Engineered System Family #1: A Microsurgical Assistant for the Augmentation of Surgical Perception and Performance

Test bed leaders: Pat Jensen, Ph.D.

Key clinicians: Eugene deJuan, MD, Donlin Long, MD, Gaylord Clark, MD, John Niparko, MD, John Kostuik, MD

1.1 Goals for the family & importance for end user community

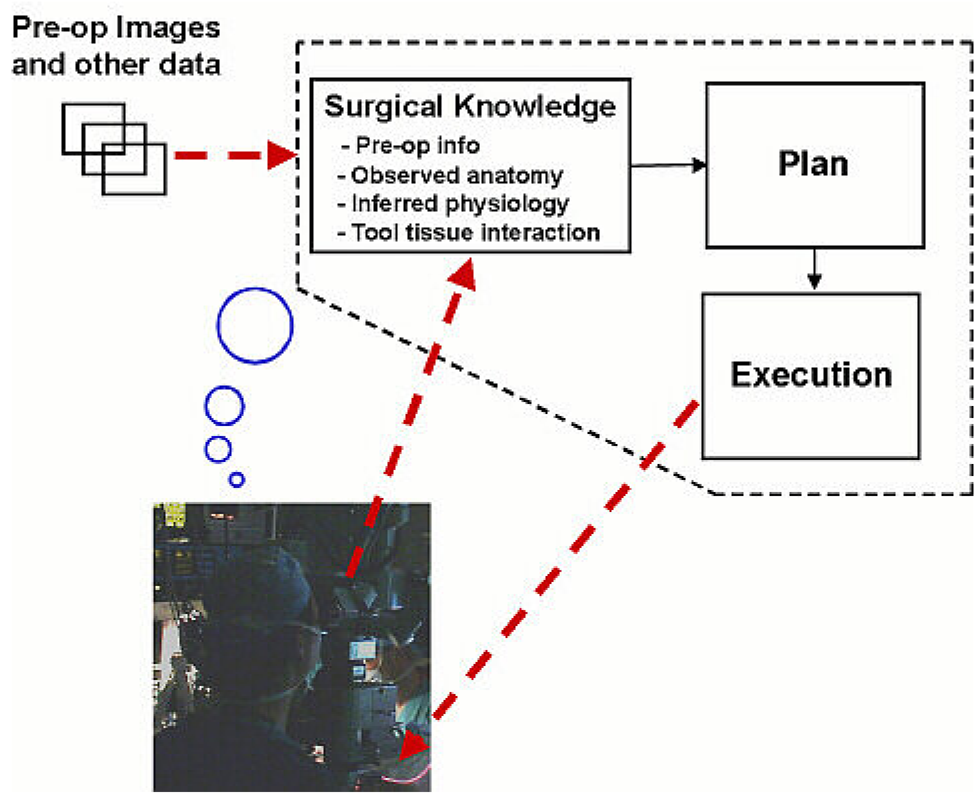

Figure 1-1: Current Microsurgical Practice. Today, the microsurgeon relies primarily on visual information from the microscope to guide hand-held surgical tools during the surgical procedure.

The vision of the Microsurgery Assistant Test Bed is to combine novel methods for augmenting the surgeon's sensory-motor manipulation abilities with novel real-time image processing and information support to significantly improve microsurgical performance and enable new procedures that could not otherwise be done. The initial focus will be on vitreoretinal surgery with other applications in microvascular surgery, neurosurgery, ENT, and spine surgery to follow. This section describes the Microsurgical Assistant Test Bed, discuses the core technology and research barriers needing to be addressed by the ERC, and relates the synergy of these efforts with the other ERC test beds.

Microsurgical procedures are typically characterized by the need to manipulate extremely small or delicate structures with hand-held surgical tools under stereo microscopic observation. These procedures are currently limited by human sensory-motor skills when operating on a micron scale. For example, during vitreoretinal surgery instruments are placed within the eye and observed through the pupil using a stereo operating microscope. The surgeon guides the instruments using visual feedback to perform a variety of tissue manipulation tasks (Figure 1-1). The retinal tissue being manipulated is very delicate and errors in manipulating it can cause permanent damage leading to blindness. Studies performed by the Johns Hopkins Microsurgery Advanced Design Lab (MADLAB) demonstrate that the limiting factors of vitreoretinal surgical performance are 1) positional accuracy (tremor & drift), 2) lack of tactile sensation during interactions between the surgical instrument and retinal tissue, and 3) view of the retina through the pupil (minimum resolution approximately 20-30 microns).

The microsurgical assistant (Figure 1-2) addresses these limitations by 1) providing the surgeon with an enhanced view of the retina during the surgical procedure and 2) augmenting the surgeon's physical ability to position instruments within the eye. The enhanced information provided to the surgeon not only encompasses optical information but also provides physiological information such as blood flow and tissue differentiation. The surgeon uses this extra information to determine the best surgical approach and because of the real-time nature of the data is able to adjust the surgical approach on the fly. Once the surgeon has determined the appropriate surgical plan, the microsurgical assistant helps the surgeon execute the plan through the use of the Steady-Hand robotic platform.

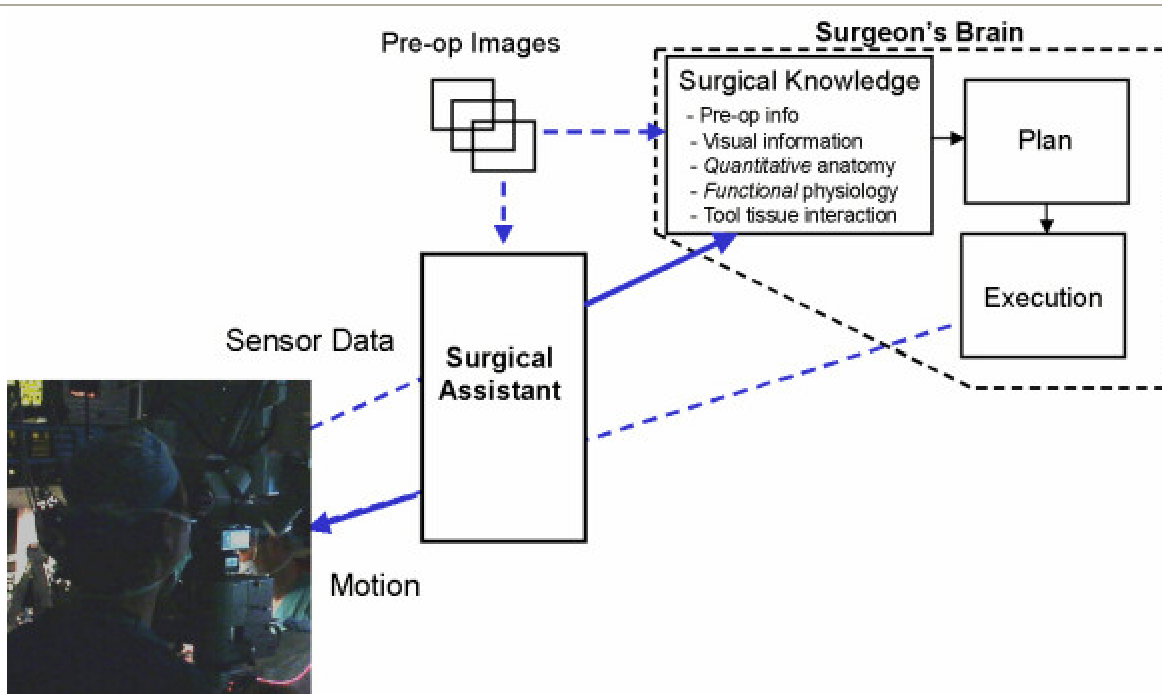

Figure 1-2: A Microsurgery Assistant. Our vision of a Microsurgery Assistant is to provide the surgeon with an augmented intraoperative understanding of the surgical environment while simultaneously augmenting the surgeons ability to manipulate, position and sense the surgical tool within that environment

From the perspective of our end user community (clinicians), the key advantages promised by our systems approach include:

- Improved accuracy and consistency of surgical procedures resulting in significantly improved outcomes.
- The ability to treat patients who could not otherwise be treated.

