The Laryngoscope

TRIOLOGICAL SOCIETY CANDIDATE THESIS

Robotic Microlaryngeal Phonosurgery: Testing of a "Steady-Hand" Microsurgery Platform

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Objectives/Hypothesis: To evaluate gains in microlaryngeal precision achieved by using a novel robotic "steady hand" microsurgery platform in performing simulated phonosurgical tasks.

Study Design: Crossover comparative study of surgical performance and descriptive analysis of surgeon feedback.

Methods: A novel robotic ear, nose, and throat microsurgery system (REMS) was tested in simulated phonosurgery. Participants navigated a 0.4-mm-wide microlaryngeal needle through spirals of varying widths, both with and without robotic assistance. Fail time (time the needle contacted spiral edges) was measured, and statistical comparison was performed. Participants were surveyed to provide subjective feedback on the REMS.

Results: Nine participants performed the task at three spiral widths, yielding 27 paired testing conditions. In 24 of 27 conditions, robot-assisted performance was better than unassisted; five trials were errorless, all achieved with the robot. Paired analysis of all conditions revealed fail time of 0.769 ± 0.568 seconds manually, improving to 0.284 ± 0.584 seconds with the robot ($P = .003$). Analysis of individual spiral sizes showed statistically better performance with the REMS at spiral widths of 2 mm (0.156 ± 0.226 seconds vs. 0.549 ± 0.545 seconds, $P = .019$) and 1.5 mm (0.075 ± 0.099 seconds vs. 0.890 ± 0.518 seconds, $P = .002$). At 1.2 mm, all nine participants together showed similar performance with and without robotic assistance (0.621 ± 0.923 seconds vs. 0.868 ± 0.634 seconds, $P = .52$), though subgroup analysis of five surgeons most familiar with microlaryngoscopy showed statistically better performance with the robot (0.204 ± 0.164 seconds vs. 0.664 ± 0.354 seconds, $P = .036$).

Conclusions: The REMS is a novel platform with potential applications in microlaryngeal phonosurgery. Further feasibility studies and preclinical testing should be pursued as a bridge to eventual clinical use.

Key Words: Microlaryngeal, phonosurgery, microsurgery, robot, robotic.

Level of Evidence: NA.

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INTRODUCTION

From office-based mirror-guided procedures in the 1860s to the beginnings of direct laryngoscopy and direct endolaryngeal surgery in the 1890s, the evolution of laryngeal surgical techniques have been driven by the promise of increased operative precision.[1] Further advances include incorporation of operating microscopes into laryngology,[2] introduction of CO_2 lasers for improved operative hemostasis,[3,4] and development of microflap techniques.[5–7] The goals with each advancement have been to better maintain, restore, or enhance the human voice,[8] paying particular surgical attention to preserving the layered microarchitecture of the vocal folds and the pliability of vocal fold tissue.[9] Imprecise surgery may cause unnecessary damage to the vibratory tissues of the vocal folds, leading to suboptimal voice outcomes. Unfortunately, current treatment paradigms cannot effectively restore pliability to already scarred vocal folds, and it is preferred by phonosurgeons that this scar be avoided in the first place by performing surgery with as much precision as possible.

Coincident with advances in microlaryngeal surgical technique has been a similar, though more rapid, evolution of robot-assisted surgery in otolaryngology. The most well-established role of robots in head and neck surgery is incorporation of the da Vinci surgical robot (Intuitive Surgical, Sunnyvale, CA) into ablative procedures of the pharynx, and transoral robotic surgery is being performed widely with a low major complication rate.[10] As robotic technologies mature, new head and neck applications being developed include approaches to

Additional supporting information may be found in the online version of this article.

