Enabling Technologies for Future Medical Devices

Medical robotics is one of the frontier areas of robotics, focusing on the application of computers and robotic technology to surgery and other medical procedures, and in planning and execution of medical interventions. In robotic telesurgery, the goal is to develop robotic tools to augment or replace hand instruments used in surgery.

Current generation of robotic telesurgical systems have far from satisfactory performance as they are still far from reproducing the dexterity and sensation of open surgery. The next generation telesurgical systems require design of smaller and higher degrees-of-freedom manipulators for use in applications such as cardiac and fetal surgery; and more importantly design of systems with higher dexterity and higher fidelity haptic feedback. The focus of our research is to develop a common framework for haptic interfacing to real and virtual environments that also would make it possible to study the kinematic design, actuation mechanisms, sensory subsystem, and controller design aspects of haptic systems within a single framework to optimize the performance of the system with respect to application-based performance criteria and the human sensory-motor abilities. Such a framework will be an invaluable tool for the development of next generation medical robotic systems that can achieve the required dexterity and manipulation fidelity, as it unifies all of the performance critical aspects of the system design.

Control design is a critical component of achieving high performance in robotic telesurgical systems, which also has significant safety implications. It is not possible to construct a single controller that does all, i.e., have very high fidelity for the subset of environments that are relevant for the task at hand, while stable for all possible environments. Therefore in most of the works in the literature, control designs are naturally biased towards ensuring the stability of the haptic system while it is coupled with arbitrary passive systems, environment and operator, at the expense of significantly lower fidelity. The alternative approach we have proposed is to use a hierarchy of controllers. The basic idea is to use a high fidelity controller during normal operation. This controller is designed for a smaller set of environment and human operator uncertainties, allowing increasing the fidelity of the system as much as possible as required by the task. If the system encounters a set of conditions beyond this limited set, such as, if the slave manipulator contacts a rigid obstacle, the importance of fidelity becomes secondary to maintaining stability, and the system switches to a high-stability, lower-fidelity safety controller.

Within this framework, we are studying more fundamental scientific questions about medical robotic system design, including studying what are proper performance objectives for the specific tasks (i.e., understanding what is meant by high performance for the surgical manipulation tasks), what are the critical and limiting factors in performance, what are the underlying critical trade-offs in the design process, and what are the relevant psychophysical factors, along with our efforts on development of next generation robotic systems for use in coronary artery bypass surgery and forms of minimally invasive surgery.
Patient Modeling & Simulation

Biological modeling occurs in many levels from sub-cellular level, to cell, tissue, organ, system, organism and finally to population level. Furthermore, the processes being modeled vary in terms of time scales, from processes measured in seconds, to processes measured in years spanning the whole life cycle of the organism, and in terms of the type of the process, from mechanical, to electrical, chemical, and physiological processes. Finally, models need to be different based on the specific need for which they are being developed, since the needs dictate what is to be included in the models in terms of issues to be highlighted, spatial-temporal scales, accuracy and computational requirements.

The current state of the field of medical simulation is characterized by scattered research projects using a variety of non interoperable or independently verifiable models. Individual simulators are frequently built from scratch by individual research groups without input and validation from a larger community. The practical implication of this is the lack of trusted and reusable models and often poorly written, unvalidated, and un reusable code. Open source, open architecture software development model provides an attractive framework to address the needs of interfacing models from multiple research groups and the ability to critically examine and validate quantitative biological simulations. Open source models ensure quality control, evaluation, and peer review, which are critical for basic scientific methodology. Furthermore, since subsequent users of the models and the software code have access to the original code, this also improves the reusability of the models and interconnectibility of the software modules.

The following technical issues need to be addressed to satisfy these requirements in development of high confidence medical and biological simulations:

1. Abstraction: In the context of biological modeling and simulation, model abstraction is an important consideration. Within a general modeling and simulation framework, different applications and different problems require different types or levels of abstraction for the each of the processes and components in the model. Therefore, the simulation framework developed needs to be able to accommodate different types and levels of abstraction for each of the different subcomponents in the model hierarchy, without artificially limiting the possibilities based on the requirements of a specific application.