In common with other test-beds are the following key advantages:

- A significantly better test bed for rapid development of novel treatments and therapy protocols.
- The ability to correlate surgical approach, technique and performance with patient outcomes.

From the perspective of society, these advantages translate into:

- Reduction in cost to society due to blindness, deafness or loss of mobility.
- Improved patient outcomes and improved surgical success rates.
- Ability to treat currently untreatable patients.

1.2 Overview of the system family (generic test bed architecture)

Our vision of a microsurgical assistant is one in which the surgeon is the primary decision-maker and surgical executor. The microsurgical assistant is not intended to take the surgeon out of the operating room or to remove the surgeon from being in direct control of the surgical procedure. Instead, the microsurgical assistant is designed to augment the surgeon's natural sensory-motor abilities thus allowing improved patient outcomes and the development of altogether novel surgical techniques. This system will provide the surgeon with a) augmented visual and haptic sensory information about the procedure being performed, b) augmented ability to position and manipulate surgical instruments, and c) the ability to perform semi-automated tasks and/or provide virtual-fixtures for safe navigation and tissue manipulation. A system block diagram is shown in Figure 1-3. Given the surgeon and wpatient located to the left and the surgeon's "brain" located to the right, the microsurgical assistant resides in the middle, enhancing both information in and physical ability out. Our planned system consists of the following modules: Steady-Hand Augmentation, Registered Interactive Models, and Surgical Knowledge. The Registered Interactive Model combines preoperative images, tissue property information from multi-modal sensor arrays and biomechanical information with the live image from the microscope in the form of a model. This model is presented to the surgeon through a special microscope having stereo video injection or image overlay capabilities. The surgeon uses this augmented view of the surgical scene to best determine the surgical approach and is then assisted by cooperatively sharing the surgical instrument with a Steady-Hand Robot. In addition, the microsurgical assistant will be able to monitor the current surgical procedure including visual information available to the surgeon, surgical approach taken by the surgeon and then followed up with resulting patient outcome. This information will be used to generate a database of Surgical Knowledge that may be used to study efficacy or to play back certain tasks in the form of semi-automated surgical macros.

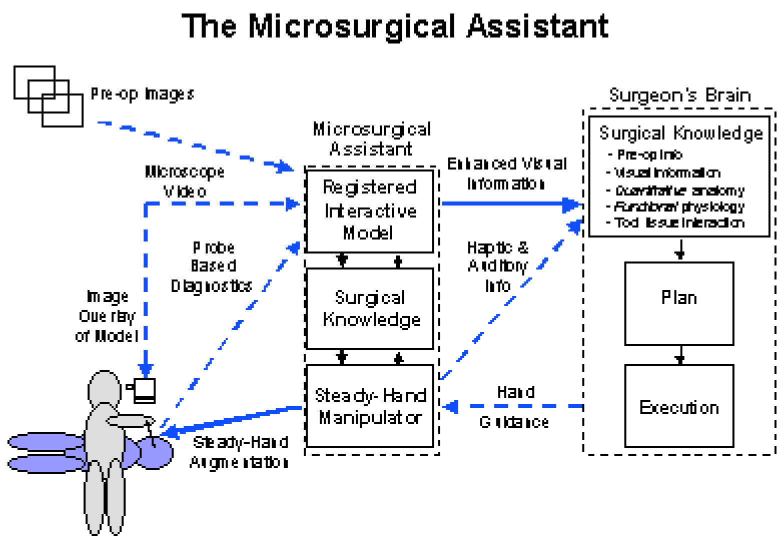

Figure 1-3 Microsurgical Assistant information flow.

Our immediate strategy for the Microsurgical Assistant Test Bed concentrates on the vitreoretinal surgery while concurrently investigating applications in ENT, microvascular and neurosurgery. We strongly believe that augmenting the ability to sense the surgical environment coupled with the ability to perform micro scale surgical tasks addresses the current limiting factors of microsurgery and will revolutionize the way surgery in these fields is performed. The motivation for this approach is heavily driven by physician input and we have a surgical representative for each specific implementation of the microsurgical assistant.

Two independent but related systems will be developed in parallel and then merged to form the basic microsurgical assistant platform. The first of these systems, "Information Enhanced Surgery", will gather intraoperative tissue diagnostic information not normally available to the surgeon (i.e.blood flow, temperature, subretinal structure, biomechanical properties, etc.), register that information with the view through the operating microscope and display it to the surgeon in real-time. The microsurgeon currently relies almost entirely upon the view through the operating microscope to both determine the surgical approach and to guide the surgical procedure. The enhanced view of the surgical site offered by the Microsurgical Assistant will allow better intraoperative decision to be made and similarly allow better monitoring of the surgical plan execution.

The second system, "Steady-Hand Augmentation", will concentrate on enhancing the positional ability and accuracy of the surgeon using the Steady-Hand robotic platform. The required motions of surgical instruments by the surgeon are on the threshold of what is humanly possible. By reducing tremor, providing long-term positional stability and augmenting haptic and tactile sensation, the surgeon will be able to execute surgical motions with greater precision than with the human hand alone.