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thyroid,[11] skull base,[12] sleep,[13] and nonoropharyngeal malignancy surgeries.[14] As familiarity with the technology increases and patient benefits are further defined, it is likely that new robotic systems will enter clinical use, and new clinical applications for robotic surgery in otolaryngology will be extended.[15]

Despite advances in microlaryngeal phonosurgical techniques and robot-assisted surgery, robots currently have a very limited role in endolaryngeal surgery of the vocal folds. In theory, the benefits of robotic surgery should translate to phonosurgery as well, with potential benefits including improved optics, increased instrument degrees of freedom, and improved surgical dexterity with improved operative outcomes.[16] Limitations for applying current robotic technologies to laryngeal surgery, however, include need to work around an endotracheal tube, instrumentation too large for phonosurgery, and difficulty manipulating robotic effector arms within the narrow working space afforded by standard retractors.[17] As a result, described applications for robotic laryngeal surgery using the da Vinci surgical robot are largely limited to procedures such as vocal cord stripping, cordectomy, and partial epiglottectomy,[18] procedures in which preservation of normal vocal fold anatomy and function are not prioritized. Resections of laryngeal tissue have reported using novel retractors[19] or with placement of effector arms outside the laryngoscope,[20] and newer retractors and instruments may eventually allow use of da Vinci surgical robots in phonosurgery.[21] Other efforts at robotically enhancing operative precision in microlaryngeal surgery include development of a robotic micromanipulator CO_2 lasers.[22] For now, however, the promise of robotic surgery is not being translated routinely into microlaryngeal phonosurgery.

To address these issues, a novel robotic ear, nose, and throat microsurgery system (REMS) has been developed.[23–28] This system emphasizes cooperative control, rather than remote control, of microsurgical instruments, the robot arm grasping the instrument shaft just next to the handle used by the surgeon. The REMS system's ability to improve precision in simulated laryngoscopy surgical tasks was demonstrated in a preliminary study,[23] which generated feedback on robot design, force allowances, and nature of a simulated surgical task, which provided the basis for this article. The present study aimed to further preclinical investigation of this novel robotic "steady hand" microsurgery platform by evaluating gains in surgical precision during performance of simulated phonosurgical tasks.

MATERIALS AND METHODS

Volunteer participants were solicited from faculty and trainees at a university-based academic otolaryngology program. Institutional review board approval was obtained, and participants consented to evaluation of their performance.

The REMS

Engineering details of the REMS have been previously described within the robotics literature, and the reader is encouraged to look there for complete details of design of the robotic manipulator.[23–28] The robotic arm's distal clamping tool holder grasps an instrument shaft immediately adjacent to the handle. The surgeon is responsible for instrument manipulation, whereas the REMS provides robotic enhancements in precision and scale of motion. Figure 1 demonstrates the robotic platform, which consists of a parallel delta stage for translational motion, together with a lightweight extension arm and wrist currently providing 2 degrees of freedom orientation for a tool holder. The overall robot is lightweight, and the parallel actuation ensures that the moving mass is quite low, thus providing good responsiveness with small actuators. Furthermore, the extension arm ensures that the structure does not intrude significantly into the surgical field. A force-torque sensor in the robotic wrist senses forces and torques exerted by the surgeon on the surgical tool, and the robot then moves the instrument with the surgeon in cooperative fashion, subject to robotic limitations on speed, force, and tremor. Different microlaryngeal instruments can be inserted and removed during performance of a procedure. The robot arm's rotary joints allow for roll and tilt degrees of freedom, whereas a tripod of robotic linear actuators provide translational motion in x, y, and z planes. Foot pedal control of stiffness in the robot arm allows for unimpeded motion during instrument placement and progressive degrees of robotic assistance during surgical maneuvers within defined allowances for speed and force of instrument motion as the pedal is released. When the pedal is released entirely, the robot is locked in place, holding the cooperatively controlled instrument perfectly still. Features of robot design as related to manipulation of microlaryngeal instruments are demonstrated in Supporting Video 1 in the online version of this article, showing translational, roll, tilt, and rotational motions.

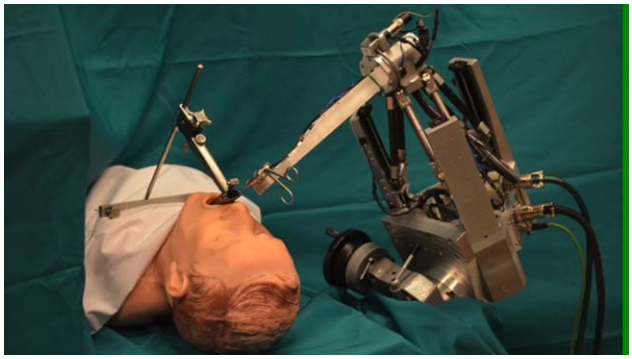

Fig. 1. The robotic ear, nose, and throat microsurgery system (REMS) set-up for microlaryngeal surgery.

