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A Cadaver Study of Mastoidectomy Using an Image-Guided Human–Robot Collaborative Control System

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Objective: Surgical precision would be better achieved with the development of an anatomical monitoring and controlling robot system than by traditional surgery techniques alone. We evaluated the feasibility of robot-assisted mastoidectomy in terms of duration, precision, and safety.

Study Design: Human cadaveric study.

Materials and Methods: We developed a multi-degree-of-freedom robot system for a surgical drill with a balancing arm. The drill system is manipulated by the surgeon, the motion of the drill burr is monitored by the image-guided system, and the brake is controlled by the robotic system. The system also includes an alarm as well as the brake to help avoid unexpected damage to vital structures. Experimental mastoidectomy was performed in 11 temporal bones of six cadavers. Parameters including duration and safety were assessed, as well as intraoperative damage, which was judged via pre- and postoperative computed tomography.

Results: The duration of mastoidectomy in our study was comparable with that required for chronic otitis media patients. Although minor damage, such as dura exposure without tearing, was noted, no critical damage to the facial nerve or other important structures was observed. When the brake system was set to 1 mm from the facial nerve, the postoperative average bone thicknesses of the facial nerve was 1.39, 1.41, 1.22, 1.41, and 1.55 mm in the lateral, posterior pyramidal and anterior, lateral, and posterior mastoid portions, respectively.

Conclusion: Mastoidectomy can be successfully performed using our robot-assisted system while maintaining a pre-set limit of 1 mm in most cases. This system may thus be useful for more inexperienced surgeons.

Key Words: Mastoidectomy, image guidance, robotic surgery, navigation, warning system.

Level of Evidence: NA.

INTRODUCTION

The role of robotic surgery in otolaryngology has expanded from transoral robotic surgery and thyroid surgery using the da Vinci surgical platform, particularly in the head and neck and skull base area.[1,2] The first robot-assisted experiment in otology was conducted in 2001, wherein a robot was used to prepare a cochlear implant bed at the surface of the skull.[3] Following this, several types of robots were developed and tested for otologic surgery, but most remain in an experimental stage. Among these robots, the most frequently reported on were developed for cochlear implantation, which drills along a predetermined trajectory line from the bone surface to the cochlea.[4–11]

As mastoidectomy is one of the most basic and important otologic surgical procedures, and robot systems for this procedure can have broad clinical applications. Several robotic devices for mastoidectomy have been developed, although most include automated robots that drill through the mastoid bone as programmed.[12–15] However, otologic surgery rarely involves mastoidectomy alone, as this procedure serves as a starting point for various types of otologic operations. Automated robotic mastoidectomy cannot yet completely replace manual otologic surgery, only offering assistance in some cases. Hence, the purpose of robot-assisted systems in these instances may not be to achieve a completely automated mastoidectomy but to improve surgical precision and

Additional Supporting Information may be found in the online version of this article.