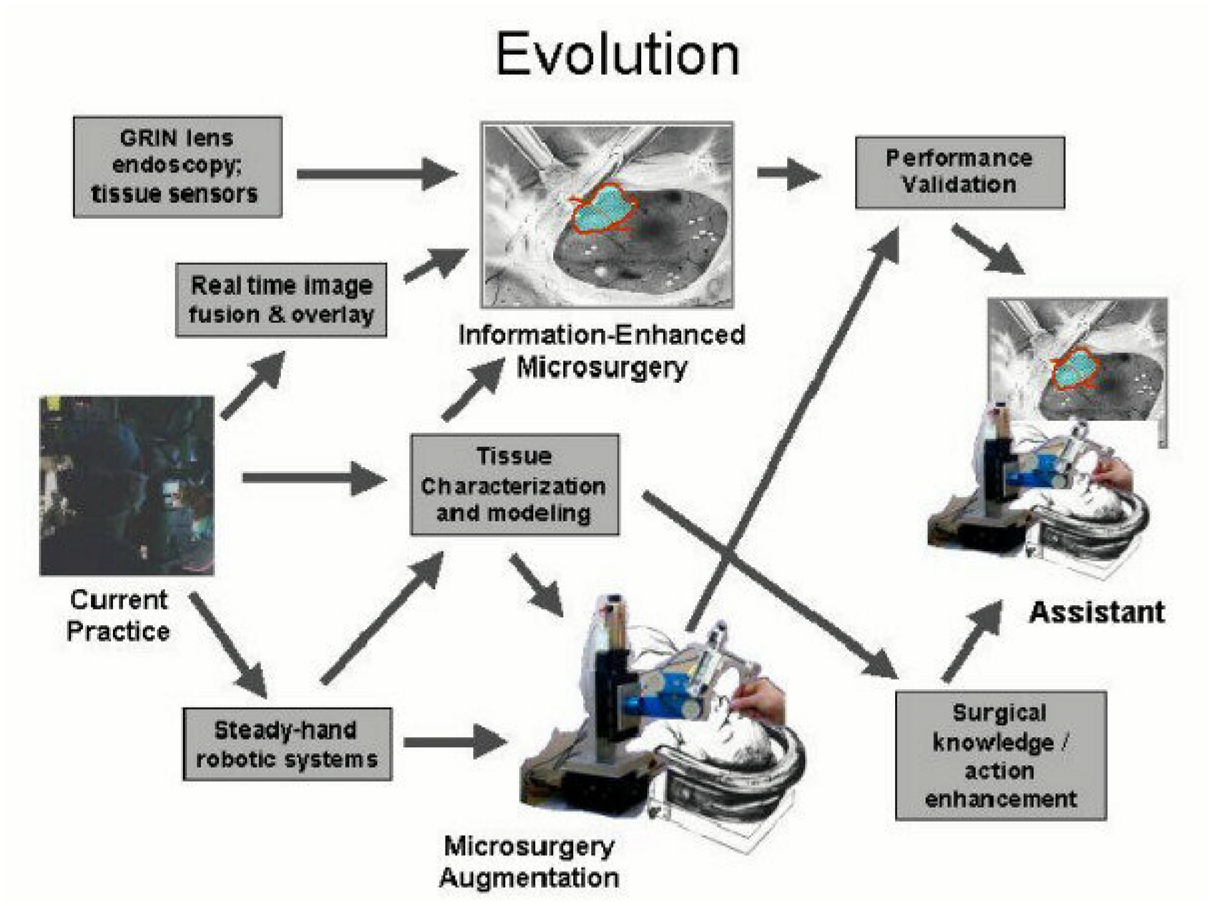

Figure 1-4: Flow of research and systems evolution in the near term to get to initial microsurgical assistant prototype. Core research topics for the microsurgery assistant progress from what is currently available given today's technology, through two separate but related systems, to a merging of these systems into a generic Microsurgical Assistant platform. This platform is based on a modular design that can be easily adapted to various microsurgical needs and requirements. Subsequently, the same basic flow of research will continue to provide enhanced capabilities. Typically, advances in tissue characterization or real time imaging will first be used to provide enhanced information to the surgeon, and the results will later be integrated into surgical action enhancements as appropriate.

The systems will be integrated through the use of "surgical macros" and "virtual fixturing" to create a microsurgical assistant capable of semi-automated or hapticaly guided tasks. This capability will be leveraged to develop haptic guiding algorithms to cannulate vessels, prevent retinal tears, and allow accurate dissection of retinal tissue layers. Surgical macros for microvascular anastomosis and knot tying will be implemented.

The components of the surgical assistant will be evaluated for mechanical performance, surgical augmentation capabilities, and improved patient outcomes. This testing will be performed both in the lab and in the clinic to ensure that these systems are beneficial to both the surgeon and the patient.

The Microsurgical Asssistant is built upon a modular platform with various components that can be integrated and utilized for specific clinical application. The medium term goals of this test bed are to migrate the basic platform developed for vitreoretinal surgery to microvascular surgery, ENT and neurosurgery while addressing unique knowledge and technology barriers that those disciplines present. For example, ENT surgery requires that the surgeon work with long instruements placed through the ear canal and manipulate small bony structures within the middle ear. A microsurgical assistant for ENT will require highly dextrous end-effectors to be developed. Also, the middle ear cannot be visualized directly as with the retina requiring novel imaging modalities to be incorporated with the surgical tools. Long term goals will merge the technology created for the microsurgical assistant with that of the macrosurgery test bed in order to address complex tasks such as heart surgery.

1.3 Motivating clinical applications areas

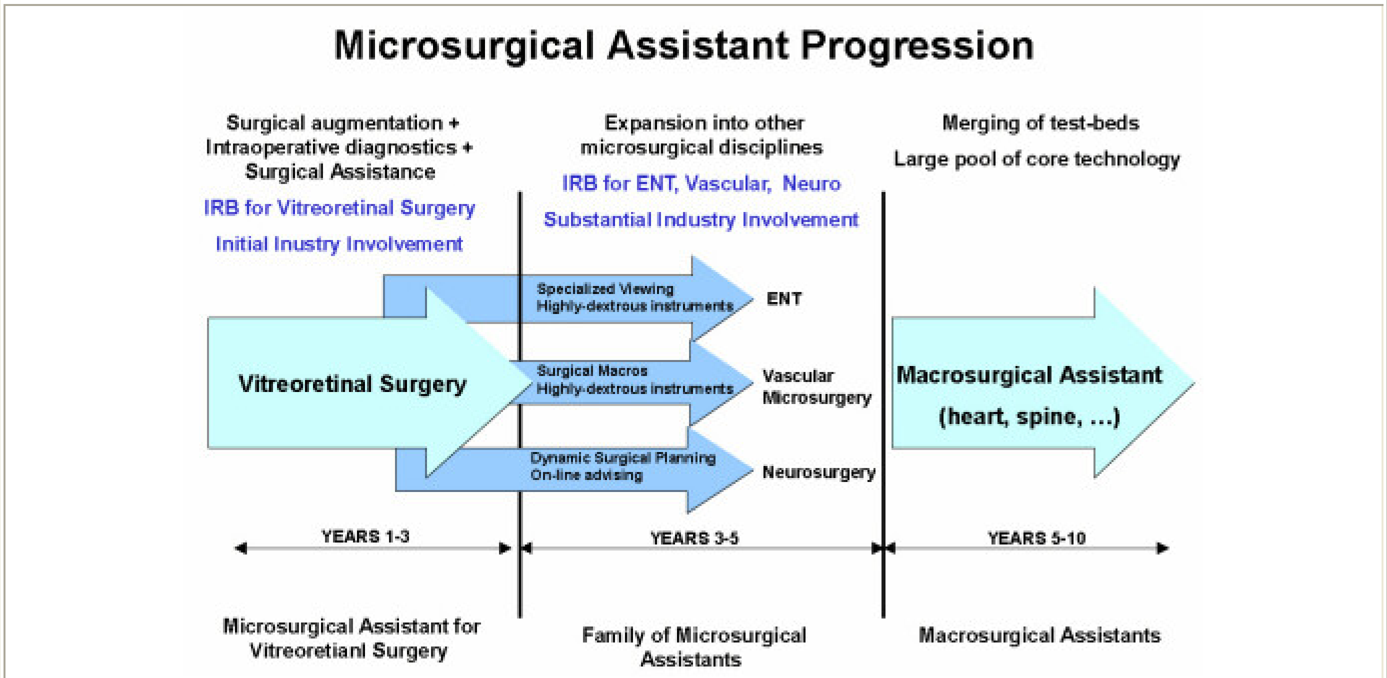

Figure 1-5: Application Evolution. The initial Microsurgical Assistant Test Bed will be targeted for vitreoretinal surgery. Our strategy hinges upon desceminating major portions of the Test Bed to other surgical disciplines including ENT, vascular microsurgery, neurosurgery and spine surgery.

The microsurgical assistant development effort is being lead by Dr. Eugene de Juan and Patrick S. Jensen, Ph.D. Dr. de Juan is a vitreoretinal surgeon with the Johns Hopkins Wilmer Eye Institute and also the director of the Microsurgery Advanced Design Lab (MADLAB). Vitreoretinal surgery is a natural starting place for a microsurgical assistant. The test bed leaders are intimate with the limitations of this microsurgical discipline and are also knowledgeable of how to apply the systems so that they address real clinical problems. Of the microsurgical disciplines, vitreoretinal surgery has several other advantages as a starting point. First, the geometry of the eye is fairly similar across patients. Secondly, the pupil provides a natural window through which surgical tools placed into the eye may be observed. Finally, the surface of the retina is easily accessed and essentially 2-D. Even so, surgical capability during retinal microsurgery is limited by both the ability to accurately manipulate surgical tools and by the lack of intraoperative information needed to guide the tools. The microsurgical assistant platform will address these clinical needs directly while providing a modular base upon which other applications can be developed.