Simulated Phonosurgery

To simulate microlaryngeal surgery closely, a mock laryngoscope with dimensions of a large modular universal glottiscope, operating microscope with 400-mm focal length, and a chair with arm supports were used. A 25-cm laryngeal forceps with its tip modified to hold a 0.4-mm- diameter needle was used, and participants were asked to draw the needle through a spiral groove, starting in the center and maneuvering the tip concentrically outward without letting the needle touch the sides. Setup for the simulated surgical task is shown in Figure 2. Contact between instrument and spiral sides target was detected through establishment of an electrical circuit to allow measurements of fail time. Four different spiral targets were used: a 2.5-mm spiral to allow familiarity with the surgical task, and then 2-mm, 1.5-mm, and 1.2-mm spirals (Fig. 3) to

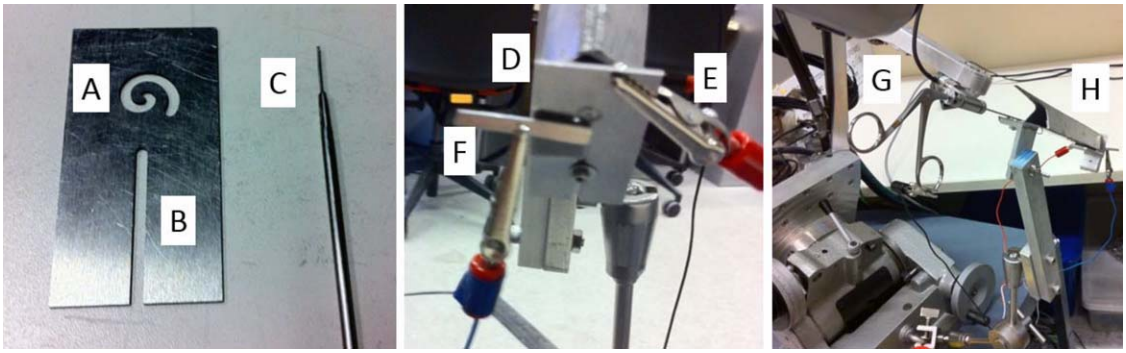

Fig. 2. The experimental setup. The spiral (A), mounting slot to allow positioning of the spiral at the end of the laryngoscope (B), and microlaryngeal needle tip (C) are shown on the left. The middle image demonstrates a view of the spiral target (D) mounted at the end of a laryngoscope with both failure electrode (E) and success electrode (F) attached. On the right, the REMS grasping arm (G) is used to hold the modified microlaryngeal needle within the laryngoscope (H). Edge of the 400-mm microscope can be seen in the upper left corner.

judge performance with and without the REMS when used with a 0.4-mm-diameter needle; this last spiral had tolerance of only 0.4 mm on either side of the needle when it was centered within the channel.

Data Collection

Following consent and a practice session with the 2.5-mm spiral to familiarize participants with the REMS and the surgical tasks, participants were asked to navigate the instrument through the spiral as quickly as possible without touching the sides. If the instrument contacted the spiral's sides, a buzzer sounded to indicate this. Each participant performed five trials with each of the 2-mm, 1.5-mm, and 1.2-mm spiral targets, both with and without the REMS. Spiral orientation was reversed in alternating trials to keep users from becoming accustomed to moving in the same direction on each trial. To limit fatigue and learning curve effects from contaminating study results, each participant was randomly assigned as to order of the trials. Some completed the study manually and then robotically, whereas others did it robotically first and then manually.

