Computer Aided Surgery 6:176–181 (2001)

White Paper: Challenges and Opportunities in Computer-Assisted Interventions

January 2001

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I. Introduction

In late June 2000, researchers at the forefront of radiology, surgery, and engineering presented the latest advances in medical imaging technologies and image-guided surgery at the annual conference of Computer Assisted Radiology and Surgery (CARS). This document highlights presentations from the panel representing the International Society for Computer Assisted Surgery (ISCAS), along with input from over 500 audience members in that session. Participants were:

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This White Paper provides a summary of some of the challenges and opportunities facing scientists in the continued development of imaging technology and computer-assisted surgical interventions. The participants highlight opportunities to further expand imaging techniques and image-guided surgery for the treatment of a wide range of diseases, and offer advice on planning and coordinating future activities, both in terms of research topics and funding policies. This report is intended to be an update to an earlier report generated by NIH Planning meetings on image-guided therapy (http://www.nci.nih.gov/bip/ISWG7.htm), which was part of a larger report available at http://www.nci.nih.gov/bip/ISWG.htm.

II. Background

A wide range of expertise from biological, medical, physical, engineering, and computational sciences, along with a significant amount of research and resources, is necessary to successfully advance biomedical computation and biomedical engineering technologies. Recent developments in computation technology have fundamentally enhanced the role of medical imaging, from diagnosis to computer-assisted surgery (CAS). During the last decade, medical imaging methods have grown from their initial use as physically based models of human anatomy to applied computer vision and graphic techniques for planning and analyzing surgical procedures. With rapid advances in high-speed computation, the task of assembling and visualizing clinical data has been greatly facilitated, creating new opportunities for real-time, interactive computer applications during surgical procedures.[1–4] This area of development, termed image-guided surgery, has slowly evolved into a field best called information-guided therapy (IGT), reflecting the use of a variety of data sources to implement the best therapeutic intervention for any given patient. Such therapeutic interventions could conceivably range from biopsy, to stimulation of tissue, to direct implantation of medication, to radiotherapy. Common to all these highly technical interventions is the need to precisely intervene with the therapeutic modality at a specific point within the patient's anatomy.

However, the effective utilization of biomedical engineering, computation, and imaging concepts for IGT has not reached its full potential. Significant challenges remain in the development of basic scientific and mathematical frameworks that form the foundation for improving therapeutic interventions through application of relevant information sources. Surmounting these challenges presents exciting opportunities for collaborative and transdisciplinary research among scientists and clinicians. The economic and healthcare benefits deriving from computer-assisted interventions are enormous.

III. Significance

As stated in the NIH's 1995 *Support For Bioengineering Research Report*, by Robert M. Nerem et al. (http://grants.nih.gov/grants/becon/externalreport.htm), an appropriate use of technology would be to replace traditional invasive procedures with noninvasive techniques, a development that would help contain healthcare costs. The current interest in research in CAS can be attributed in part to considerable clinical interest in the benefits of minimally invasive therapies (MIT). The advantages of MIT include smaller incisions, less trauma to the patient, decreased likelihood of postoperative complications, and faster recovery time, all of which contribute to lower healthcare costs and return patients to work sooner.

Although many surgeons have become more accustomed to minimally invasive procedures, even experienced surgeons encounter difficulties performing them. In addition to steep learning curves for utilizing MIT instrumentation, exposure is by definition limited, and surgeons must rely on their knowledge of anatomy to guide surgical tools through blood and tissue toward the region of interest. Such approaches can be disorienting, and may result in imprecise localization of the pathology and increased probability of intraoperative error. Image-based surgical guidance, on the other hand, addresses these limitations associated with MIT. Image-guided surgical navigational systems have now become the standard of care for cranial neurosurgical procedures in which precise movement through the brain is of utmost importance.