The surgical limitations addressed by the microsurgical assistant for vitreoretinal surgery are also present in other microsurgical disciplines. Each subsequent application of the microsurgical assistant will address these limitations while expanding the capabilities of the overall system. We have identified microvascular anastomosis as a logical "next step" for the microsurgical assistant since it will require only slight modifications from the base unit. This delicate procedure requires that from four to eight sutures be placed, tightened and knotted in a 1mm vessel. This is extremely fatiguing for the surgeon with each vessel taking between 10 and 30 minutes to complete. Complications include tearing the vessel, twisting the vessel during suturing and placing sutures through both the front and back of the vessel wall, essentially blocking the flow of blood. Intraoperative diagnostics will be used to monitor microvascular blood flow while force sensing end-effectors will prevent the vessel from tearing during suturing or penetrating the back of the vessel. The steady-hand robotic platform will be used to help place the suture and surgical knot tying macros will be developed to speed up and simplify the procedure.

Both ENT surgery and neurosurgery will require that novel imaging modalities be integrated with the surgical assistant end-effectors. These end-effectors must be small, non-invasive, highly dexterous and precise.

Once an IRB for vitreoretinal surgery is in place, we will pursue IRB approval for microvascular reconstruction, ENT surgery, and neurosurgery. Longer-term goals include targeting minimally invasive surgery on the beating heart.

1.4 Critical Engineering Knowledge and Technology Barriers

1.4.1 Quantification of surgical performance and surgical outcome

There is a strong need to evaluate the efficacy of procedures performed using the microsurgical assistant but also to develop validation techniques for the other CISST ERC test beds. The microsurgical assistant has been developed based on initial studies addressing human performance during microsurgery. However, the data from these studies is far from complete and additional data is not available from the literature. Validation techniques capable of quantifying human performance and surgical robot performance are required. These same techniques can be used to validate the "augmentation" capabilities of the microsurgical assistant when compared with the baseline data. Technology to assess actual surgical performance and relate that information to clinical outcomes is also needed. Information resulting from these tests will be utilized to gain fundamental knowledge about the limitations of microsurgery, surgical performance following augmentation and how varying aspects of microsurgical augmentation affect surgical patient and clinical outcome.

1.4.2 Augmentation of human micro-scale performance

Humans possess superb manual dexterity, visual perception, and other sensory-motor capabilities. They are able to combine these capabilities with versatile "intelligence" to perform an astonishing variety of tasks ranging from simple daily living to workplace activities such as farming, factory assembly, or surgery. Humans perform best at a "human scale", as dictated by our physical size and with manipulation capabilities roughly corresponding to the tasks routinely performed by our cave man ancestors. Although quite diverse, the human sensory-motor system can only respond to specific ranges of stimuli and similarly is capable of physical feats only within certain limits. For tasks lying outside of these capabilities, we build tools and through the use of these tools, are able to perform super human tasks such as flying through the air, lifting heavy objects, breathing under water and seeing infrared light.

Microsurgical procedures are demanding tasks that require both precise manipulation and human judgement. The delicate nature of motions required for microsurgical procedures are at the lower limit of what is humanly possible and further complicated by a lack of proprioceptive and tactile feedback. Methods for augmenting human performance during micro-scale manual manipulations are needed.

1.4.3 Characterization and semi-automation of microsurgical tasks

Very little is currently known about the information surgeons use to make intraoperative decisions, how that information relates to the development of a surgical plan by the surgeon, and how that surgical plan is ultimately implemented through the motion of surgical instruments. By studying this process, specific tasks that are either time consuming to the surgeon or extremely difficult to do by hand may be identified and automated through the use of the microsurgical assistant.

1.4.4 Real-time intraoperative assessment of the surgical environment

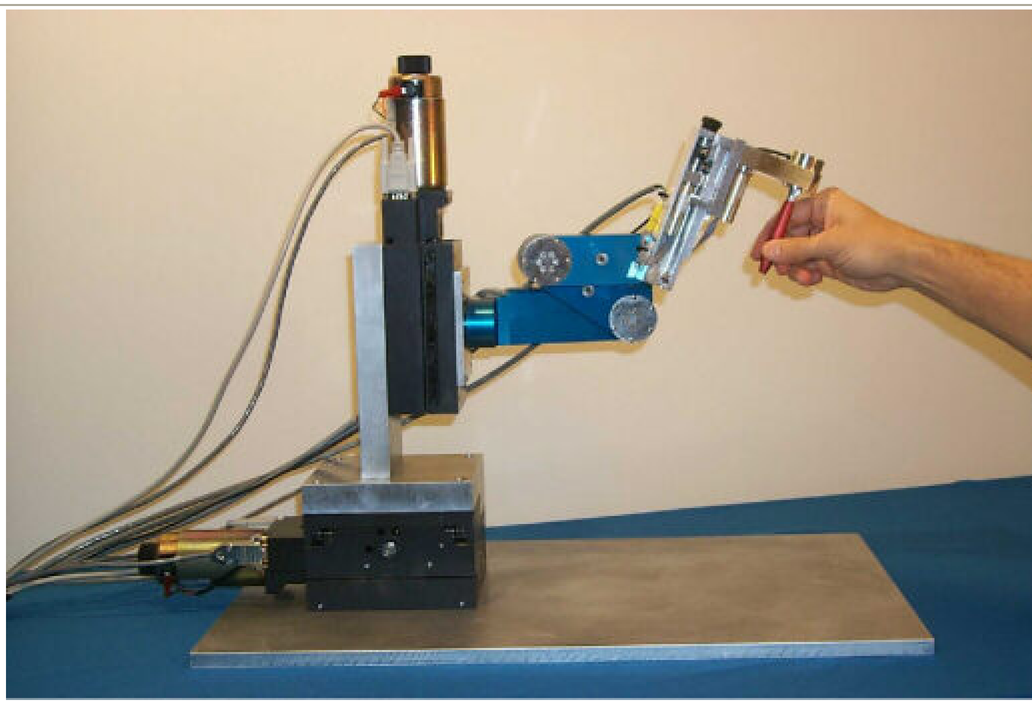

Figure 1-6: Steady-Hand augmentation system. The Steady-Hand robot cooperatively shares a surgical instrument with a human operator. The surgeon grasps and guides the surgical tool while the robot provides tremor free motion, haptic augmentation, and the ability to perform semi-automated tasks.

Methods of providing real-time intraoperative information to the surgeon about the surgical procedure are needed. Although preoperative and postoperative imaging techniques in microsurgery are common, only optical information is typically used during the actual surgical procedure. While optical information is useful for guiding surgical instruments, the information contained in the optical image does not adequately convey information about the surgical environment. For example, the ability to image blood flow, sub-surface structures, nerve fiber layers, tissue boundaries, and tissue biomechanical properties would all provide valuable intraoperative information to the surgeon but cannot currently be ascertained through the operating microscope.

1.5 Research and Major Tasks

1.5.1 Research Task 1: Steady-Hand Augmentation

Microsurgical procedures are particularly demanding physical tasks that require both precise sensory-motor capabilities and human judgement. The delicate nature of motions required for microsurgical procedures are at the lower limit of what is humanly possible and further complicated by a lack of proprioceptive and tactile feedback. To advance beyond current microsurgical techniques, the limitations imposed by human perception and physical ability must be circumvented. Due to the complex and interactive nature of microsurgery, it is neither sufficient nor desired to replace the surgeon with a machine. Instead, tools that augment human manipulation skills and perception capabilities while exploiting the human's natural strengths are sought. The goal of this research task is to develop a clinically useable and novel approach to human performance augmentation called *Steady-Hand Augmentation*.

Existing microsurgical robotic devices require that the surgeon relinquish immediate contact with the surgical tool and further be physically removed from the surgical site. Our Steady-Hand Augmentation approach will allow surgical instruments to be held simultaneously by both the surgeon and a specially designed augmentation device (Figure 1-6). During surgery, the surgeon grasps the tool and manipulates it in the exact manner in which he or she is accustomed. The Steady-Hand Augmentation platform simultaneously holds the instrument and provides tremor cancellation, tactile sensation amplification and haptic augmentation. The result will be a surgical tool possessing the precision and sensitivity of a machine but with the manipulative transparency and immediacy of hand-held surgical tools.