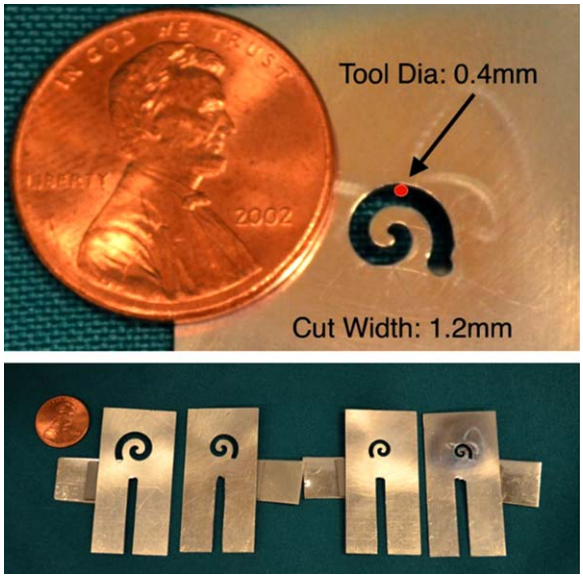

Fig. 3. The spirals, shown next to a penny. From left to right, the width of the spiral channels are 2.5 mm, 2.0 mm, 1.5 mm, and 1.2 mm, respectively. The 0.4-mm diameter of the microlaryngeal needle is represented by the red dot in the upper image.

Statistical Analysis

For each participant, mean fail time was calculated over five trials with each combination of spiral size and the REMS versus manual performance. Paired analysis was performed, comparing the participants' fail times with the REMS to manual fail times. As fail time was bounded at the lower limit by zero, raw data for fail time did not follow a normal distribution; however, in this paired analysis, the population of differences for each participant between robot times and manual times could potentially follow a normal distribution. With that in mind, these calculated differences between the two operative conditions at each spiral width were analyzed with a Shapiro-Wilk test for normality at a 5% significance level. If the range of differences for any particular test condition had a normal distribution, then paired t test was utilized to compare robot versus manual performance. If the population of differences did not have a normal distribution, then a Wilcoxon signed rank test would have been performed instead. Statistical significance was assigned to results at a $P < .05$ level.

Descriptive Analysis

Participants provided feedback on the REMS using a survey form. This form asked each participant to provide their level of experience (attending vs. resident/fellow) and then used a five-point Likert scale (poor, poor-to-fair, fair, fair-to-good, good) to assess opinions on the degree to which the surgical task was a fair representation of microlaryngeal surgery, self-assessment of surgical skill with and without the REMS, and ease of use of the REMS. Participants were also asked for yes/no answers about whether a bimanual REMS would be preferred to a unilateral REMS, and about whether they would or would not use the robot clinically.

RESULTS

Nine participants volunteered for the study – these included two laryngologists, two head and neck surgeons, one general otolaryngologist, one laryngology fellow, and three residents. Mean fail time for each participant for each test condition are shown in Table I.

TABLE I.
Fail Times for Each Participant at Each Test Condition.

	Subject	1	2	3	4	5	6	7	8	9
Manual	2 mm	0.491	0.295	0.426	0.409	0.521	0.233	0.533	0.088	1.949
	1.5 mm	1.338	0.778	0.763	0.727	1.442	0.542	0.369	0.265	1.788
	1.2 mm	1.167	0.849	0.537	0.642	2.326	0.524	0.371	0.243	1.154
Robot	2 mm	0.000	0.041	0.056	0.024	0.000	0.052	0.472	0.151	0.611
	1.5 mm	0.000	0.033	0.061	0.012	0.000	0.004	0.286	0.096	0.183
	1.2 mm	0.430	0.000	0.286	0.528	0.044	0.115	1.085	0.188	2.919

Data are presented in seconds.

Of the 27 different test conditions (nine participants at each of three spiral widths), 24 out of 27 comparisons show reduced fail time in the REMS group as compared to the manual group. Additionally, there were five test conditions that yielded zero fail time, and each of these five errorless series of runs were achieved with use of the robot. Demonstration of the experimental setup and representative trials with the 1.2-mm spiral both with and without the REMS assistance are shown in Supporting Video 2 in the online version of this article.