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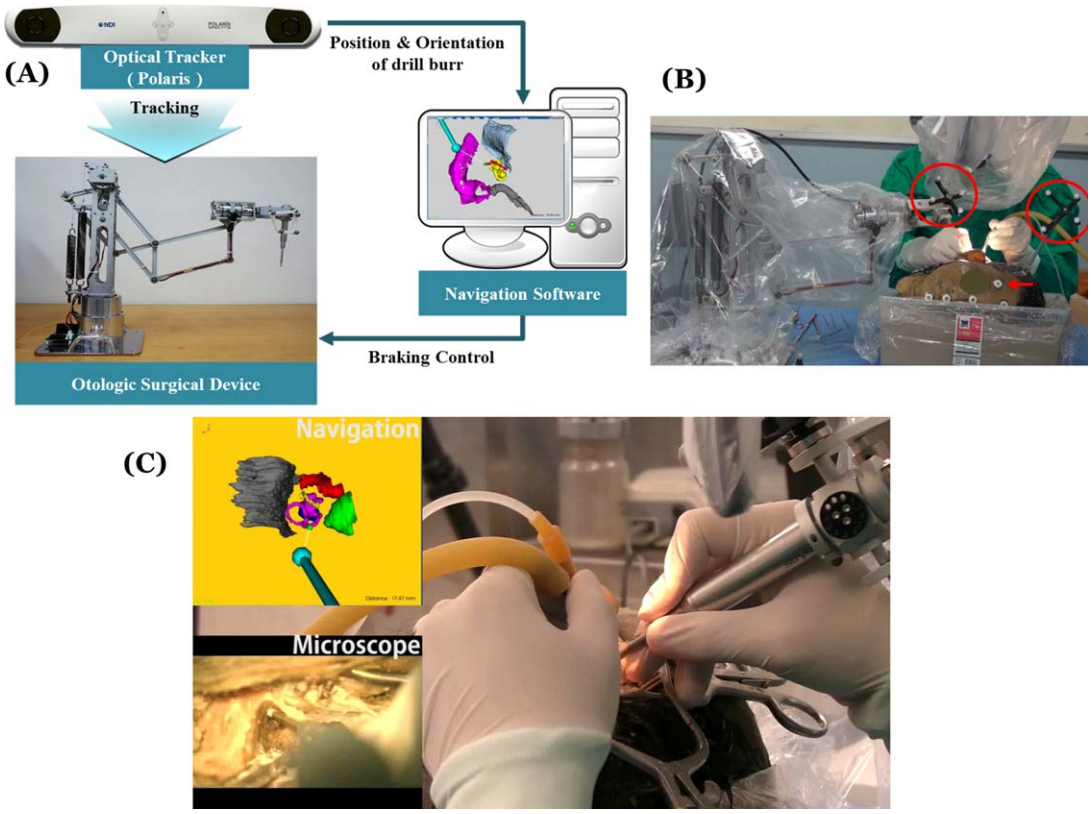

Fig. 1. (A) The robot-assisted surgical system comprises a robot arm, navigation software, and tracker. (B) Two markers (red circles) are mounted on the drill and the skull of the cadaver (red arrow), respectively. (C) The warning system provides the operator with a microscopic view of the mastoid bone being drilled, a virtual view of the segmented organs with the tool tip, and warning signals via sounds and a colored screen.

provide enhanced situational awareness through image guidance. A human–robot collaborative system may be slower than a fully automated robot in some procedures. However, a collaborative drill system has several advantages over an automated drill robot, such as its availability for a wide range of surgery, the possibility of soft-tissue work between drillings, and greater familiarity for the surgeons.

In the present study, we developed a statically balanced surgical robot that uses pre-set bone structures to set boundaries for the surgeon. A previous temporal bone replica study has assessed the feasibility of using a serial-type robot system.[16] Here we investigated the safety and feasibility of our statically balanced surgical robot system compared to traditional mastoidectomy and describe our preclinical findings in cadaveric experiments.

MATERIALS AND METHODS

Robot System

A passive-type surgical robot was developed for preclinical experimentation. The advantage of this device is its higher speed than a motor-controlled type robot. Moreover, due to its light and compact nature, it is portable and can easily be set in an operating room. This passive surgical robot also has a counterbalancing mechanism with six degrees of freedom. Two counter-springs are attached to the extended links to guarantee counterbalance over its entire workspace. Moreover, it has a braking feature in cases of emergency, which involves five electromagnets instead of motors. Figure 1A shows the configuration of this robot-assisted surgical system. Markers were mounted on the surgical drill and the surface of the face of the cadaver to track the position and orientation of the surgical drill and cadaver via optical sensors (Fig. 1B). An optical tracking system (Polaris Spectra, Northern Digital Inc., Waterloo, Canada) was used. The overall volume root mean square (RMS) distance error of the Polaris Spectra is about 0.35 mm.[17] The surgical drill was mounted on the holder of the robot system. Preoperatively, a three-dimensional (3D) model of the patient was developed using computed tomography (CT) data obtained via 3D scanning of the cadaver's head. Certain segmented structures, such as the facial nerve, are usually targets of interest in the clinical setting. When the drill burr approaches the target, the robot-assisted system sends auditory cues to alert the operator (Fig. 1C). This alarm can be set based on the distance of the drill burr from the target. If the drill burr approaches within this set distance from the target, the brake is applied and further movement of the drill towards the target is stopped to avoid damage. For instance, if the distance is set to 1 mm to a specific target, the robot system constantly calculates the distance between the drill burr and the target; once this distance is reduced from 3 mm to 1 mm, the system sends an alarm. If the distance becomes <1 mm, the drill movement stops entirely. The operator can set multiple targets and the robot system calculates these distances simultaneously. The brake system can be unlocked using a foot pedal.