This research task addresses Barrier 1.4.2 during microsurgical procedures and provides critical procedure input for Barrier 1.4.3. The procedure outcomes resulting from using Steady-Hand Augmentation will be used to address Barrier 1.4.1.

Several modular components of the Steady-Hand robot currently exist and some preliminary testing has been performed on these components. However, as addressed below, several research barriers must be addressed before the platform can be successfully used in a clinical setting.

We are currently in negotiations with potential industrial collaborators for replication, licensing, and FDA approval.

Project A: Force control for microsurgical robots (Whitcomb, Jensen, Taylor, Berkelman)

The Steady-Hand robot utilizes information from two force sensors located on the Steady-Hand platform. The first sensor monitors guiding forces between the surgeon and handle of the surgical tool while the second monitors the forces generated between the tip of the surgical instrument and the tissue being manipulated. The goal of this research project is to develop robust control algorithms that will provide steady-hand appreciation of compliant and non-linear tissues to the surgeon. It is not currently understood how a cooperative robot may be controlled in a robust and intuitive manner when dealing with two highly non-linear environments (the surgeon's hand and the tissue being manipulated). This is a significant research project and constitutes a novel and critical area of research. The success of this project is dependant upon the development of force sensing surgical instruments.

Research & Technology Milestones

- Steady-Hand algorithms are currently under development
- Demonstration of robust control with compliant and non-linear tissues
- Integration into surgical demonstration
- Extensions to include additional control inputs and vision guiding
- Future implementations

Project B: Microsurgical sensors and actuators JHU: (Whitcomb, Jensen, Stoianovici; CMU: Riviere)

The steady-hand robot control algorithms require that force sensing surgical tools be incorporated into the end-effector. These sensors monitor interactions between the surgical tool and the tissue being manipulated. As described above, this information is used in conjunction with force information between the surgeon's hand and the handle of the surgical tool to guide the instrument during surgery. There is a strong need for sensors capable of measuring mN scale forces in multiple degrees of freedom. These sensors must be small (less than 1mm in size) and capable of either being either disposable or autoclavable. This research project has applications in other ERC related efforts including percutaneous needle driving and tissue property characterization.

Research & Technology Milestones

- Implement and test 1-DOF strain gage based sensor
- Implement and test 3-DOF strain gage based sensor
- Investigate capacitance and optical sensors
- Port design to various surgical instruments and devices

Project C: Systems integration and OR compatibility (JHU: Jensen, Berkelman, Taylor, Whitcomb, de Juan)

An important step in making the vision of a Microsurgery Assistant a reality is to transfer bench-top technology out of the laboratory and into the operating room. This will require an in-depth understanding of hospital regulations, safety precedents established by existing systems, and operating room procedures. An area of core engineering research and development is to modify the Steady-Hand platform for use on humans, rigorously test the device on animal models in-vivo, and gain Internal Review Board (IRB) approval for use during vitreoretinal surgery. We plan on utilizing substantial industry support to replicate the base Steady-Hand platform and to assist in gaining IRBs for fields other than ophthalmology. The hardware and software modules developed for this purpose will be a part of the core ERC technology and will be leveraged upon by other test-bed systems.

Research & Technology Milestones

- Modify existing Steady-Hand platform to be OR compatible. This includes hardware, software and safety modifications
- Identify industrial partner (in negotiation, commitment by
- Hardware replication through support from industry
- Test the platform in-vivo
- IRB approval for 3rd hand endoscopy for vitreoretinal surgery
- IRB approval for "steady-hand" surgical tools
- IRB approvals for other microsurgical disciplines
- FDA approval and commercialization of Steady-Hand Platform for microsurgery

1.5.2 Research Task 2: Tissue characterization and modeling

Microsurgeons currently rely almost exclusively on the view through the operating microscope to guide surgical instruments during microsurgery. The surgeon uses this optical information for many purposes. For instance, by observing tissue deformation, the surgeon can ascertain when the instrument contacts tissue or when the tissue is about to yield. Physiological or functional cues can also be indirectly inferred from the images by observing coloration, pattern and shape. However, optical information alone is not capable of truly quantifying many desired attributes important for proper intraoperative decision making. By developing novel probe-based and microscope-based sensors, we aim to characterize both the structure and function of the selected tissue region. These sensors will aim at sub-surface structural imaging, thermal imaging, blood flow determination, neurosensory monitoring, and biomechanical property determination. Information from these sensors will be collected and combined with the view through the operating microscope to develop a working model of surgical site. This research project directly addresses Barrier 1.4.4 and will be used as a data input to Barrier 1.4.1.

Project A: Tissue property sensing (Thakor, Etienne-Cummings, Jensen, Fichtinger - JHU)

The goal of this research effort is to develop technology for assessing properties of retinal and prostate tissue using optical, ultrasonic, and force sensing means. The proposed technology will be suitable for real-time acquisition and feedback of tissue properties to the surgeon. The ability to characterize tissue during the surgical procedure is broadly applicable across the test bed systems being developed by the CISST ERC. For the Microsurgical Assistant, this information will be initially used to generate models of the retina including tissue layers, blood flow and neural activity. This model will be presented to the surgeon for enhanced intraoperative visualization and also directly coupled to the Steady-Hand robot to guide the surgeon in the delivery of surgical treatments. The knowledge base established in developing this technology will be applied to other surgical disciplines.

The following research plan is proposed:

- We will first design a camera for infrared spectroscopic imaging system. We will use silicon (CCED or MOS) sensor and employ near infrared filters to obtain images in the oxy- and deoxyhemoglobin bands. From these images we will obtain oxygen perfusion of the tissue. We expect to highlight the blood vessels as well as differentiate the perfusion in these vessels.

- Next, we will develop an imager that will use an LCD-tunable filter attached to the camera. The camera image will be tuned to the wavelengths of interest

- Ratiometric and other images will be obtained. The goal of this study is to identify tissue properties: is it ischemic, is it cancerous (may be highly vascularized or may be necrotic)? Once video images are obtained, hyperspectral imaging algorithms will be developed for classification of tissue properties.

- Next, we will develop an optical bench system which will allow simultaneous acquisition of visible and mid to far infrared images. The mid to far infrared images

- Next, a fiber optic system suitable for vitreoretinal surgical probe will be developed. Imaging will be done through single or multi-mode fibers or fiber bundles. GRIN lens focusing devices will be attached to the fiber. Optical filtering will be carried out at the detector. Suitable visible and IR selective fibers and filters will be designed within the surgical probe.

- The IR spectroscopy and hyperspectral imaging will then be extended to the study of prostate tumors and surgery.

- An alternative and parallel approach will be to use ultrasound probe and sensing (for further details see Task 3, Project C).

Research & Technology Milestones

- MOS sensor and filter design, fiber and grin lens based probe; vitreo-retinal testing.
- IR camera imaging, display and analysis; application to percutaneous test-bed.
- Hyperspectral image analysis and tissue classification research.

Project B: Biomechanical modeling of retinal tissue (Howe - Harvard)

The goal of this research is to model the biomechanical properties of biological tissue and update that model in real-time based upon intraoperative feedback from tissue characterization sensors. Information from the model will be presented to the surgeon for visualization and also used to drive the microsurgical assistant for specific tasks such as membrane peeling without tearing, vessel puncture, and subretinal surgery.