Paired analysis of mean scores for all nine participants collectively is show in Table II. In each case, the collection of differences between robot-assisted fail time and manual fail time for each participant were found to have a normal distribution, and a paired *t* test was therefore used to assess statistical difference between the robot versus manual test conditions. For all spiral sizes taken together and for each of the 2.0-mm and 1.5-mm test conditions individually, performance with the REMS was statistically more precise than performance manually. Among all nine participants, difference between the REMS and manual performance did not reach statistical significance in the most challenging 1.2-mm test condition. However, when subgroup analysis of this challenging 1.2-mm spiral width was performed, those most familiar with microlaryngeal surgery (the two laryngologists, one laryngology fellow, and two head and neck surgeons—participants 1, 2, 3, 6, and 8, respectively) demonstrated statistically improved performance with the robot, with fail time of 0.204 ± 0.164 seconds for the REMS as compared to 0.664 ± 0.354 seconds for the manual condition ($P = .036$). Conversely, this 1.2-mm test condition remained difficult for those participants least familiar with microlaryngeal surgery even with the robot, with roughly similar performance in both the REMS and manual test conditions (1.144 ± 1.257 seconds REMS vs. 1.123.±.0.865.seconds manually, $P = .98$).

Descriptive Feedback

Results from participant questionnaires are summarized in Table III. Of the nine participants, five performed the simulated surgical task first, whereas four performed with the REMS first, consistent with randomization of this process. All surgeons were right handed, an important factor as the robot was set up for unilateral use in the surgeon's right hand. Six of the participants had previously used a robot in head and neck surgery. Likert scales utilizing a 5-point scale (1 = not at all, 2 = fair, 3 = good, 4 = very good, 5 = excellent) indicated that participants thought the simulated phonosurgery task was a very good representation of microlaryngoscopy. Similarly, ease of robot use was considered very good. All participants self-rated surgical skill more highly with the robot than without, and all judged ability of the robot to aid surgical performance in real, rather than simulated, phonosurgery to be very good to excellent. All participants indicated desire to use the REMS clinically once available, and all expressed a preference for the possibility of bimanual rather than one-sided robotic assistance.

DISCUSSION

As measured by fail time, the REMS platform improved precision of simulated phonosurgery compared to unaided, manual performance. Improvement was seen when all test conditions were analyzed collectively and also in breakout analysis of 2.0-mm and 1.5-mm spiral conditions. In the most demanding simulated condition with the 1.2-mm spiral, the REMS aided surgical performance among a subgroup of surgeons (laryngologists and head and neck surgeons) most familiar with microlaryngeal surgery, but did not aid performance across the entire cohort of participants. Subjective feedback correlates well with objective demonstration of improved

TABLE II.
Fail Times Across All Participants for Each Condition.

	All Three Spirals	2.0 mm	1.5 mm	1.2 mm
Manual fail time	0.769 ± 0.568	0.549 ± 0.545	0.890 ± 0.518	0.868 ± 0.634
Robot fail time	0.284 ± 0.584	0.156 ± 0.226	0.075 ± 0.099	0.621 ± 0.923
P value	.003	.019	.002	.52

Data are presented in seconds as mean ± standard deviation with statistical comparison.

TABLE III.
Subjective Feedback on Uses of the REMS Platform in Simulated Phonosurgery.

	Participant								
	1	2	3	4	5	6	7	8	9
Manual or robot first	M	R	M	R	M	R	M	R	M
Experience	6	6	4	2	3	6	3	7	7
Specialty	L	L	L	N/A	N/A	HN	N/A	HN	O
Left or right handed	Right	Right	Right	Right	Right	Right	Right	Right	Right
Used robot before	Y	Y	N	N	Y	Y	Y	Y	N
Experiment fair representation	4	5	4	3	5	5	3	3	3
Skill without robot	2	3	3	3	2	2	2	2	3
Skill with robot	5	5	5	4	5	5	3	4	4
Robot ease of use	5	5	4	3	5	4	3	4	4
Robot aid in real use	5	5	5	4	5	4	4	5	5
Better if bimanual?	Y	Y	Y	Y	Y	Y	Y	Y	Y
Would use it clinically?	Y	Y	Y	Y	Y	Y	Y	Y	Y

Experience is quantified by: 1 = medical student, 2 = junior resident, 3 = senior resident, 4 = fellow, 5 = attending <5 years, 6 = attending 6–10 years, 7 = attending >10 years. Subspecialty is quantified by: L = laryngology, HN = head and neck, O = other. Residents are marked N/A as they do not have a subspecialty yet. N = no; N/A = not applicable; M = manual; R = robot; REMS = robotic ear nose and throat microsurgery system; Y = yes.

surgical performance achieved through the REMS. Participants found the REMS platform easy to use; all felt surgical performance was better with the REMS than without, and all expressed desire to incorporate the REMS into their clinical practices once available.