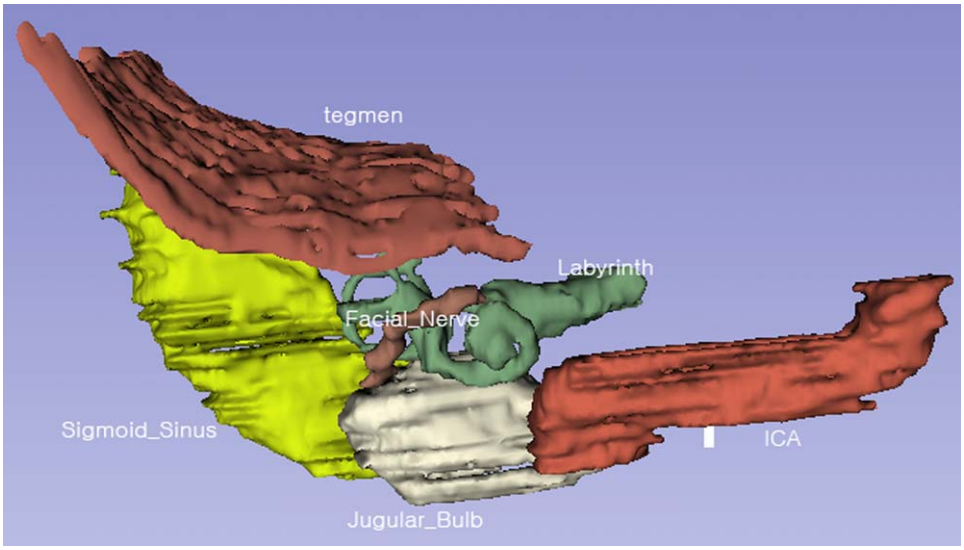

Fig. 2. Segmented surrounding structures that should be protected in the temporal bone during mastoidectomy. Each segmented target has different colors that can be easily distinguished. ICA = internal carotid artery

Cadaveric Experiments

The experimental settings in the present study were similar to those adopted by the previous report on a temporal bone replica.[16] Preoperative CT image acquisition was the first step in the procedure. The image was acquired with a slice thickness of 0.6 mm, using the temporal bone protocol, as in human clinical settings. A preoperative CT dataset of the cadaver was input into an open-source software program for image guidance, as previously reported (3DSlicer, www.slicer.org).[16] The structures requiring protection, such as the region of the facial nerve in the temporal bone, from the first genu to the level of the mastoid tip, were segmented and extracted as a model comprising a finite number of spheres. The sigmoid sinus, jugular bulb, internal carotid artery, middle fossa dura, and labyrinth, including semicircular canals, were also separately segmented in a similar manner. The volume data of the segmented structures were covered with a 1 mm thick safety margin, and were set as a forbidden area (Fig. 2).

We used the paired-point method to register the temporal bone coordinates to the CT image coordinates. We attached fiducial markers on the surface of head in physical space before taking the CT scan. Points were selected with a digitizing probe (or tracking probe) at the fiducial markers. The corresponding points in the preoperative CT were selected using a mouse click event in the 3D slicer. The fiducial registration error (FRE) of the approach depends greatly on the distance from the tracking system to tracked object, how well the fiducial points were selected in both the physical and image spaces, and how many fiducial points were used. In this study, we positioned the tracking system as close to the cadaver and robot system as possible, to minimize the effects of the spatial error of the tracking system.[17] In addition, we used at least seven fiducial points, which are distributed evenly, to expect high accuracy at the level of deeply located target structures, and we carefully selected paired points in the both spaces. As a result, the FRE was measured to be less than 1 mm. Segmentation and image processing for each cadaver was done within approximately 30 min, and the registration of the temporal bone before each experiment using processed image data also took about 30 min, on average.