Patient-specific image data sets such as CT (Computed Tomography) or MRI (Magnetic Resonance Imaging), once correlated with the physical location of the patient's anatomy, can provide surgeons with detailed spatial information about the region of interest. Surgeons can then use these images to precisely target and localize pathologies for therapeutic intervention. Intraoperative computer-assisted imaging improves the surgeons' ability to follow preoperative plans by showing them where they are, and where they need to go, without damaging delicate tissues. Thus, the combination of CAS and MIT provides the advantages of MIT with the added benefits of greater precision and the increased likelihood of complete and accurate resections. The junction between CAS and MIT presents research opportunities and challenges for imaging scientists and clinicians in universities, medical centers, and industry for the treatment of disease, patient rehabilitation, and improving healthcare.

IV. General Requirements

Solutions to problems in biomedical image processing require:

A) Patient-Specific Models: Unlike simulation, IGT requires that modeling data be matched specifically to the patient being treated, because standard fabricated models based upon "typical" anatomy are inadequate during actual surgical procedures upon a specific patient. Patient-specific images can be generated preoperatively (e.g., by CT or MRI), or intraoperatively (e.g., by ultrasound or X-ray)

B) High Image Quality: IGT depends on spatially accurate models. Images require exceptional resolution to portray realistic and consistent information that surgeons can rely on to evaluate what they are looking at and make intraoperative decisions.

C) Real-Time Feedback: Current systems make the surgeon wait while new images are being segmented and updated. Hourly operating room (OR) costs are $1000–2000/h, depending on the hospital; thus fast, dynamic feedback should be made available, and the latencies associated with visualization, segmentation, and registration should be minimized.

D) High Accuracy and Precision: A recent AANS survey of 250 neurosurgeons disclosed that surgeons had little tolerance for error (1–2-mm accuracy in general, and 2–3 mm for spinal and orthopedic applications). All elements of visualization, registration, and tracking must be accurate and precise, with special attention given to errors associated with intraoperative tissue deformation.

E) Repeatability and Robustness: IGT systems must be able to automatically incorporate a variety of data so algorithms work consistently and reliably in any situation, not just in select, controlled cases.

F) Correlation of Intraoperative Information with Preoperative Images: This is a key area of interest to biomedical engineers and is especially critical for compensation of tissue deformation. Whether produced by microscopes, endoscopes, fluoroscopes, electrical recordings, physiological stimulation, ultrasound machines or other surgical instruments, preoperative and intraoperative images and information need to be incorporated into and correlated by the surgical guidance system.

G) Intuitive Machine and User Interfaces: The most important part of any IGT system is its usability. The surgeon's attention must be focused on the patient, and not the details of the computational model. Systems should be automated to reduce the number of people required to run them, thus making them more affordable to use. Further, the information provided by the device must be appropriate for each stage of the procedure and strictly relevant to the task at hand. Extraneous or irrelevant information will impair the ability of the interventionalist to focus on the task at hand.

Specific Recommendation Regarding Scientific Review

We reiterate Recommendation 2 from the 1995 *Support For Bioengineering Research Report* that "The NIH should significantly expand representation of the medical and biological engineering community on advisory groups and in the peer-review process. Substantially increased representation of bio-engineering researchers on study sections will improve the quality of the review process" for biomedical imaging- and biomedical engineering-related proposals, which will "improve the quality of funded research." Although the basic scientific components of biomedical computation and imaging are the same, the parameters for utilizing them vary significantly from one discipline to another. The requirements for computer-assisted diagnostics (CAD) may not be necessary for information-guided interventions. For example, diagnosticians inspect 3D data sets for the purpose of identifying pathologies. By the time the patient undergoes therapy, ***diagnostic "analysis and quantification" requirements need to change to "localization and targeting" for IGT. For purposes of surgical navigation, this is a complex shift demanding separate study sections that can completely evaluate the problems associated with IGT.***

V. Challenges and Opportunities

No matter where Centers of Excellence are located, the need for basic research in real-time visualization and data correlation is critical if researchers are to transfer imaging technologies into efficient IGT tools. Effective utilization of IGT generates new challenges and opportunities. These are:

- *Visualization Standards:* Clinical 3D visualization has made significant progress during the last two decades. However, such technologies have not yet been widely accepted in clinical practice because physicians are more familiar with the 2D images that were presented to them during medical training. Although standards for 2D imaging have long been established, they are different from standards required for 3D images. To make 3D imaging more reliable and widely used, we suggest that protocols be developed for the following:

    - *Standards in 3D image acquisition.*
    - *Standards in visualization parameters to categorize various tissues in 3D models.*
    - *Standards for interpreting 3D images.*

- *Validation Standards:* During the last decade, many surgical navigation software and instrumentation products have been developed and their relative accuracy reported. However, the validity of these systems is not comparable based on a set of common parameters. In part, discrepancies in the reported errors result from a lack of scientific data sharing, and the overabundance of methods used to measure and analyze system errors. There is a need to fund principal investigators who are willing to set standards for measuring the precision of various components (e.g., registration error vs. tracking error) of computer-assisted surgical systems. To make the validation process more compatible across platforms, we suggest protocols for:

- *Breaking down "overall system error" in any given system to its basic components.*
- *Establishing comprehensive protocols wherein all basic error components can be tested and measured using the same criteria.*
- *Initiating open dialog between the Centers of Excellence for communicating and sharing validation analyses and results.*

- *Automated Segmentation:* One of the topics of major interest in the medical imaging community over the last three decades has been developing application-specific algorithms for automated image segmentation and clustering. These efforts have been carried out primarily by radiology centers, and significant progress has been reported. The drawback of automated solutions is that they are computationally expensive, not always robust and repeatable, and as a consequence, are not always practical or reliable for surgical applications. There is a need to tap into nontraditional disciplines for redefining the requirements and deliverables of new segmentation algorithms. We suggest support for the following:

  - *Students and PIs from not only the field of medical image analysis but also from the fields of computer vision, mathematics, and statistical pattern recognition to design fresh segmentation concepts.*
  - *Identifying and conveying the interventional requirements of image segmentation versus diagnostic requirements to the scientific community.*
  - *Segmentation research based on IGT requirements (i.e., interactivity may be acceptable to make such algorithms faster and more reliable).*

- *Real-Time Visualization*: It is critical that surgeons interact with systems in a way that does not hinder performance. Therefore, the visual images necessary for navigation have to be generated at highly interactive rates, which is difficult to achieve using conventional, software-only solutions. Various groups have been working on implementing techniques for rendering medical-imaging data sets rapidly, but such algorithms are largely focused on 3D rendering of preoperatively acquired data. Areas of opportunity include:

  - *Real-time volumetric data deformation techniques.*
  - *Fast 3D visualization of intraoperatively acquired data, such as ultrasonic images.*
  - *Mechanisms for intuitive presentations of 3D information during ongoing surgical procedures, such as augmented reality.*

- *Data Correlation:* One of the biggest sources of error in CAS is tissue deformation that occurs after preoperative scans are taken and results from the position of tissue during the therapeutic intervention. Incorporation of intraprocedural changes, by correlating intraoperative data (US, EEG, stimulation, X-ray, and video) with the preoperatively acquired data (MRI, CT, PET) provides physicians with the preoperative data's high image quality while giving them a quantifiable method for calculating tissue deformation based on intraoperative data. Unlike radiological image/image data correlation (also known as registration), patient/image spatial registration for IGT is mainly conducted intraoperatively. Areas of opportunity include the following:

  - *2D/3D registration (e.g., intraoperative X-ray or endoscopic data registration with CT/MRI).*
  - *Identifying and developing quantifiable methods for the prediction and interpolation of tissue deformation during therapeutic procedures.*
  - *Developing novel mathematical algorithms for more precise and robust registration methods.*

- *Tracking Techniques:* One of the main limitations of CAS is accurate tracking of instrumentation. Tracking surgical tools in a stereotactic space is often done using optical tracking and/or magnetic tracking systems, both of which have limitations, such as requirement for direct line of sight or susceptibility to magnetic distortions. Significant improvements are necessary to develop truly usable systems that can track any instrument in any part of the anatomy. The NIH can advance the field by supporting research in:

- ○ *Designing novel instrumentation for tracking medical instrumentation. Special emphasis should be given to miniaturized tracking systems using nano-and microfabrication technology.*
- ○ *Investigating the effects that tissue types may have on sensing equipment for tracking.*
- ○ *Computer-controlled effectors (e.g., robots and control libraries), and interface standards (software and hardware) that can add tracking capabilities in a "plug and play" format to a variety of surgical tools.*

- *Machine and Human Interface:* Physicians must be able to focus on the patient and the procedure rather than on devices. Graphical interfaces must be interactive to allow the physicians to select from a variety of possible visualization formats. The machine interface (e.g., robotic arms) needs to be designed in a way that conforms intuitively to the physicians' needs, not vice versa. All other performance specifications, such as object tracking, trajectory enforcement, and geometrical transformations, should be carried out automatically. So far, very little attention has been paid to the usability of computer-assisted systems. Funding research in the following areas can enhance the effective utilization of CAS technology:

- ○ *Smart tools that can conduct intraoperative anatomical imaging, perform functional/molecular analysis, and/or assess the trajectory of the surgical path.*
- ○ *Smart displays that minimize the surgeon's need to coordinate hand-eye movements and that enhance exposure of the pathology.*
- ○ *Customized human/computer interaction interface tools for the sterile OR environment that eliminate the need for keyboards and a mouse yet are easy for the surgeon to interact with, such as virtual touch-pads, voice activation tools, electronic whiteboards, and video conferencing to facilitate interaction, surgical management, training, and collaboration.*
- ○ *Robotically activated devices under direct control of surgeons for "scaling" macroscopic movements of the surgeon to the microscopic confines of the surgical field (more dexterity).*

- *New Clinical Applications for Emerging Technologies*: Specific diseases and clinical/surgical applications must drive functional product development; surgeons should not be constrained by tools that have been developed prior to a clinical need. The introduction and implementation of new technologies in clinical practice could increase healthcare costs. Systems should be evaluated based on cost increase versus potential health benefits. Areas of opportunity include:

- ○ *Set the gold standard for assessing the impact of specific technologies on medicine.*
- ○ *Measure the benefits and drawbacks of different IGT technologies.*
- ○ *Create a training environment for teaching IGT technologies to the next generation of physicians.*

VI. Conclusion

The promise of IGT can only be realized by bridging the interdisciplinary natures of clinical, engineering, and computational research. Only by tight integration of these disciplines can the true power of biomedical imaging and bioengineering technologies be used in treating the majority of patients within the United States. With increased funding and effective cooperation among researchers and clinical practitioners, IGT and CAS (as a subset of biomedical imaging and biomedical computation) can advance healthcare while containing its costs.

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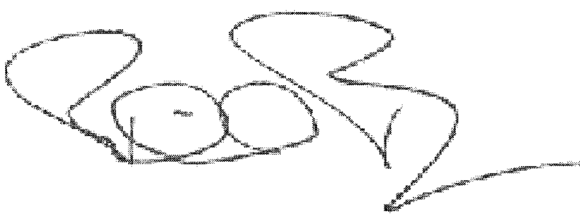

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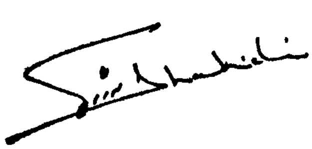

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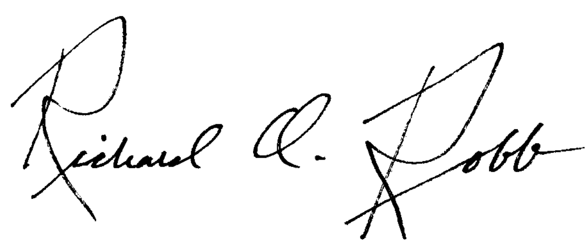

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