Research & Technology Milestones

- Perform bench top assessment of retinal tissue in various normal and disease states using palpation with Steady-Hand robot
- Develop retinal model based on palpation information and integrate real-time updates from force sensors
- Utilize model information to guide the microsurgical assistant for membrane peeling and virtual fixturing

- Expand the biomechanical model to include bony structures and cartilage. Adapt for use in ENT and microvascular reconstruction

1.5.3 Research Task 3: Registration and display of intraoperative information

Project A: Registration of intraoperative information for microsurgery (Wolff - JHU, Grimson - MIT)

The primary goal of this research project is to develop multi-modal mapping of retinal structure and function using 1) pre-operative images, 2) intraoperative images from the operating microscope and 3) data from Steady-Hand probe-based sensors. The primary barrier in accomplishing this task is the ability to register, in real-time, the retina as viewed by the surgeon through the stereo operating microscope with data from the three sources listed above. Specific goals of the project are to:

1. Demonstrate the ability to register pre-operative flourescein angiograms (FA) with the image from the operating microscope in real-time.

2. Develop Multi-modal registration capabilities:

    a. Demonstrate the ability to register the image acquired from a GRIN lens endscope held by the Steady-Hand manipulator with the image from the operating microscope. This will require knowledge about the position of the endoscope in relation to the eye and to the micrscope but will be utilizing two similar imaging modalities with differing scales.

    b. Demonstrate the ability to register non-image based Steady-Hand held sensor information such as ultrasound, OCT and biomechanical model data with the image from the operating microscope.

3. Incorporate deformable registration techniques to register data sets with the view from the stereo microscope showing a detached retina during retinal translocation procedures or retinal detachments. This task depends upon deformable registration methods being developed for other CISST ERC test-beds.

Research & Technology Milestones

- Real-time registration of pre-operative FA images with the view from the stereo operating microscope
- Develop Multi-modal registration capabilities: Demonstrate the ability to register the image acquired from a GRIN lens endscope held by the Steady-Hand manipulator with the image from the operating microscope. This will require knowledge about the position of the endoscope in relation to the eye and to the micrscope but will be utilizing two similar imaging modalities with differing scales. Demonstrate the ability to register non-image based Steady-Hand held sensor information, such as optical coherence tomography and ultrasound, with the image from the operating microscope

- Incorporate real-time deformable registration techniques to register data sets with the view from the stereo microscope showing a detached retina during retinal translocation procedures or retinal detachments

Project B: High-resolution display of intraoperative information (Kumar - JHU, Hawkes - Guys)

This research effort will leverage work done by David Hawkes at Guys Hospital in London to allow models of the retina and subsequent surgical sites (middle ear, microvessels, spine, etc.) to be injected into the surgical microscope and overlayed within the surgeon's field of view. This is the final step in providing enhanced visual information about the tissue being operated on to the surgeon and addresses Barrier 1.4.4.

Research & Technology Milestones

1. Apply for instrumentation grant to replicate David Hawke's system at JHU
2. Integrate stand-alone stereo visualization tool for model testing. This will be based on off-theshelf technology available within the ERC
3. Build, test and integrate the registered image injection microscope

Project C: Tissue motion tracking for microsurgery (Hager, Ettiene-Cummings, Thakor, Jensen - JHU)

The goal of this project is to develop real-time tracking capabilities for internal eye structures, to integrate same with steady-hand robot, and to test the integrated system in clinical application. An immediate goal of this research will be to utilize tracking techniques for the purpose compensating for cardiac and respiratory motion during surgery and for guiding a robot-held micropipette into a pre-selected location of a retinal vein. Both hardware and software solutions for tissue motion tracking will be investigated. Long-range goals include the migration of these techniques to other microsurgical disciplines.

We propose to pursue the following course of action:

- In the near term, Hager and Ettiene-Cummings will pursue software and hardware based approaches to tracking based on stored image sequences. In parallel, Jensen will develop new probe hardware with an integrated GRIN lens and micro-pipette.

- As soon as possible, a skeleton system for testing will be set up. This will allow for testing on an artificial eye and eventually on cadavers.

- Both hardware and software solutions will be tested for accuracy and ability to deal with small (e.g. respiratory) induced motions. Evaluation of possible techniques for dealing with large motion will begin. This will most likely interface with real-time registration.

- In the second phase, the skeleton system will be upgraded to a fully functional test system using the results of year one. Testing and development of methods for dealing with large motions will continue through this year and be integrated toward the end of year 2.

Research & Technology Milestones

- Development of tracking algorithms for retinal surgery
- Integration and testing of tracking for the Steady-Hand platform
- Demonstration of software tracking algorithms for retinal surgery
- Incorporation of software tracking for retinal vein cannulation
- Demonstration of hardware tracking as an alternate approach
- Migration to other microsurgical disciplines

1.5.4 Research Task 4: Surgical Action Enhancement

Project A: Surgical macros and virtual fixturing (Howe - Harvard, Taylor - JHU)

The ultimate goal of this effort is to completely automate routine soft tissue procedures through the use of real-time force and video signal processing and computational tissue models. In the near term, we can develop the building blocks for this goal that will immediately increase precision and ease the surgeon's workload. The initial effort will focus on surgical Macros and Virtual Fixturing, control subroutines invoked by the surgeon to assist in completing surgical tasks. A surgical macros is a sequence of commands that the robot executes autonomously. Macros may be preprogrammed or "taught" by the surgeon in a specific case, and may involve varying degrees of sensory feedback and contingent control. An example is needle driving: the surgeon positions the needle at the point of entry into the tissue, then activates the macro that advances the robot gripper along the curvature of the needle. A virtual fixture is a computer-generate constraint that simplifies task execution by reducing the number of degrees of freedom or precision requirements. These fixtures are analogous to computer mouse features such as snap-to-grid and acceleration, which makes it simpler to precisely position the cursor or quickly move across large distances. This area of research directly addresses Barrier 1.4.3.

A likely target task is automated knot tying, which will relieve the surgeon of the need to coordinate both instruments to loop the suture into a knot. Once the surgeon grasps an end of the suture in each robot instrument, the "knot tying subroutine" will take over. Because the robot controller knows the relative location of each instrument, it can coordinate their movements to circle the suture into the knot configuration. This step can be performed using only joint position sensing. If force sensing is added to the robot, the automatic subroutine can be extended to pull the knot to a programmed tension against the tissue. In addition, if real-time image processing is performed on the endoscope signal, the knot can be tightened until the desired degree of tissue deformation is achieved. Other useful subroutines include cutting precisely aligned incisions, driving suture needles in accurate patterns, and safe automated retraction of organs and vessels. In the context of ophthalmic surgery, subroutines may include automatic detection of contact with the retina, determining retinal geometry from multipoint contacts, and automated canulization.

Research & Technology Milestones

- Analyze surgical tasks, both bottom up (what macros and fixtures would surgeons like now?) and top down (what capabilities are needed to completely automate tasks?)
- Duplicate Steady Hand robot (4 axes); configure as minimally-invasive surgical manipulator (fixed incision point)
- Measure and analyze forces and motions in vessel suturing, with focus on setting correct tension and needle depth

- Implement initial fixtures and macros for micro-anastomosis (~1mm diameter vessels)
- Research (and measure?) vessel mechanics, specifically properties related to manipulation, cutting, and suturing
- Develop model of relationship between robot actions (grasping, puncture, needle driving, etc.) and tissue response (deformation, tearing, etc.) (also see biomechanical modeling of tissue project)
- Develop and test anastomosis macros and fixtures
- Expand into other microsurgical disciplines

1.5.5 Research Task 5: Performance validation

Project 1: Performance validation of the surgical assistant (Riviere - CMU, Jensen, Thakor - JHU)

This project aims to develop precision techniques and instrumentation to quantify surgical performance, and to use this technology to validate the performance of Test-Bed systems developed within the CISST ERC. This performance validation is essential for the transition of ERC Microsurgical Assistant systems from the laboratory to the operating room and directly addresses Barrier 1.4.1. Research topics include baseline evaluation of unassisted human performance (tremor, drift, tactile sensation, etc.), baseline test-bed performance evaluation (precision, repeatability, etc.), comparisons between baseline data and augmented human performance using the Microsurgical Assistant augmentation modules, and eventual clinical outcomes analysis quantifying the "value" of the microsurgical assistant. The two main aspects of this research will be the continued development of needed instrumentation and the use of this instrumentation to perform the validations outlined above.