Mastoidectomies were performed in cadaveric heads, after registration, using our robot system in a temporal bone dissection room at Asan Medical Center (AMC). Various procedures, ranging from simple mastoidectomy (SM) to intact canal wall mastoidectomy (ICWM), were performed on each ear. Postoperative CT images were obtained to evaluate the results. The same type of CT and protocol was used to ensure study homogeneity (Fig. 3).

Analysis

As the entire procedure used in this experimental cadaveric study was new, we needed to create suitable guidelines for evaluation. Given that the purpose of the robot-assisted system is to help the operator to perform a more precise surgery, we attempted to create guidelines that are applicable in actual surgical settings. Hence, we established a guideline comprising

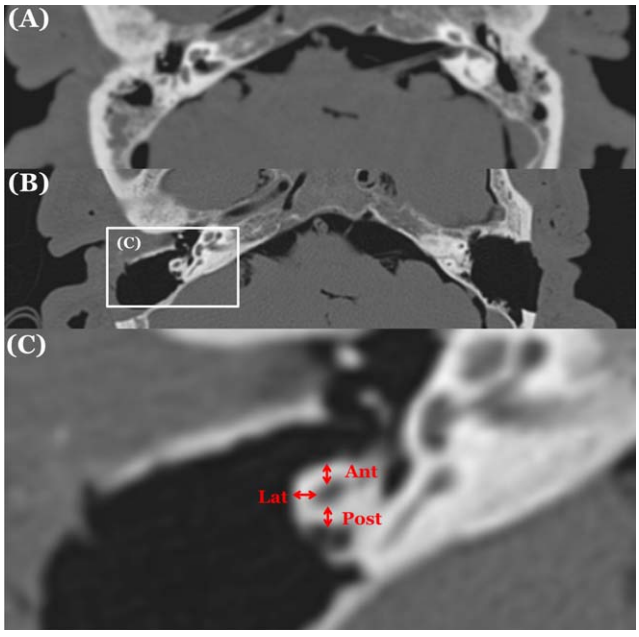

Fig. 3. (A) Preoperative CT scan of a cadaveric head used for segmentation. (B) Postoperative CT scan. (C) Focused view of postoperative CT scan at facial nerve. The red lines represent the thickness of the remaining facial canal in each direction at the pyramidal portion. Ant = anterior, Lat = lateral; Post = posterior

TABLE I.
Data on the Cadaveric Ears, Operators, and Types of Mastoidectomy Used in this Study.

Case number	Cadaver Number	Side	Operator	Type of mastoidectomy
1	1	Left	Experienced surgeon	Intact canal wall mastoidectomy
2	2	Left	Experienced surgeon	Intact canal wall mastoidectomy
3	2	Right	Inexperienced surgeon	Intact canal wall mastoidectomy
4	3	Left	Inexperienced surgeon	Simple mastoidectomy
5	3	Right	Experienced surgeon	Simple mastoidectomy
6	4	Left	Experienced surgeon	Intact canal wall mastoidectomy
7	4	Right	Inexperienced surgeon	Intact canal wall mastoidectomy
8	5	Left	Experienced surgeon	Simple mastoidectomy
9	5	Right	Inexperienced surgeon	Simple mastoidectomy
10	6	Left	Experienced surgeon	Intact canal wall mastoidectomy
11	6	Right	Inexperienced surgeon	Intact canal wall mastoidectomy

three parameters, which may be applicable in clinical settings as well:

1. **Time**
   We created the mastoidectomy protocol such that the time required for the procedure could be measured (Supporting Information Appendix 1). Although the actual surgery was not as clear-cut as this protocol, we attempted to follow the protocol as much as possible. A microscopic view of the mastoidectomy in the cadaveric temporal bone was recorded during the entire operation. After excluding the time during which the procedure was halted for various reasons (eg, the time needed to change the drill burr, which took dozens of seconds to register in the robot system), we calculated the total time required for the mastoidectomy procedure alone. Moreover, we compared this time parameter with the time required to complete the mastoidectomy during actual tympanomastoidectomy surgery without a robot in patients with chronic otitis media. The average time for mastoidectomy was evaluated in 10 videos recorded during the tympanomastoidectomy surgery using the same protocol for time evaluation. The procedures were performed by an experienced surgeon (JWC), and the videos were reviewed by other researchers (MHY, HSL). As in the robot experiment, we excluded stopped duration during the mastoidectomy procedure such as time spent for electrocauterization due to bleeding (by contrast, there was no bleeding in the cadaver experiment), or time needed to remove the soft tissue granulation in mastoid (by contrast, the cadaver had a healthy mastoid, which did not require soft tissue manipulation). This part of the study protocol was assessed by the institutional review board (IRB) of AMC and was exempted from the need for approval.
2. **Safety**
   We used a checklist for structures that could possibly be damaged during actual surgery (Supporting Information Appendix 2). These structures include the sigmoid sinus, tegmen, external auditory canal, facial nerve canal, lateral semicircular canal, chorda tympanic nerve, and ossicles. After mastoidectomy was performed, an outside otologist (who did not drill the specific cadaver bone but knew the operator) assessed damage to these structures by inspecting the actual post-experiment cadaver bone using a microscope and microdissector. There were no cases of facial canal damage. After the experiment, we also reviewed the videos and postoperative CT images for the presence of damaged structures.
3. **Thickness of the bony facial canal**
   To measure the thickness of the bony canal, we examined the postoperative CT images. As the type of mastoidectomy differed between cases, the pyramidal and mastoid segments of the facial nerve were both selected for evaluation, as they could both be damaged following different types of mastoidectomies (Supporting Information Appendix 3). The measurement was performed along two axes (lateral, posterior) in the pyramidal portion and three axes (anterior, lateral, posterior) in the mastoid portion. The thinnest thickness was used among several slices of the CT scan in each axis. However, during the SM procedures, only the posterior portions of the pyramidal and mastoid segments are drilled, and hence, only the thickness of these two areas was analyzed in SM cases. By contrast, during posterior tympanotomy with ICWM, the anterior and lateral portions are both drilled, and hence, both were included in the analysis.

RESULTS

Mastoidectomy was performed in 11 ears of six cadaveric heads (one ear was not used due to technical problems, including errors related to the markers). Five surgeons participated in this cadaveric study, including three who had <2 years of otologic surgery experience (MHY, HSL, CJY) and two who were otologic experts with >15 years of otologic surgery experience (JWC, SHL). SM and ICWM were performed in four and seven ears, respectively. After completing the simple mastoidectomy procedure, posterior tympanotomy was performed in cases with ICWM. Table I provides information on the cadaveric ear, type of operator, and type of mastoidectomy. The preset distance was 3 mm for the alarm system for every target structure, whereas the preset distance for the brake system was 1 mm for only the facial nerve, due to drilling convenience.

The results of the time parameter are summarized in Table II. The videos of cases 6 and 7 were missing, and hence their results were not included in the time evaluation. The average time for SM was 1176.1 s (approximately 20 min) and the additional time for ICWM after SM was 909.0 s (approximately 15 min). The average time for SM was longer in inexperienced surgeons (1439.0 s) than experienced surgeons (965.8 s),

TABLE II.
Times Required for Each Procedure During Mastoidectomy According to the Time Evaluation Guideline (unit: seconds).