The simulated phonosurgery task was set up to model microlaryngeal surgery, with table height, chair with arm supports, mock laryngoscope built to dimensions of a large universal modular glottiscope, and operating microscope with a 400-mm focal lens, all chosen to parallel clinical conditions as closely as possible. As rated by participants, the simulated surgical task was thought to be a good-to-excellent representation of phonosurgery. Although other phonosurgical phantoms might have been more biologically oriented with the use of cadaver larynges or simulated phonotraumatic lesions, this study required a task that allowed precise electronic collection of fail times and therefore used a conductive metal spiral surgical target. Face validity of task appropriateness is supported by increased fail time as the spiral was narrower, and also by improved discrimination between robot and manual performance at the most challenging test condition in a group of experienced phonosurgeons compared to a group of otolaryngologists with less clinical experience in microlaryngoscopy. The study design tried to minimize bias as much as possible, randomizing participants to robot or manual conditions first, alternating spiral patterns from clockwise to counter clockwise between trials to reduce a learning effect, using five runs within a particular condition to allow use of mean fail time, and allowing as many trial runs as desired by the participant at an introductory 2.5-mm spiral to ensure participants were familiar with study design and robot operation prior to data collection.

One potential limitation of the current study design is reliance on fail time as a measure of surgical performance. Surgical pacing could potentially influence total fail time, as the longer one took to navigate the spiral, the more time the needle was at risk for contacting the sides. Conversely, racing through the spiral might yield low fail time even if surgical precision was poor, because total time for that trial might remain low even if the needle contacted the sidewall for the entire run. To limit this potential bias, participants were asked to perform each task as precisely as possible. In practice, whatever bias might be introduced in this fashion would also be expected to artificially suppress, rather than boost, the impact of the REMS on surgical precision. By helping to slow and guide motion of the instrument, depending to what degree the foot pedal was pressed, the robot slowed rather than accelerated the surgical task. Had results been calculated as percent of fail time rather than absolute fail time, it is likely that benefits of the robot would have been even further magnified.

This REMS platform is novel among current robotic systems as applied to microlaryngoscopy. First, this system offers shared control of microlaryngeal instruments, with the benefits of preserving fundamentals of surgical approach and visualization that are familiar to laryngeal surgeons. The REMS is compatible with all existing laryngoscopes, telescopes, microscopes, and microlaryngeal instrumentation, and the basic setup of direct suspension microlaryngoscopy is unchanged while using the REMS. Shared control, augmented by robotic assistance in steadiness and precision, allows for true haptic feedback for the surgeon. Evolutions in the REMS design will allow for possible safeguards to be built into the robot relative to surgical boundaries, force limitations with tissue handling, and potential programming of the robot for automatous performance of discrete tasks. As technologies evolve, for instance, a bimanual REMS might not only facilitate advanced phonosurgical techniques, such as suturing, but might be programmed to perform this task automatically. Beyond phonosurgery, other possible applications in otolaryngology might

include microvascular reconstruction and skull base, sinus, and neuro-otologic surgeries. As the REMS platform advances from a table-top platform to a self-contained, mobile system, which could be used in operating rooms, future studies will be necessary. Studies should investigate gains in operative precision in preclinical models, such as this, and others in investigate translational possibilities in animal or cadaver models.

