
Surgical Instruments for Robotic Open Microsurgery

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1 Introduction

1.1 Summary

Microvascular surgeries require a great degree of precision, accuracy, and stability for successful operations. In many cases, the microvascular anastomosis of vessels during free tissue transfer are the most technically challenging and critical portion of these already long procedures. Controlling hand tremor during vein suturing is invaluable, and even skilled surgeons who have spent years perfecting a steady hand still exhibit a slight tremor. The negative effects of hand tremors are magnified at the microsurgical scale. Existing systems such as the daVinci Surgical System have been hastily adapted to assist in microsurgery; however, no robotic system has been developed to specialize in cooperatively controlled robotic microsurgery. The Robotic Ear Nose and Throat Microsurgery System (REMS) was developed by Dr. R. Taylor, Kevin Olds, and Marcin Balicki to address this pressing issue. The robot was initially built and tested for laryngeal phonosurgeries, however its application will be expanded to include microvascular anastomosis. This project will attempt to redesign the tool set and attachment mechanism of the REMS for seamless integration of suture needle holders, improving the ease, efficiency, and accuracy of microsurgical procedures.

1.2 Background and Significance

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 continue to 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 technical complexities of microvascular techniques, a surgeon's inherent dexterity and essential tremor are limiting factors to operative time and surgical efficiency. Novice surgeons struggle with mastery of these techniques. This is especially true in microvascular surgery where the hard skills and inherent tremor of the operator are magnified. To our knowledge no robotic system exists to enhance the surgeon's ability to perform microvascular surgery.

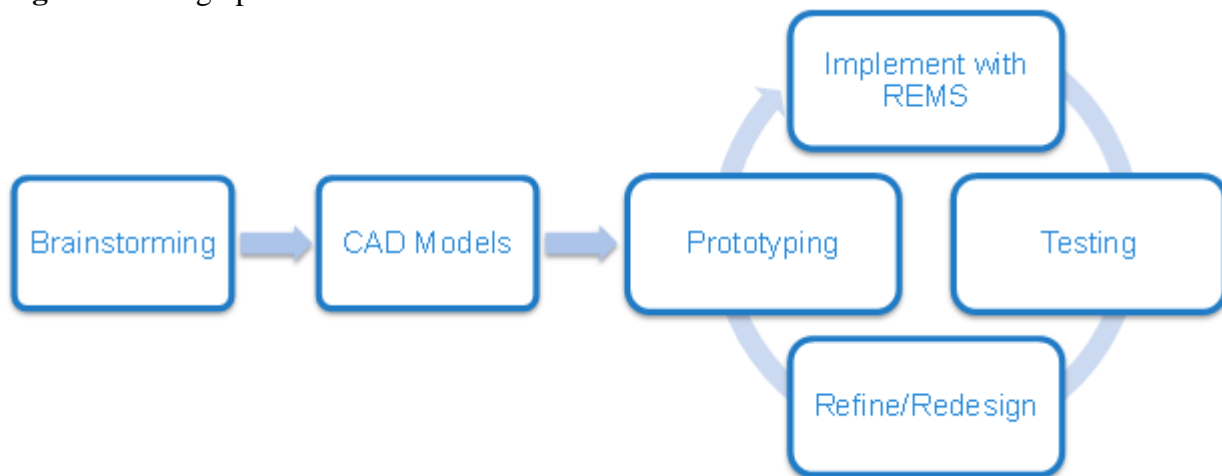
The Robotic Ear Nose and Throat Microsurgery System (REMS) is an external, non-invasive gantry unit that was developed as a stabilizing mechanism for the surgeon's primary instrument. A force-feedback control system eliminates the surgeon's hand tremor, enhances control over fine motor movements and maintains haptic feedback for the user. The applications for such a device extend well beyond microvascular surgery. Within the domain of Otolaryngology, these include, but are not limited to otology, laryngology, sinus and skull base surgeries. We believe that by designing new tools based on initial studies and conducting clinical trials to evaluate the improvements to ergonomics, operation time, and accuracy, it is possible to further develop the concept of cooperative robotic microsurgery.