Research & Technology Milestones

- Complete second generation of ASAP (3-D micron-scale surgical instrument tracking hardware for testing surgical performance)
- Study performance baseline of unasssisted ophthalmological surgeons via ASAP. Complete any needed refinements to force sensing
- Positional accuracy tests of microsurgical assistant systems in simple targeting
- Performance tests of microsurgical assistant in realistic tasks, with position tracking and force sensing for contact and applied force level. Comparison with prior state of the art
- Use of ASAP and force sensing for developing surgical macros (described above) will occur in parallel with the above
- Methods for tracking patient outcomes will be developed and used to determine the efficacy of the microsurgical assistant for various microsurgical procedures

1.6 Benchmark Applications

The basic paradigm of the microsurgical assistant transcends all microsurgical disciplines. Our modular approach to systems development allows the basic platform, once developed for vitreoretinal surgery, to be rapidly applied to other disciplines such as open vascular microsurgery with very little modification. Other disciplines such as ENT and neurosurgery will require additional knowledge and technology barriers be addressed and the results incorporated into the basic microsurgical assistant platform. This section discusses specific clinical applications of the microsurgical assistant and the barriers associated with system implementation.

1.6.1 Vitreoretinal surgery

As described above, vitreoretinal surgery has several limitations inherent to human performance that are addressed by the microsurgical assistant. By addressing these limitations, new treatments for debilitating retinal conditions can be developed and current treatments can be performed with greater accuracy and precision, hopefully leading to better surgical outcome. The following surgical tasks are :

Targeted surgical tasks

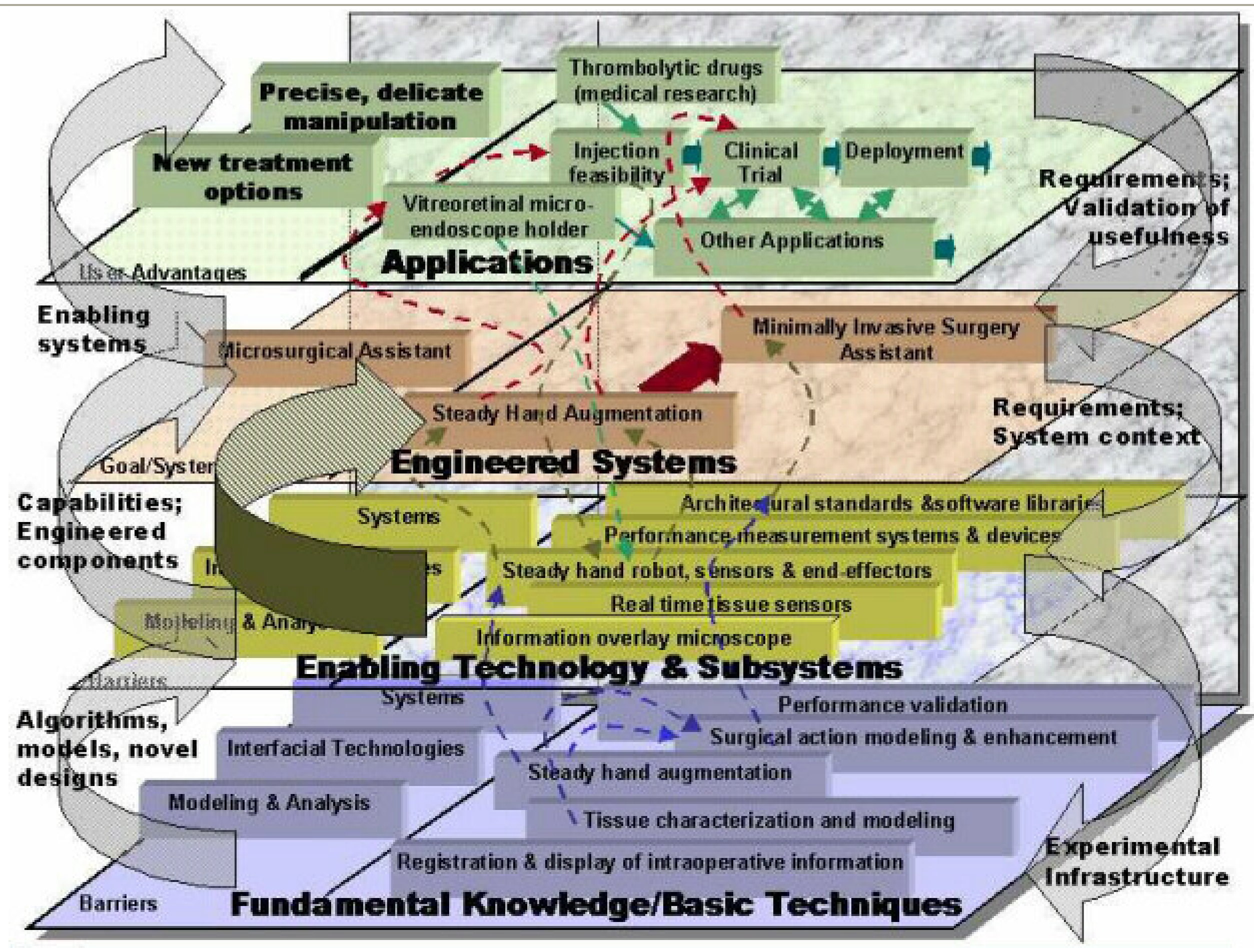

Figure 1-7: Multi-tier diagram for retinal vein cannulation application. This diagram illustrates some of the interactions in one focusing application of our microsurgery assistant test bed. The goal is to inject clot dissolving drugs into 100 micron diameter retinal vessels. If successful, this application could lead to an effective treatment for one of the leading causes of blindness in people over 70. Currently, surgeons can see the clot but cannot do much about the consequences. There is concurrent research at JHU and elsewhere on this therapy idea. A gating capability is the ability to insert a 10 or 20 micron diameter cannula into the vessel and hold it there while the drug is injected. In the near term, we will use our first generation steady hand robot to evaluate the therapy concept in animal models. This work will help drive the development of basic guiding and vision/sensor-adaptation methods (e.g., for vessel motion, if needed). Concurrently, we will pursue a less safety-critical application, manipulation of very small

endoscopes in retinal surgery. This application will provide early clinical experience that can help drive development of a usable clinical system, which will then be used for clinical trials of the injection therapy. As experience is gained, this application will provide one environment for development of surgical action enhancements, such as aiding in puncturing the vessels, thus contributing to development of surgical assistant capabilities.

- Third hand
    - Endoscope holding - Here the Steady-Hand robot is used to hold a high-resolution endoscope within the eye, allowing the surgeon to perform bimanual manipulations within the surgical field of view of the endoscope. This task will be the initial target of an IRB designed to get the endoscope into the OR. The basic measurement of performance in this task is tremor in the endoscopic image when held by the robot as compared to held by hand.

- Retinal vein occlusion
    - Cannulation - Retinal vascular occlusive disorders constitute the second lading cause of blindness in patients over 70 years of age and currently have no viable cure. We propose to cannulate the occluded vessel with a robot held, micron scale pipette and deliver clot dissolving drugs directly to the site of occlusion. The scale of motions and steadiness required for this procedure are too delicate to be performed by the human hand alone. Success will be measured by demonstrating the ability to place a cannula within occluded retinal vessels of patients, a task currently not possible.
    - Sheathotomy - A second approach to retinal vascular occlusions is to release the 10 micron thick layer of tissue surrounding the occluded vessel in order to dislodge the clot. This approach has been attempted with modest success by hand, but could be made much more reliable and repeatable of force sensing instruments and a steady-hand robotic assisant. A comparison study relating the visual acuity of patients treated with and without the microsurgical assistant will be performed for evaluating success.

