Surgical Instruments for Robotic Microsurgery

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1 Introduction

Microvascular surgery is at the cornerstone of several reconstructive procedures throughout Otolaryngology – Head and Neck Surgery and has become commonplace in training programs across the country, with more than one in eight academic otolaryngologists reporting microvascular training [1]. Specifically, free flaps remain the preferred method of reconstruction for complex defects after ablative procedures including oncologic resections. These procedures have continued to improve over the past 10 years and currently demonstrate success rates exceeding 95% in the literature [2-6]. However, these procedures have a high overall cost due in large part to lengthy hospital stays and long operating times [7]. In many cases, the microvascular anastomosis of vessels during free tissue transfer remains the most technically challenging and critical portion of these long procedures. In addition to the technical complexities of microvascular operations, a surgeon’s inherent dexterity and essential tremor are limiting factors to operative time and surgical efficiency. Controlling hand tremor during vein suturing is invaluable as even skilled surgeons exhibit a slight tremor, the negative effects of which are magnified at the microsurgical scale.

The Robotic Ear, Nose, and Throat Microsurgery System (REMS) was developed by Dr. R. Taylor, Kevin Olds, and Marcin Balicki to address this issue. The robot was initially built and tested for laryngeal phonosurgeries, however its application was expanded to include microvascular anastomosis. Microvascular anastomosis requires a very technically advanced skill set, given that the vessels have a diameter of only 2-3 mm. Procedures on this scale require a high level of eye-microscope-hand coordination and delicate tissue handling using fine, fluid motions. By implementing and refining the REMS, a cooperatively-controlled steady-hand robot, it is possible to eliminate hand tremor, which is the most detrimental factor when operating at such a small scale. It is necessary to determine an accurate and objective method to simulate and evaluate the procedures before concluding the efficacy of a robotic microsurgery system.
The goal of this project was two-fold: first, to validate the use of the REMS as a tool in microvascular anastomosis procedures, and second, to expand the available tool-set for this procedure by designing new needle drivers compatible with the REMS.

2 Problem

2.1 Validation of REMS for Microvascular Anastomosis

The first goal of this project was to validate the use of the REMS for microvascular anastomosis procedures. To do so, it was necessary to establish a method to objectively understand the effect of using a cooperatively-controlled, tremor-reducing robot for a micro-scale procedure. By testing both manual and robot-assisted procedures, it was possible to evaluate the effectiveness of the REMS as a tool for micro-scale procedures based on metrics including procedure time, tremor, tissue handling, and quality of results.

2.2 Design of New Tools

The second goal for this project was to expand the set of tools available for the REMS. The tools that can be used with the REMS must adhere to several requirements, the first and most important being that the tool must be suited well for the task at hand (ie. holding micro-scale needles for suturing). The tool must also have an effective interface to the REMS’ arm, meaning it must attach securely and rigidly to the force sensor. Rigidity of the tool attachment is vital to ensure maximum cancellation of tremor and accurate response of the robot to a user’s movement. Additional criteria and design limitations include ergonomics, weight, and safety to the user. For high quality needle holders, it is helpful to have a high surface contact between the jaws of the tip when they close, to have a locking mechanism that holds the tips closed for needle maneuvering, and to have a quick release tool attachment unit to quickly switch between robotic and manual operations.
3 Experimental Approach

3.1 Testing environment and model

The validation experiment performed was based heavily on the procedure given by Nimmons et. al. in their paper, “Validation of a Task-Specific Scoring System for a Microvascular Surgery Simulation Model” [8]. The model for this experiment used store bought chicken thighs, which were dissected to identify the ischiatic neurovascular bundle. The elements of the vasculature were then separated from the nerve and the artery was transected, leaving the surgical area of interest shown in Figure 2. Previous studies have validated the use of the chicken thigh model as an accurate representation of the vasculature present in a free-flap, thereby supporting the use of this cost-effective and available model for this study.

Test subjects were recruited by our medical advisor, Allen Feng, to create a sample of medical students of varying experience. Prior to the experiment, each participant watched a video explaining the process of microvascular anastomosis. They were also given a tutorial of the procedure by Allen Feng to explain their task in this specific context. The expected results were partial anastomoses consisting of three sutures, each secured by three instrument ties using 7-0 needles, as shown in Figure 3. The tools given for the surgery, shown in Figure 4, were vessel dilators (top) as the left hand tool and the needle drivers (bottom) as the right hand tool.

The needle driver shown in Figure 4 was also compatible with the REMS to ensure that the tools were preserved between testing modalities. At the start of the robot-assisted trial, participants were taught how to use the robot and were then given time to become accustomed to the movement of
the robot and to the limits of motion. Robotic software parameters, specifically gains and filters for different movement directions, were kept constant between all trials, but the position of the robot was changed to accommodate changes in the size and preference of different test subjects.

To further ensure preservation of the environment for a microvascular anastomosis, participants used a microscope, with a constant focal length of 200 mm, coupled with a video recorder to allow for analysis of technique following the experiment.

