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Quantifying the Benefits of Robotic Assistance in Various Microsurgical Procedures

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INTRODUCTION

While advances in surgical and optical technologies have led to the advent of microsurgical procedures, it is now the limitation of human dexterity that limits the use and extent of these procedures. Robotic systems that offer finer motor control and improved precision may allow a larger number of patients to benefit from these interventions that are currently constrained by human ability [1]. The Galen robot is a next generation research system of the original Robotic ENT Microsurgical System (REMS), a 5 degree of freedom robotic platform designed primarily for microsurgical applications. It works cooperatively with the surgeons, can hold adapted standard surgical instruments with its universal surgical tool exchanger and identification system, and helps mitigate hand tremor, which may offer advantages over conventional interventions in the form of reduced damage to the surrounding tissues and time savings in the operating room [1-2]. This paper summarizes the methods and findings of three studies conducted to quantify the benefits of using the robot over freehanded approaches. Specifically, the authors have studied the use of the platform in simulated microlaryngeal phonosurgery, microvascular anastomosis, and stapedotomy tasks.

Disclaimer: The Galen System is under development by Galen Robotics, Inc. and is not for commercial sale.

MATERIALS AND METHODS

1 – Microlaryngeal Surgery Study

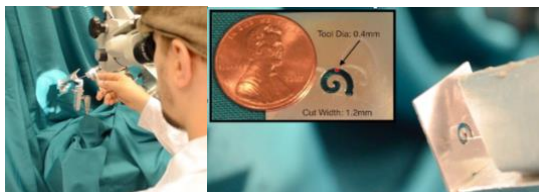


Fig. 1 Left: Microlaryngeal study setup. Right: Close up of the smallest spiral and the tool tip inserted into it.

The setup for the microlaryngeal surgery study was devised to simulate phonosurgery by traversing a spiral channel using a mock laryngoscope under microscopic vision [3]. Nine participants of varying experience levels were tasked with guiding a 0.4 mm diameter microlaryngeal needle through spirals of three different channel widths both with and without the REMS while

avoiding contact with the sides of the slot. Data was collected in the forms of contact time – time the needle spent touching the edges of the spiral – and a survey to elicit feedback from the participants.

2 – Microvascular Surgery Study

Six naïve participants and one expert were recruited for this study. To simulate microvascular anastomosis, a chicken thigh model was used [4]. Participants were seated at a surgical microscope and tasked with performing three front wall sutures with three knots tied per suture on an artery of 2.4-3.0 mm inner diameter, with and without REMS assistance for their dominant hand. Along with measuring time to completion (TTC), a new microvascular tremor scale (MTS) was used to score the performance, and the interrater reliability of the scale was determined.

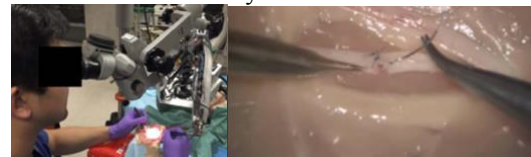


Fig. 2 Left: Microvascular study setup. Right: close up of REMS-assisted trial.

3 – Stapedotomy Study

A middle ear phantom modeling the view of the incus a surgeon would have after removing a calcified portion of the stapes was created using 3D printed parts and a force/torque sensor (ATI Nano 17, Apex, North Carolina) [5]. Six participants were asked to place and crimp a piston prosthesis onto the model both freehanded and with robotic assistance, three times each. The means of both the maximum force applied to the model incus and the change of force over time (dF) were recorded for prosthesis placement and for crimping.

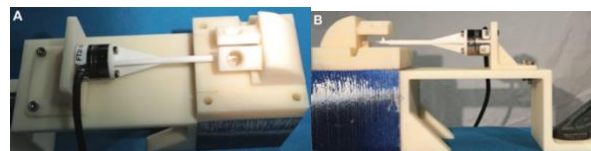


Fig. 3 Stapedotomy study setup. Left: Stapedotomy visualization. Right: 3D-printed incus.