That a REMS might have a niche in clinical practice can be deduced from the limitations of current robotic technologies in microlaryngeal surgery. As technologies evolve, it is likely that each platform will develop to have its own relative strength and drawbacks. At present, however, there is no existing robotic platform that adds robotically assisted improvements in operative precision to microlaryngoscopic phonosurgery. The da Vinci platform is the current workhorse in head and neck transoral robotic surgery, but it is not currently designed for microlaryngeal surgery, with instruments that are too large for direct laryngoscopy approaches or precise microlaryngeal work within the endolarynx.[21] The existing da Vinci descriptions of laryngeal surgery are mostly limited to cordectomy, partial epiglottectomy, vocal cord stripping, and arytenoidectomy,[17,18,29] procedures that do not prioritize preservation of normal vocal fold anatomy and function. Because of these limitations, new retractors and custom instrumentation are being designed to allow for phonosurgery with the da Vinci platform, and preliminary studies with three cadavers used these new instruments to perform phonosurgical techniques such as microflap elevation in addition to cordectomy, arytenoidectomy, and anterior commissure excision, with emphasis on feasibility rather than documentation of operative precision.[21] As instruments and retractors become further refined, microlaryngeal applications of the da Vinci platform will certainly evolve, though the system will remain one in which the surgeon operates remotely with a three-dimensional vision system rather than with the familiar laryngoscope and operating microscope.

Other robotic systems have been applied to laryngeal surgery as well, also mostly in feasibility studies. The Medrobotics Flex system (Medrobotics Corp., Paramount, MA) uses a physician controller to drive a flexible snake-like device into the supraglottic region, where a distal chip endoscope provides visualization of the operative field. Working off a monitor, the surgeon operates flexible tools passed through lateral working accessory channels on each side of the robot. Surgical manipulation of these tools is manual, rather than robotic assisted. An initial publication documented ability of the flexible robot to visualize the larynx without suspension laryngoscopy,[30] and a further preclinical study has shown successful epiglottectomies in five cadaver specimens and a vocal cord excision in a single cadaver specimen.[31] Similar robotic systems have been described for manipulation of rigid[32] and flexible[33] endoscopes, though the benefits in each case are limited to robotic control of the endoscope itself rather than any robotically enhanced precision of surgical tools otherwise.

There is a newer da Vinci robot that combines a single flexible stereoscopic camera and three flexible articulating snake-like endoscopic instruments within a single instrument arm.[34] This single arm can be brought into an operative field transorally, and then effector arms are deployed. Currently, the instruments are 6 mm in diameter, and the jointed instruments require a working space described as roughly the size of a tennis ball, with preclinical anatomic studies being limited at present to the lateral oropharyngeal wall.[35] Another preliminary study focuses on possible gains in endolaryngeal operative dexterity using RealHand high-dexterity instrumentation (Novare Surgical, Cupertino, CA) designed for natural orifice transluminal endoscopic surgery. In an animal laryngeal model, this study demonstrated that with modification, these tools may be suitable for laryngeal procedures.[36] These dexterous laparoscopic instruments are still operated manually, however, and this technology does not offer any robotic assistance in instrument manipulation.

These many studies point to the collective desire to enhance surgical precision for glottic microsurgery, extending benefits of robotic surgery beyond current descriptions of epiglottectomy and cordectomy. As the field evolves, techniques will become more sophisticated and instruments will become smaller. The REMS platform offers several benefits when applied to phonosurgery, including cooperative control of instruments, haptic feedback, and incorporation of standard microlaryngoscopy techniques and instrumentation rather than remote operation. The REMS may also have applications wherever increased precision of instrument manipulation is desired, including microvascular, skull base, neuro-otology, and other otolaryngology procedures. In the future, the REMS's filtering of surgical motions through robotic cooperative control may allow gains in operative precision to be extended to programming of surgical boundaries related to patient anatomy or tissue forces, and might even allow for automatous performance of programmed maneuvers. Further study of this promising technology will be necessary in both laboratory and preclinical models.

CONCLUSION

The REMS is a promising novel technology. It offers objective improvement in surgical precision over manual surgery during performance of a simulated phonosurgery task. Subjectively, participants found the REMS easy to use, felt that their surgical performance was improved by the REMS as compared to the unaided condition, and expressed a desire to use the REMS in their clinical practice. Further laboratory and preclinical testing of the REMS will be necessary to help bring the REMS into clinical practice.

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