2. Heterogeneous physical mechanisms and models of computation: Another issue that arises with the varying types of abstractions is the requirement on the simulation framework to be able to handle heterogeneous physical mechanisms and models of computation. The models can be in the form of continuous or discrete deterministic processes, stochastic processes or their combinations, which is referred to as hybrid models of computation.

3. Customization to patient specific physiology: It is necessary to use patient specific models during simulation in most of the grand challenge applications described. Therefore the models in the simulation need to be customizable. This actually ties to the open architecture design of the simulation framework, which needs to allow loading and working with custom data sets generated by third parties.

4. Validation: Validation of the models and the underlying empirical data is a basic requirement for reusability of the models. It is also important to have mechanisms to track the assumptions of the individual models and model data within a complex simulation environment, to ensure that
the aggregate assumptions behind the models and the abstractions satisfy the requirements of the application at hand.

5. **Modularity through encapsulation and data hiding:** It is necessary to develop standard model interfaces in the form of software APIs for interconnection of models. The API and the overall framework need to be able to support hierarchical models and abstraction of the input-output behavior of individual layers or subsystems for the level of detail desired from the simulation model. The object oriented programming concepts of encapsulation and data hiding facilitates the modularity of the components. This also provides mechanisms to interface and embed the constructed models and other computational modules to a more sophisticated model.

6. **Support for parallel and distributed computation:** The simulations envisioned in the grand challenge applications typically require extensive computation not available at the level of basic desktop computers. Therefore, the developed framework needs to include support for parallel and distributed computation.

Simulations of organs which employ models of individual cells easily become computationally intractable. For example, the simplest cardiac cell models have two variables while realistic models can have dozens, and the total number of cells in the human heart is on the order of 10¹⁰ (in the tens of billions). Therefore, extraneous details must be abstracted away so that only relevant information is actively simulated. However, as models of biological systems typically are nonlinear in nature, many ordinary and valuable analysis techniques for differential equations, and model reduction do not apply. Therefore, there is a significant need for fundamental research in the area of mathematical and computational tools for efficient modeling, analysis, model reduction and abstraction, and simulation of large multiscale systems.

**Embedded, Real-Time, Networked System Infrastructures for MDSS**

Virtual environments are a promising new medium for surgical planning and training. The user interacts with virtual environments through haptic devices which allow him to perform surgery on a simulated patient by manipulating simulated organs using simulated surgical instruments. The accessibility of surgical virtual environments would be substantially extended by network communication. The resulting network simulations would enable continuing education and advanced training over wide geographical areas. Furthermore, networks would support remote access to surgery planning tools that require sophisticated computing facilities or that provide for surgeon collaboration. However, most current networks lack Quality-of-Service (QoS) guarantees at the detriment of simulation realism and effectiveness.

The long-term objective of our research is the establishment of a framework for networked surgical simulations that are usable, effective, and compelling. The primary focus of our current work is to identify methods to remediate the lack of QoS guarantees in current data networks in the context of networked virtual environment based surgical simulations, with the goal of developing a middleware for networked surgical simulation and a framework for its evaluation. This framework will be used to investigate innovative methods for a surgical simulation to deal with low network QoS, with adaptation to changes in network latencies to achieve a graceful degradation of performance during intermittent adverse network conditions and facilitate recovery when conditions improve.
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M. Cenk Cavusoglu received the Ph.D. degree in Electrical Engineering and Computer Science from the University of California, Berkeley, in 2000, the M.S. degree from the University of California, Berkeley, in 1997, and the B.S. degree from Middle East Technical University, Ankara, Turkey, in 1995. He is currently an Assistant Professor in the Electrical Engineering and Computer Science Department of Case Western Reserve University, Cleveland, OH.

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