3.2 Evaluation procedure

Prior to the experiment, participants were given a questionnaire to gauge their experience, both generally and specific to the task of micro-surgery. Following the experiment, they were given another questionnaire to record their opinions such as comfort with the task, how using the REMS changed the task, and overall feelings towards the use of the REMS for the procedure. The surveys provide both quantitative information such as years of experience, which can be used to normalize the scores, and qualitative information such as general opinion towards the use of an assistive robot for a micro-scale procedure.

The major source of quantitative data comes from the analysis of the video and scoring using the Objective Standardized Assessment of Technical Skills (OSATS) customized for the microvascular anastomosis procedure, outlined by Nimmons et. al. From the OSATS for urologic vasovasostomy, experienced microvascular surgeons updated the checklist with relevant criteria. The updated criteria, shown in Appendix A, consists of evaluations for task specific scores (TSS) and a global rating scale (GRS). Task specific criteria evaluate proficiency at different skills needed in the procedure, such as loading the needle, ability to pass the needle through the tissue, and tying clean knots, all with reasonable dexterity. The global criteria deal with the general ability to perform the procedure, such as smoothness of the operation, handling of instruments and tissue, and the overall result. Using these criteria, it is possible to quantitatively score each subject’s performance in the procedure.

Given that our sample consists of medical students who are novices to this specific surgery, it is expected that the task specific scores will be low or show no trend across the trials. However, the global scores should show improvement from the free-hand to the robotic trials. Criteria such as tissue and instrument handling, economy of motion, and smoothness of motion are key areas where the REMS can outperform manual operation by eliminating hand tremor.
4 Experimental Results

Though quantitative analysis of results using OSATS scores is incomplete, qualitative analysis of trial videos and exit questionnaires confirms our hypotheses. It was expected that since the REMS acts as a low pass filter to movement, high frequency tremors would disappear during the anastomosis. Even during raw viewings of the trial videos, tissue handling and smoothness of movement visibly improve.

The subjects were asked which operation mode they felt was the most accurate, which mode they felt was the most time efficient, and which mode they preferred overall. All of them reported that the robotic mode was more accurate due to the decrease in tremor. Responses for time efficiency were mixed; some subjects reported that the robot assisted procedure was faster since less time was spent struggling to account for tremor, while others felt that even though the quality of movement improved, the robot also forced them to move slower. Finally, preference was nearly unanimous, with the exception of one subject that the robot-assisted procedure was preferable compared to the manual operation.

Test subjects also reported feelings towards specific aspects of the procedure. The most commonly reported difficulty regarding the overall procedure came from the technique required to perform the instrument ties. As for the use of the REMS, the most common complaint was with regard to the limited range of motion of the robot arms. Subjects often had difficulty adjusting to the limits of the arms and needed more time to become accustomed to how to move to avoid limits and how to correct the motion after reaching a limit.

Overall, it is believed that further quantitative analysis using the specialized OSATS criteria will verify the observations described above. Increasing the sample size will also create a more reliable distribution of scores. In the future, it will be possible to use these scores and the responses to post-trial questionnaire to optimize the use of the REMS for microvascular procedures.
5 Tool Design

The design process used for the development of the surgical instruments followed a standard engineering design sequence, beginning with brainstorming. Once optimal designs were identified based on desired specifications, computer aided models were created to aid in the prototyping process. Through the use of machine shop tools and materials, the instruments were fabricated and incorporated into the REMS. The testing phase consisted of the use of phantoms to evaluate the effectiveness of the new instruments. Based on feedback from the results of the phantom tests and from mentors, the instruments were refined or redesigned to meet the specifications.

The first tool that was designed was the adapter needed to mount the needle drivers shown in Figure 4 to the REMS. Figure i in Appendix B shows the CAD models created for this part. Using this model, the adapter was constructed both manually and using 3D printing techniques. Though 3D printing provides an efficient method to quickly produce many copies of the part, the manually created version made of aluminum provides the benefit of greater rigidity and thus greater accuracy. Figure 5 shows the adapter used to couple the needle drivers to the REMS. Design and construction of the adapter was vital to the validation study since this tool was used throughout all the trials.

The second tool that was designed was custom designed to test the possibility of articulating a needle driver above the force sensor. Figure 6, below, and Figure ii in Appendix B show models of the custom designed needle drivers. The area labeled (M) marks the area where the needle drivers will be mounted onto the end of the robot arm. The benefit of a tool implemented in this manner is a possible increase in accuracy since the end of the robot arm can remain close to the
operating area. Doing so causes the forces to be resolved close to the force sensor, producing less torque on the force sensor. By keeping the force sensor close to the area of interest, the robot arm can make smaller movements in response to a user input. Though it was originally planned to use a design that mimicked the deformable mesh grip of the Eye Robot tool, shown in Figure iii of Appendix B, it was not possible to produce the right level of tension with spring steel wires. Rather, spring steel sheets were shaped as shown in Figure 6. Using the spring steel sheets still produced 180° symmetry with passable ergonomics. Though this tool was not tested in an anastomosis procedure, preliminary movement tests show that the custom built tool integrates well with the REMS.