2 Technical Approach

2.1 Design Approach

The design process used for the development of the surgical instruments will follow a standard engineering design sequence, beginning with brainstorming. Once optimal designs have been identified based on desired specifications, computer aided models will be created to aid in the prototyping process. Through the use of machine shop tools and materials, the instruments will be fabricated and implemented to be used with the REMS, including applying changes to the movement algorithm to account for the different tools. The testing phase will consist of the use of phantoms to evaluate the effectiveness of the new instruments; the evaluation procedures are further explained in Section 2.2. Based on feedback from the results of the phantom tests and from mentors, the instruments will be refined or redesigned to meet the specifications. Figure 1 shows this process, including the initial brainstorming and design phases and the cyclic prototyping and testing phase.

Figure 1: Design process



2.2 Evaluation Procedure

Preliminary testing of the new surgical instruments will follow a procedure similar to that described by Kevin Olds in the preliminary evaluation of the REMS.^[8] Using the same testing phantom, shown in Figure 2, first round evaluations will be performed to test the movement of tools after implemented into the REMS.

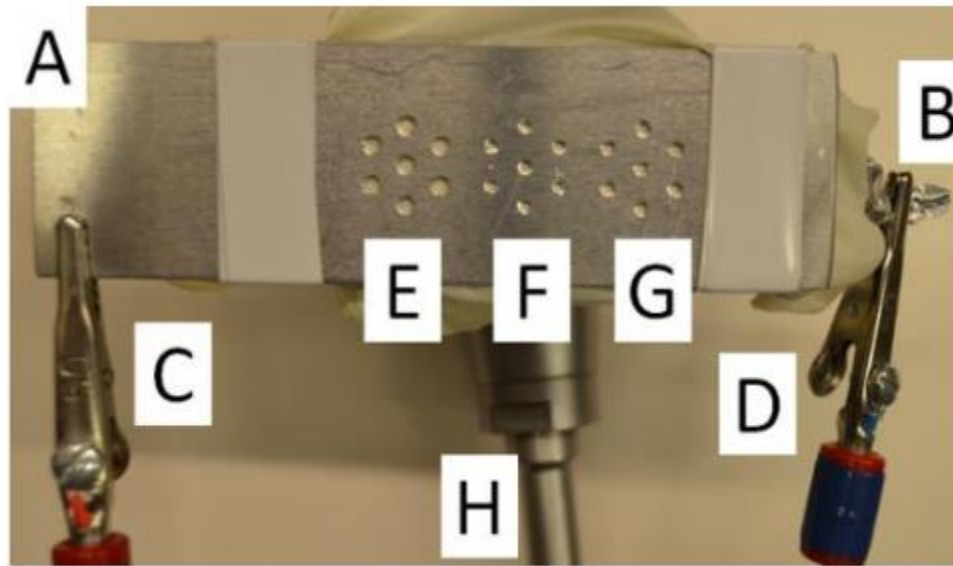


Figure 2: Testing Phantom ^[8]

A) Perforated aluminum plate B) Foil layer C) Failure electrode D) Success electrode
E) 2.0 mm holes F) 1.2 mm holes G) 1.5 mm holes H) Passive support stand

Following preliminary design testing, mock operations will be performed by Dr. Richmon and Allen Feng to determine the effectiveness of the new tools in a microvascular anastomosis procedure.

Finally, extensive studies will be performed using sufficient samples of medical students to perform similar procedures, first, a pilot study using existing tools, and secondly, an evaluation of the newly designed tools. Major factors of evaluation include ease of use, ergonomics, efficiency, and accuracy of movement.

3 Project Plan

This section describes what will be achieved by this project, including three levels of deliverables, dependencies that must be resolved to reach the goals, and a projected timeline to accomplish the maximum deliverables.