	SM procedures								ICWM procedures			
Case number	Cortical bone	EAC	Sigmoid sinus	Tegmen	Antrum	Sinodural angle and tip	Incus	Total SM	Facial nerve	Posterior tympanotomy	Total ICWM	Total
#1	50	22	45	40	30	63	60	310	150	685	835	1145
#2	80	45	70	70	40	45	50	400	120	230	350	750
#3	60	100	110	110	100	140	80	700	230	270	500	1200
#4	180	264	158	205	317	308	570	2002				2002
#5	90	123	205	205	365	275	301	1564				1564
#8	90	130	247	305	324	280	250	1626				1626
#9	100	150	100	375	275	200	467	1667				1667
#10	60	100	110	110	230	200	119	929	261	1075	1336	2265
#11	100	180	160	180	300	300	167	1387	113	1411	1524	2911
Average	90.0	123.8	133.9	177.8	220.1	201.2	229.3	1176.1	174.8	734.2	909.0	2085.1

Modified from the time evaluation guideline (Supporting Information Appendix 1).
Video recordings of cases 6 and 7 were unavailable.
EAC = external auditory canal; ICWM = intact canal wall mastoidectomy; SM = simple mastoidectomy.

and inexperienced surgeons also took additional time for ICWM after SM (inexperienced 1012.0 s vs. experienced 840.3 s). To evaluate the time required for actual mastoidectomy in chronic otitis media patients, 10 cases (five cases of SM and five of ICWM) were used for the analyses. The time required for actions such as changing the drill burr, bleeding control, and soft tissue manipulation was not calculated, and only drilling time was measured. The average time required to complete the SM was 634.2 ± 350.6 s (approximately 10 min; 10 surgeries), which was shorter than that in the cadaver experiment. Moreover, the additional time required for ICWM after SM was 509.0 ± 112.2 s (approximately 8.5 min; five surgeries), which was also shorter than that required in the cadaver experiment.

Despite the use of the alarm and braking systems in the robot, some damage was noted in four cases, including three cases involving an inexperienced surgeon. A tegmen defect, resulting in the exposure of the middle fossa dura without the tearing of the dura, was the most common type of damage (three of four cases). No damage was observed in the other seven cases (Table III).

The thickness of the facial canal on postoperative CT images was measured in five areas. The average thickness on the lateral and posterior axes of the pyramidal portion, and the anterior, lateral, and posterior axes of the mastoid portion was 1.39 ± 0.34, 1.41 ± 0.46, 1.22 ± 0.49, 1.41 ± 0.76, and 1.55 ± 0.76 mm, respectively (Table IV, Fig. 4). The least bony thickness was observed at the anterior axis of the mastoid portion (0.68 mm) and the greatest bony thickness was noted at the posterior axis of the mastoid portion (2.95 mm). Although there were 12 areas (30% among total 40 areas evaluated) in eight cases that showed a thickness of <1 mm, the average thickness of all axes in both portions was >1 mm. In both the pyramidal and mastoid portions of the facial nerve, the average remaining bone thickness increased in the anterior, lateral, and posterior portions, in that order. The average bony thickness was closer to 1 mm in experienced surgeons (1.28 mm) than inexperienced surgeons (1.49 mm).

DISCUSSION

Image-guided navigation systems have become widely used in endoscopic sinus surgery and operations for skull base tumors in the field of otolaryngology.[1] Moreover, the role of robot-assisted surgery in otorhinolaryngology is rapidly increasing, particularly in the head and neck area. Although several types of robot systems have been developed for otologic surgery, most are not yet commercially available.

Rothbaum et al. described a robotic assistance system that can help with the micropick fenestration of the footplate during stapes surgery.[18] A recent preliminary study on the use of a handheld micromanipulator for

TABLE III.
Results of the Safety Evaluation Parameters in the Four Cases With Damage.

Case	3	4	5	7
Sigmoid sinus exposure (-1)		−1		
Sigmoid sinus tear (-2)				
Tegmen exposure (-1)	−1		−1	−1
Tegmen and dura tear (-2)				
EAC wall perforation (-1)				
Facial nerve exposure (-1)				
Facial nerve damage (-2)				
LSCC dehiscence (-1)				
Chorda tympanic nerve cut (-1)				
Ossicles damage (-1)				
Total safety score	9	9	9	9

The score starts at 10 in accordance with Supporting Information Appendix 2. If there is damage, the score is reduced by 1, and if there is direct damage to the sigmoid sinus, dura or facial nerve, then it is reduced by 2. The other seven cases did not exhibit any damage and were hence not listed in the table.
EAC = external auditory canal; LSCC = lateral semicircular canal

TABLE IV.
Remaining Thickness of the Bony Facial Canal After Mastoidectomy in All Cases (mm).