RESULTS

1 – Microlaryngeal Surgery Study

Nine participants completing three different spiral widths led to 27 sets of data to compare [3]. Of those, 24

show reduced contact time in the REMS group compared to the manual group. Additionally, five test conditions yielded no contact time at all, all of which were achieved with robotic assistance. The overall contact time was significantly decreased when using the REMS over freehand, as well as with the larger two spirals. When subgroup analysis was performed of the smallest spiral width, the group more familiar with microlaryngeal surgery demonstrated improved performance with the robot whereas those without did not.

Evaluation of the exit surveys indicated that all participants determined that they thought the task was a good representation of laryngoscopy, rated their surgical skill more highly with the robot than without, and indicated a desire to use the robot once clinically available.

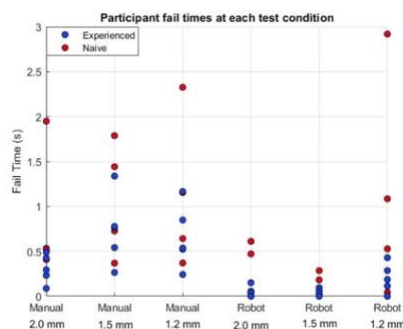


Fig. 4 Results of the spiral experiment

2 – Microvascular Surgery Study

The microvascular naïve participants received a mean MTS score of 2.40 freehand and 0.72 with REMS-assistance, more than a three-fold reduction [4]. While the score was also reduced for the microvascular expert, the difference was not significant. The time to completion did not have a significant difference between free-hand and REMS-assisted trials for either the naïve or the expert participant(s); however, there was a meaningful reduction in TTC between the first and second trial, regardless of the set of conditions they started with which they started.

To determine the inter-rater reliability of the MTS, the Intraclass Correlation Coefficient (ICC) was calculated. Between seven expert microvascular raters, the ICC for consistency was 0.914.

A qualitative self-assessment was performed through an exit survey. All six naïve participants found the REMS more accurate and thought it improved instrument handling and stability compared to freehand. Five out of six also preferred using the REMS over the freehand procedure.

3 – Stapedotomy Study

Across all participants, the mean maximum force exerted while crimping the prosthesis around the simulated incus freehanded was 469.3 mN, which was significantly more than the robot-assisted value of 272.7 mN; the placement force and there was no significant difference in dF value between freehand and robot-assisted crimping [5]. Comparison of the freehand performance of the expert participant versus the non-expert participants revealed that the expert surgeon applied significantly less force during

placement ($p = 0.002$) and crimping ($p = 0.004$), along with significantly less dF during crimping ($p < 0.0001$). Evaluating the expert participant's freehand performance against the nonexpert robot-assisted performance reveals no significant difference between the two groups.

CONCLUSION

The studies discussed above examine the use of a cooperatively controlled robot in three different microsurgical applications – microlaryngology, micro-anastomosis, and stapedotomies. In simulated phonosurgery, the system offered objective improvement in precision over the participants' manual performance [3]. Subjectively, the participants felt that the REMS aided their performance and expressed an interest in using the REMS in their clinical practice [3]. The second study demonstrated that it is feasible to use the REMS in microvascular anastomosis for microvascular naïve subjects, as well as showed that the MTS was a reliable grading system for assessing microvascular tremor [4]. Finally, the stapedotomy study showed that the robot was able to help reduce the maximum force exerted while crimping a stapes prosthesis around a simulated incus [5]. Along with that, the nonexpert surgeons went from applying significantly more force during placement and crimping as compared to the expert to having no significant difference between them [5].

These studies represent the beginning of an effort to quantify the benefits of using a cooperatively controlled robot in microsurgical procedures. Further testing can be done in order to include more middle strata in terms of participant expertise to better define the robot's role in teaching and clinical settings. Furthermore, additional studies mimicking different surgical procedures can elucidate the robot's potential contributions to those types of operations.

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