 mm. The phantom was then printed with a stereolithographic printer (Stratasys uPrint SE, Eden Prairie, Minnesota; Figure 2).

Forces/torques applied to the sensor were recorded continuously in real time, as was stereo microscopic video of the simulated surgical task. As the incus was mounted on a rod a distance away from the force sensor, there was a leverage effect. As such, to properly resolve the torques, they were divided by a 60.25-mm offset from the sensor to the incus. This represented the distance between the force sensor and the location on the model where the surgical task was being performed. After the force/torque logs from the sensor were synchronized with a video of each procedure, the maximum force applied during placement and crimping of the prosthesis was determined. The magnitude of the change in force over time (dF , mN/s), was then calculated by measuring the time between the initiation and resolution of the maximum force during prosthesis placement and crimping, respectively.

This was done for each trial and participant. dF was included as an outcome measure in this study, as a sudden large magnitude increase in force on the ossicular chain may cause stapes subluxation and subsequent damage to the membranous labyrinth or perilymphatic fistula. Similarly, a sudden increase in intraotic pressure, regardless of stapes subluxation, may be a mechanism for immediate sensorineural hearing loss after stapes surgery.^{25,26} A large-magnitude dF would represent these described clinical scenarios.

Study Design

After approval from the Johns Hopkins Homewood University Institutional Review Board, 6 participants were recruited to participate in the study: 3 otolaryngology—head and neck surgery residents, 2 neurotology fellows, and 1 fellowship-trained neurotologist. Participants were each given a 5-minute tutorial on operation of the *REMS*, after which they were asked to place and crimp a piston prosthesis in the simulated middle ear model described here. Participants placed and crimped the prosthesis 3 times freehand, then performed 3 trials of the same task with robotic assistance. A total of 3 trials per technique was chosen to minimize the effects of fatigue and task learning on outcomes, while data from Nguyen et al⁹ guided the participant number for this prospective feasibility study. To perform the robot-assisted prosthesis placement and crimping, conventional otologic instruments were fit with custom-built adaptors to articulate with the *REMS* (Figure 3). All trials (robot and freehand) were performed with an operating microscope. A speculum was not used; however, the working space was constricted within a simulated external auditory canal (Figure 2A), and participants were encouraged to stabilize their operative instrument in the same manner that they would in the operating theater—that is, using their nondominant hand as a stabilizer and fulcrum (see Supplemental Video, available in the online version of the article). Additionally, an ENTroll surgical chair (Medtronic XOMED, Jacksonville, Florida) with adjustable padded armrests was used for all trials. These efforts were taken to maximize the fidelity of the surgical task by mimicking the techniques and conditions utilized in the operating theater by the fellowship-trained neurotologist.

The forces and dF on the simulated incus were then calculated as described for the prosthesis placement and crimping of each trial. The means (over the 3 trials) of the freehand and robotic-assisted maximum forces and dF were then determined for each participant during prosthesis placement and crimping. Robotic and freehand mean forces were then compared using a linear regression model treating maximum force and dF measures between individual participants as independent, but accounting for intraparticipant correlation in these measures across trials. A similar linear regression model was used to compare freehand performance for prosthesis placement and crimping between the expert participant (fellowship-trained neurotologist) and the remainder of participants. This was followed by a comparison of the expert participant's freehand performance with the remaining participants' robotic performance with the same model described here. This was done to determine how robotic assistance among less-experienced stapes surgeons may affect their performance in comparison with the baseline of a fellowship-trained neurotologist. Analysis was completed in Stata 15 (StataCorp LLC, College Station, Texas) with an alpha of 0.05 for statistical significance.

Results

The mean maximum magnitude of force during prosthesis placement was 126.4 ± 73.6 mN and 105.0 ± 69.4 mN for the freehand and robotic techniques, respectively ($P = .404$). For prosthesis crimping, the mean maximum magnitude of force was 469.3 ± 225.2 mN and 272.7 ± 97.4 mN for the freehand and robotic techniques, respectively ($P = .049$). Mean dF during freehand placement was 248.2 ± 141.3 mN/s versus 157.9 ± 107.1 mN/s for robotic placement ($P = .264$). Similarly, mean dF during prosthesis crimping was 272.2 ± 138.3 mN/s and 163.7 ± 150.0 mN/s for the freehand and robotic techniques, respectively ($P = .100$) (Table 1).