- Diabetic retinopathy
    - o Epiretinal membrane removal - Currently, epiretinal membranes are removed routinely as a treatment for diabetic retinopathy. However, due to the minute forces involved in retinal surgery, the surgeon cannot feel the interactions between the tool and the tissue. This lack of tactile and haptic feedback has been demonstrated to slow down manual manipulation tasks and increase the rate of errors. We propose to investigate utilizing the augmented haptic sensation of the Steady-Hand robot to assist the microsurgeon in peeling these membranes. Haptic fencing will be implemented to prevent the surgeon from pulling too hard on the membrane, potentially damaging the underlying membrane. A comparison study relating the visual accuity of patients treated with and without the microsurgical assistant will be performed for evaluating success.

Application milestones

- Third hand
    - Development of OR compatible third hand platform
    - Clinical testing under IRB approval
    - Commercial deployment with FDA approval
- Retinal vein occlusion
    - Development of cannulation and sheathotomy end-effectors and tracking hardware
    - Clinical testing of both approaches under IRB approval
    - Commercial deployment with FDA approval
- Diabetic retinopathy
    - Development and rigourous testing of steady-hand control algorithms and virtual fixtures for cooperative control of surgical instruments
    - Clinical testing under IRB approval
    - Commercial deployment with FDA approval

1.6.2 Microvascular reconstruction

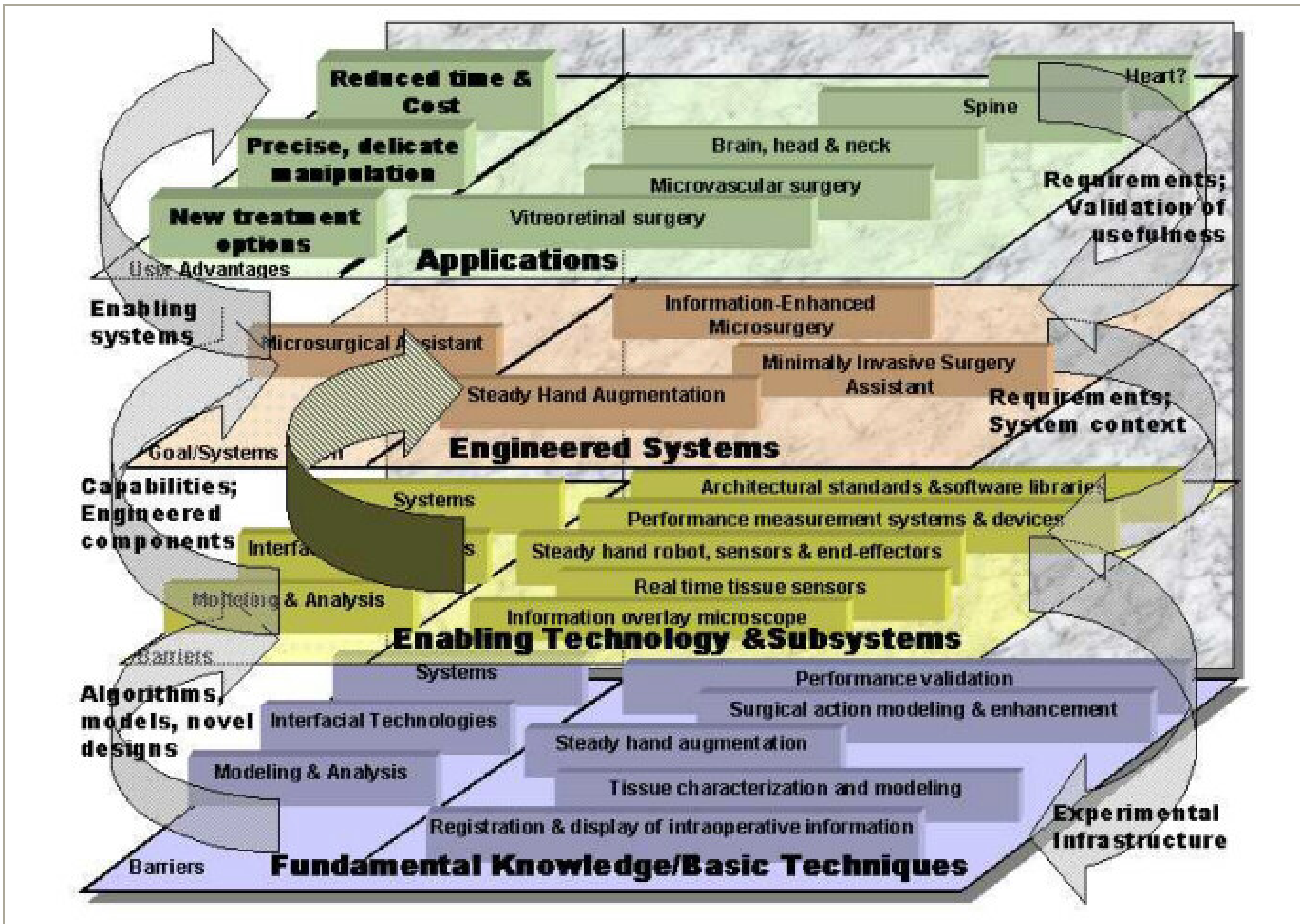

Figure 1-8: Multi-tier strategy summary chart for microsurgical assistant systems.

We are currently investigating how to best apply the microsurgical assistant towards vascular microsurgery. The project 1.5.4 Surgical Macro and Virtual Fixturing will investigate the current surgical demands and has targeted this application for development of surgical macros. We aim to assist the surgeon in placing the sutures both accurately and safely utilizing semi-automated suturing and knot-tying algorithms.

- Microvascular anastomosis
  - Understanding of current microvascular anastomosis techniques
  - Development and demonstration of bench top solution
  - IRB approval for microvascular anastomosis using the microsurgical assistant
  - Clinical testing under IRB approval
  - Commercial deployment with FDA approval

1.6.3 Others

Following the same methodology as that used to implement the microsurgical assistant for vitreoretinal and microvascular surgery, we will simultaneously investigate applications in ENT surgery, spine surgery, neurosurgery and eventually heart surgery.

1.7 Key Technology/Component Deliverables

1.7.1 Steady hand robot

- Computer controller architecture
- Modular robot control software library
- RCM
- Z-theta stages
- Force sensing end-effectors
- Steady-Hand force control algorithms
- Tissue motion tracking hardware and software modules

1.7.2 Information enhanced surgery modules

- Probe based tissue property sensors
- Microscope based tissue property sensors
- Biomechanical models of retinal and other tissues
- 2.5D model of retinal structure and function
- Real-time registration methods for 2.5D models
- Real-time multi-modal data fusion methods
- Registered image injection into operating microscope

1.7.3 Surgical assistance modules

- Surgical macro libraries for semi-automated task execution
- Virtual fixture modules to assist in surgical tasks

1.7.4 Validation modules

- MADSAM / ASAP tremor analysis suites
- Tactile sensation modules
- Inertial sensor for recording surgical macros
- Validation techniques for evaluating clinical outcomes

1.7.5 Surgical techniques

- Retinal vein cannulation
- Retinal vessel sheathotomy
- Epiretinal membrane peeling
- 3rd hand endoscopic platform
- microvascular anastomosis

1.7.6 Systems

- Microsurgical assistant for vitreoretinal surgery
- Microsurgical assistant for microvascular reconstruction