Location	1	2	3	4*	5*	6	7	8*	9*	10	11	Average ± SD
Pyramidal portion												
Lateral thickness	0.7	0.93	0.83			1.4	1.02			2.45	2.43	1.39 ± 0.34
Posterior thickness	1.55	1.82	2.2	1.02	1.14	1.54	1.16	1.03	0.84	1.16	2.1	1.41 ± 0.46
Mastoid portion												
Anterior thickness	1.11	0.93	1.85			1.95	1.1			0.91	0.68	1.22 ± 0.49
Lateral thickness	0.78	0.82	1.96			1.17	0.92			1.36	2.87	1.41 ± 0.76
Posterior thickness	2.08	1.06	2.81	1.07	1.12	2.95	0.82	0.82	1.3	1.74	1.24	1.55 ± 0.76

*In cases of simple mastoidectomy (4,5,8,9), only the posterior thicknesses of the pyramidal and mastoid portions were analyzed.
SD = standard deviation

robot-assisted stapes footplate surgery was also published, which indicated a significant reduction in position errors and mean duration time spent in dangerous zones.[19] Moreover, most experimental surgical robots in otology have been developed for direct cochlear access in cochlear implantation procedures, as mentioned above.[4–11,20,21] However, these are totally automated robot systems and have few other clinical applications, as they can only be used for cochlear implantation, which accounts for a small portion of various surgeries requiring mastoidectomy.

Furthermore, a totally automated robot system would still require supervision by a surgeon.[15] A major objective of the experimental use of a robot system is to achieve a level of patient safety equivalent to that present in current clinical practice. As previously mentioned, experienced surgeons may not require the assistance of robots during mastoidectomy. Hence, our non-automated human–robot system may serve as a viable alternative for an otologic robot by not interfering with the surgeon's routine manual drilling procedure unless important structures are at risk for damage.

Although the brake system can be preset for all individual structures, the drill was set to stop when it reached within 1 mm of the surface of the facial nerve. When the brake was pre-set to stop at all structures (labyrinth, sigmoid sinus, tegmen, jugular bulb, internal carotid artery), the drill stopped too frequently. Although the brake can be released using a foot pedal, these frequent stops impeded the flow of the procedure. Therefore, we activated the brake only for the facial nerve, whereas an alarm system was activated for the other structures during the experiment. Surgeons found no difficulty using the drill connected to the multi-articulated arm, because the drill was very smoothly movable without much force.

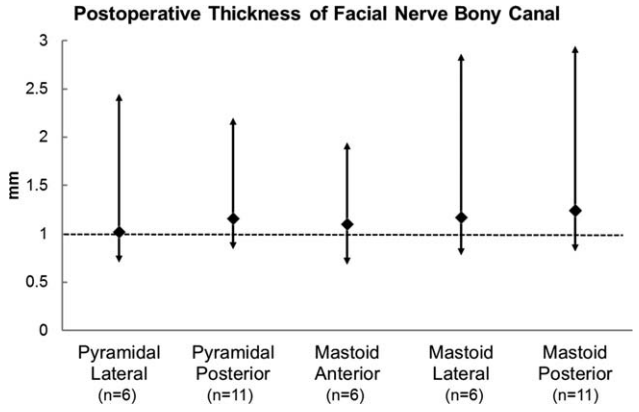

Fig. 4. Range of bony thicknesses in the postoperative CT scan in each area of the facial nerve. The rectangle represents the median thickness of each portion.

We evaluated the time parameter to assess the efficacy of our robot system for mastoidectomy. The temporal bone of a cadaver usually does not have chronic otitis media, and hence, direct comparison to actual surgery time may be meaningless. Compared to an actual mastoidectomy time in patients, the time taken with the cadaver experiment was longer by approximately 9 min in SM and 6.6 min in additional ICWM procedures. Nevertheless, the use of an unfamiliar robot system rather than the drill used in real surgery, which surgeons are familiar with, appeared to be acceptable for most of the surgeons, and operation time may become reduced through familiarization with the robot system.