6 Significance

For microsurgeries requiring a high level of precision and accuracy, a tremor-reducing steady-hand robot is essential. Even with years of training, skilled surgeons still exhibit slight tremors that make surgeries such as vein anastomoses painstakingly difficult. Among currently available surgical robots, there is no system other than the REMS that provides steady-hand admittance control for microsurgeries. Master-slave robots (ie. the DaVinci system) have difficulty operating is small workspaces, making them unsuitable for microsurgeries. Other admittance style steady-hand systems address only a sub-branch of microsurgeries, making them too specialized for our purposes. Thus, the REMS is ideal for general purpose microsurgical procedures.

As the results show, robot assisted vein anastomoses with the REMS are significantly more effective than manual vein anastomoses. We believe these results are promising enough to soon begin in vivo testing. Once we finish implementing the custom tools into the REMS, we expect to see even better results as the system will be acting closer to the surgeon’s workspace.
7 Management Summary

Overall, we were able to work well together as a team to achieve our goals. Given that we were a group of two, coordination of tasks was straightforward. Maintaining proper communication with our mentors was vital, especially for the planning of trials and status update meetings. With regard to the division of labor, we worked together for the majority of the tasks, namely manufacturing the custom tool and conducting the trials for the validation study. Delegation of tasks was based on personal skill sets, with Pranav performing software tasks, such as troubleshooting the REMS and managing trial data, and with Zaid producing CAD models of the parts shown in Appendix B. In summary, we were able to draw from our respective skill sets to pursue our goals.

Acknowledgements

This project was made possible with the support from our mentors, the medical students who agreed to be a part of the validation study, faculty from the Laboratory for Computational Sensing and Robotics at Johns Hopkins University, and Johns Hopkins Medicine.
Appendix A – OSATS Criteria

Tables I and II of the paper show the criteria for task specific scores (TSS) and a global rating scale (GRS), respectively. [8]

### TABLE I.
Microvascular Objective Structured Assessment of Technical Skills (OSATS)-Task Specific Score.

<table>
<thead>
<tr>
<th>Correct</th>
<th>Incorrect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Passing needle through tissue</td>
<td></td>
</tr>
<tr>
<td>1. Loads needle in drive 1/2 to 2/3 from needle tip</td>
<td></td>
</tr>
<tr>
<td>2. Needle does not wobble in driver</td>
<td></td>
</tr>
<tr>
<td>3. Needle enters tissue perpendicularly</td>
<td></td>
</tr>
<tr>
<td>4. Forceps handle vessel adventitia to provide counter traction</td>
<td></td>
</tr>
<tr>
<td>5. Dilator is appropriately used</td>
<td></td>
</tr>
<tr>
<td>6. Needle is pulled through tissue following its curve</td>
<td></td>
</tr>
<tr>
<td>7. Suture is pulled out parallel to the tissue</td>
<td></td>
</tr>
<tr>
<td>8. Suture tails are left at the correct length</td>
<td></td>
</tr>
<tr>
<td>9. Appropriate depth tissue bite on each side</td>
<td></td>
</tr>
<tr>
<td>10. Sutures are spaced appropriately</td>
<td></td>
</tr>
<tr>
<td>Knot tying</td>
<td></td>
</tr>
<tr>
<td>11. Three or more square throws are tied</td>
<td></td>
</tr>
<tr>
<td>12. Efficient handling of suture while tying</td>
<td></td>
</tr>
<tr>
<td>13. Appropriate tension on suture while tying</td>
<td></td>
</tr>
<tr>
<td>14. Tissue well-approximated but not strangulated</td>
<td></td>
</tr>
<tr>
<td>Total correct /14</td>
<td></td>
</tr>
</tbody>
</table>

*Tasks are scored as “correct” if done correctly >75% of the time.

### TABLE II.
Microvascular OSATS-Global Rating Scale.

<table>
<thead>
<tr>
<th>Worst</th>
<th>Best</th>
</tr>
</thead>
<tbody>
<tr>
<td>Economy of motion</td>
<td>1</td>
</tr>
<tr>
<td>Instrument handling</td>
<td>1</td>
</tr>
<tr>
<td>Respect for tissue</td>
<td>1</td>
</tr>
<tr>
<td>Flow of operation</td>
<td>1</td>
</tr>
<tr>
<td>Overall result</td>
<td>1</td>
</tr>
</tbody>
</table>
Appendix B – CAD Models

*Figure i:* Model of adapter for forceps shown in Figure 4. Both the top and side holes were threaded for the corresponding screws.

The top and side holes were threaded as shown. The larger hole on the bottom of the adapter press fit to the back of the needle driver.

*Figure ii:* Model of the custom made needle drivers, shown in different views.

*Figure iii:* Original design for custom needle drivers, modeled after the deformable mesh grip design from the Eye Robot tool.
References