3.1 Deliverables

Minimum

Computer-aided design of suture needle holder and tool attachment unit

Based on meetings with mentors and medical advisors, a set of specifications will be established and used to create a set of designs for the possible instruments and mechanisms to be used with the REMS. Using computer aided design tools, such as SolidWorks, models will be developed, which will be used to construct rapid prototypes.

Pilot study with existing simple tool

Using a procedure similar to that described by Olds ^[8], a study will be performed testing the existing tool to identify shortcomings and areas for improvement. Results of this study will be compiled in a paper and compared against past results.

Expected*Usable prototypes of suture needle holder and tool attachment unit*

Based on the produced CAD models and feedback from mentors, the proposed designs will be constructed. Following construction of the tools and testing with the REMS robot, designs will be revised and reconstructed to fix shortcomings and flaws.

Implementation of tools with REMS robot

For each iteration of the designs, the tools will be implemented with the REMS, testing factors such as structural fit, ergonomics, and effectiveness. To do so, changes will also be made to the software to account for the changes in the shape and use of the tools. Finally, phantom tests will be performed as a first round of evaluation.

Design documentation

Maintain a notebook of documentation, including design schematics, evaluations, and test results.

Surgical testing in mock OR by Dr. Richmon

Following phantom testing, mock surgical testing will be performed by Dr. Richmon and/or Allen. Mock operations provide greater insight into the use of the tools, specifically in terms of the accuracy of the scenario and the experience of the user.

Maximum*Conduct clinical study on viability of new tools with medical students, under the supervision of Allen Feng and Dr. Richmon*

Using a procedure similar to that described by Olds [8], a study will be performed testing the newly designed tools against existing instruments. Evaluations will be performed on factors such as ease of use (including ability to attach and remove tools easily), ergonomics, and, most importantly, accuracy.

Re-design and optimize the REMS movement algorithm and/or mechanisms

After completion of the major hardware components, adjustments will be made to the existing software framework and algorithms used by the REMS. This includes possible improvements the mathematical processes and safeguards introduced to algorithms that can currently cause movement to jam or trap the tool into a local minima of a path.

3.2 Dependencies

Dependencies include factors that must be resolved to continue the progress of the project. The following table provides a list of dependencies and planned resolutions.

Dependency	Resolution
Machine shop certification	Register by end of February Estimated to be \$200 total for training fees
Access to steady-hand robot	Schedule time to work with robot, at least ten hours per week. Already have J-Card access to mock OR.
Materials to design prototypes	Check availability of materials in machine shop Purchase remaining materials
Funding for materials and prefabricated components	Request funding from Dr. Taylor Estimated up to \$2000, based on number of iterations and availability of materials.
Scheduling of mock operations and study	Schedule with Dr. Richmon and Allen Feng at least two weeks in advance
Recruiting of medical students for study	Coordinate with Allen Feng to recruit suitable sample size of medical students

3.3 Projected Timeline and Milestones

	February	March	April	May
Preliminary Research				
Obtain CAD diagrams for REMS robot				
Finish project plan				
Read background studies				
Written project proposal				
Design and Rapid Prototyping				
CAD designs for needle holder and tool attachment unit				
Rapid prototyping of designs				
Approval of designs by mentors				
Implementation				
Construct working models of tools				
Implement modified tools into REMS robot				
Assess viability of solution (phantom testing)				
Redesign and reconstruct prototypes as necessary				
Pilot Study				
Recruit medical students as subjects for studies				
Conduct pilot study with existing tools				
Evaluation				
Conduct mock operations with Allen and/or Dr. Richmon				
Conduct full clinical study				
Optimize movement mechanism and algorithm of REMS				

Milestone	Expected completion	Status
Project plan presentation	February 12	Complete
Complete project proposal	February 19	Complete
Confirmation of designs	March 6	Planned
Complete pilot study	March 30	Planned
Checkpoint presentation	April 9	Planned
Implemented tools	April 10	Planned
Complete mock operation	April 20	Planned
Complete clinical study	April 30	Planned
Poster presentation	May 8	Planned

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