Comparison of freehand performance in prosthesis placement and crimping between the expert stapes surgeon and other participants revealed a significant difference in mean maximum force during prosthesis placement (41.5 ± 30.7 mN vs 139.0 ± 68.7 mN, $P = .002$) and crimping (204.3 ± 49.0 mN vs 522.3 ± 208.6 mN, $P = .004$), along with a significant difference in dF for prosthesis crimping (77.4 ± 33.5 mN/s vs 311.2 ± 116.7 mN/s, $P < .0001$). There was, however, no significant difference in dF for prosthesis placement between the experienced stapes surgeon and the other participants (Table 2).

In evaluation of the expert participant's freehand performance in comparison with the remaining participants' robotic-assisted performances, there was no significant difference in mean force during prosthesis placement (41.5 ± 30.7 mN vs 104.3 ± 74.1 mN, $P = .065$), crimping (204.3 ± 49.0 mN vs 258.5 ± 82.9 mN, $P = .171$), dF during placement (141.0 ± 124.3 mN/s vs 146.3 ± 97.9 mN/s, $P = .893$), or dF during crimping (77.4 ± 33.5 mN/s vs 175.2 ± 160.8 mN/s, $P = .212$; Table 3).

Discussion

Stapes surgery is an inherently challenging procedure owing to the limited working space, the manipulation of milli-metric structures, and the application of subnewton forces to perform the surgical task. Several modifications to the surgical technique aimed at decreasing the degree of difficulty have been described, yet the procedure is still subject to innate limitations in human performance. These include involuntary motions, such as jerk, drift, and tremor, which can inhibit microsurgical precision and accuracy.²⁷ Much of microsurgical training involves developing methods to compensate for and reduce these involuntary movements in an effort to minimize their effect on operative performance. Owing to its cooperative control mechanism, where the user and robot manipulate conventional surgical instrumentation together, the *REMS* offers continuous tool stabilization designed to do just this. This capability was previously demonstrated in microlaryngeal and microvascular surgical tasks.^{21,22} For the purposes of this study, we sought to evaluate these technical benefits in a clinically relevant objective manner. Prior studies demonstrated that experienced surgeons apply less force to the ossicular chain during stapes surgery than do novices,^{9,12} perhaps due to a reduction in the aforementioned involuntary movements. As such, forces applied to the modeled incus during prosthesis placement and crimping were our primary outcome measures for this study. Important to note is that coauthors with relevant disclosures in relation to the investigated technology

were not active participants in study design or data analysis. This was an intentional effort to minimize any inherent bias that may have been present as a result of their preexisting financial relationships.

There was significant reduction in mean force during prosthesis crimping with use of the *REMS* in comparison with the freehand technique. Mean force was also less during prosthesis placement with use of the *REMS* versus freehand; however, this approached but did not reach statistical significance. Similarly, ΔF was less for prosthesis placement and crimping with the *REMS*, although values did not reach statistical significance. One potential explanation for the improved outcomes seen in crimping but not placement is the alteration in haptic feedback with the *REMS*. Although the technology does preserve an aspect of haptics given the cooperative control design, especially when compared with currently available master-slave robotic systems, it is still dampened in comparison with the freehand technique. This characteristic would be expected to have a greater impact on placement of the prosthesis on the incus, where tactile feedback from the prosthesis and incus are frequently invaluable to successful positioning. As such, the moderately decreased impact of the *REMS* seen during prosthesis placement is not surprising.