There was no major damage to important structures, including the facial nerve, in any case. Minor damage to certain structures during the experiment was observed in three of five cases involving the less experienced surgeons and was more frequent than in the experienced surgeons (one of six cases). Nevertheless, minor damage, including a small tegmen defect without tearing of the dura or sigmoid sinus exposure, is not uncommon in an actual mastoidectomy.[22]

To evaluate the intraoperative accuracy of our robot system, we measured the remaining bony thickness of the facial canal. There was variation in the axis and the portion of the facial nerve in different cases, but the average thickness was close to the preset distance of 1 mm in most instances. Although the brake was activated in all cases during the experiment, the thickness was less than the preset distance in 40% of cases, and the average bony thickness differed from the preset distance of 1 mm. The reasons for these errors include CT resolution error, registration error, and errors with the optical sensor. However, no cases of facial nerve exposure or intraoperative damage, as determined via postoperative CT scans, were noted. During mastoidectomy, the facial nerve is commonly monitored using electromyography (EMG) to prevent unintended damage; however,

the exposure of the facial nerve often occurs in such cases, although catastrophic facial nerve damage rarely occurs.[23] In a previous study, Anso et al. assessed the possibility of identifying the facial nerve using EMG in robotic direct cochlear access.[24] However, our system did not include a fully automated robot, but instead represented a human–robot collaborative system. Hence, we were able to use a routine facial nerve monitoring system similar to that used in normal mastoidectomy without a robot.

One limitation of our study is that we did not compare differences in performance between the system as active and inactive. Such an experiment could indeed provide evidence for the enhanced safety of the system, but it would require a relatively large number of cadaver, so it remains for future study.

Our human–robot collaborative control system has several advantages. First, its usability in tympanomastoidectomies in clinical settings is clear from our current findings. Its efficiency, safety, and accuracy were well verified in our preclinical cadaver experiment. Although there were also several limitations of note, we expect to test our system under actual mastoidectomy conditions after making further improvements. The fact that the registration by the robot of different sizes of drill burr is not automated and requires an engineer to select the appropriate size on a computer is a point that needs to be improved in our system, as is the time spent in registration. The automated registration of various drill burrs without the necessity of other procedures will be needed for the actual commercialization of the robot system. Another possible improvement would be the registration of different sounds for the alarm, as the present system has only one type of sound, which increases in volume as important structures are approached. To enable the surgeon to differentiate which structures are neighboring through the alarm alone, different sounds should be connected to different structures.

Second, our robot can be used to train less-experienced surgeons, including residents and fellows, in the mastoidectomy procedure. Experienced surgeons rarely produce damage to critical structures; however, for inexperienced surgeons, drilling through the complex anatomy of the temporal bone may be challenging.[16] In terms of time, safety, and thickness, inexperienced surgeons showed relatively worse results than experienced surgeons in our experiment. However, there were no critical complications such as damage to the facial nerve, labyrinth, dura, or large vessels. Some may raise the issue that inexperienced surgeons trained on the system may come to rely on it and not develop expertise outside of it. However, our system can be useful at the start of the learning curve, and as the system advances, our robot will be helpful to all surgeons.

Third, the results of using our robot system could support the development of clinically applicable automated robot systems in the near future. Although a fully automated robotic instrument may not be very useful for mastoidectomy, the automation of some of the procedures of otologic surgery may be helpful for surgeons in the future. One of the objectives for developing a robot system is to help less-experienced surgeons achieve better performance. In this context, robot assistance can be beneficial in preventing damage from mastoidectomy. After approval of the Korean Ministry of Food and Drug Safety of our robot for electrical and engineering safety, its efficacy should be confirmed through clinical study.

CONCLUSION

We developed a human–robot collaborative control system that assists with manual drilling and protects preset structures during mastoidectomy. The preclinical testing of this system using the temporal bones of cadavers revealed its feasibility. Our findings may support the development of a viable otologic surgery robot for clinical use in the near future.

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