Importantly, when freehand trials with stratification for experience performing stapes surgery were examined, the expert stapes surgeon applied significantly less force during prosthesis placement and crimping, along with significantly less ΔF during prosthesis crimping. One would expect these results given the significantly greater experience of the fellowship-trained neurotologist in surgical management of otosclerosis and prior work demonstrating a decrease in force applied to the ossicular chain during prosthesis manipulation by more experienced surgeons.^{9,12} As such, these outcomes support the notion that our model provided a suitable simulation of the intended surgical task. Moreover, comparison of the *REMS*-assisted trials of the nonexpert participants with the freehand trial of the expert participant demonstrated no significant difference in any of the outcome measures evaluated. However, the expert freehand performance for placement of the prosthesis approached statistical significance for superiority versus nonexpert robot-assisted performance ($P = .065$). We again attribute this comparatively limited effect of robot assistance on prosthesis placement to the alterations in haptic feedback with the *REMS*. These findings can consequently be interpreted as the *REMS* being a tool that allows less-experienced surgeons achieve technical outcomes in the simulated surgical task that are similar to those of the expert evaluated in this series. Note, however, that our model evaluated only the technical aspects of stapes surgery, such as prosthesis manipulation, and did not account for features that often have a greater effect on patient outcomes, such as surgical decision making. Nonetheless, preliminary outcomes demonstrate feasibility and promise with *REMS*-assisted stapes prosthesis placement and crimping, which may ultimately translate to clinical utility of the technology.

Conclusions

REMS-assisted stapes prosthesis placement and crimping are feasible, with a significant reduction in force applied to a modeled incus during prosthesis crimping in comparison with the freehand technique. There was no significant difference seen in robotic-assisted versus

freehand force during prosthesis placement, perhaps due in part to a reduction in haptics with the *REMS*. The use of the *REMS* did, however, allow less-experienced participants to reduce the force that they applied on the incus during the surgical task to levels commensurate with the freehand performance of the expert surgeon evaluated in this study. Accordingly, the *REMS* may prove to be a promising adjunct and tool to aid less-experienced middle ear surgeons with management of otosclerosis, although further studies are needed to elucidate this.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1. Robotic ENT Microsurgery System. The second iteration for the technology is depicted with a 1.8 $\times$ -greater working space than the original. Freedom of movement is illustrated in the x , y , and z planes within the delta stage, with roll and tilt stage-actuated degrees of freedom.

Figure 2.

The 3D-printed middle ear model is depicted from (A) superior and (B) lateral views. The 3D-printed incus can best be seen in the lateral view, while the stapedotomy is visualized in the superior view. The incus has been mounted to a 6-degree of freedom force/torque sensor.

Figure 3.
Conventional otologic instrument modified with a custom-built adaptor to articulate with the Robotic ENT Microsurgery System.

Table 1.Freehand vs Robotic-Assisted Performance.^a

	Freehand	Robotic	P Value
Placement			
Maximum force, mN	126.4 ± 73.6	105.0 ± 69.4	.404
dF, mN/s	248.2 ± 141.3	157.9 ± 107.1	.264
Crimping			
Maximum force, mN	469.3 ± 225.2	272.7 ± 97.4	.049
dF, mN/s	272.2 ± 138.3	163.7 ± 150.0	.100

Abbreviation: dF, change in force over time.

^aValues are presented as mean ± SD. Bold denotes statistical significance ($P < .05$).

Table 2.Expert vs Nonexpert Freehand Performance.^a

	Expert Participant (n = 1)	Nonexpert Participants (n = 5)	P Value
Placement			
Maximum force, mN	41.5 ± 30.7	139.0 ± 68.7	.002
dF, mN/s	141.0 ± 124.3	269.6 ± 134.5	.062
Crimping			
Maximum force, mN	204.3 ± 49.0	522.3 ± 208.6	.004
dF, mN/s	77.4 ± 33.5	311.2 ± 116.7	<.0001

Abbreviation: dF, change in force over time.

^aValues are presented as mean ± SD. Bold denotes statistical significance ($P < .05$).

Table 3.Expert Freehand vs Nonexpert Robotic-Assisted Performance.^a

	Expert Participant (Freehand)	Nonexpert Participants (Robotic)	P Value
Placement			
Maximum force, mN	41.5 ± 30.7	104.3 ± 74.1	.065
dF, mN/s	141.0 ± 124.3	146.3 ± 97.9	.893
Crimping			
Maximum force, mN	204.3 ± 49.0	258.5 ± 82.9	.171
dF, mN/s	77.4 ± 33.5	175.2 ± 160.8	.212

Abbreviation: dF, change in force over time.

^aValues are presented as mean ± SD.