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Workshop Report

Final Report of the Technical Requirements for Image-Guided Spine Procedures Workshop*

April 17–20, 1999, Ellicott City, Maryland, USA

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SECTION 1: WORKSHOP OVERVIEW

Introduction

The "Technical Requirements for Image-Guided Spine Procedures" Workshop was held April 17–20, 1999, in Ellicott City, Maryland. The general objective of the Workshop was to determine the technical requirements for image-guided procedures in the spinal column, the spinal cord, and the paraspinal region. While the Workshop title indicated a focus on image-guided procedures, the Workshop's participants were encouraged to think more broadly and to include computer-assisted and robotically assisted spine procedures in their review. The workshop was by invitation only, and approximately 70 experts, about two-thirds of whom were Ph.D.s and one-third M.D.s, participated.

This document is organized as follows. After this introductory section, Sections 2–7 contain the reports of the six working groups. Each working group report consists of an overview and segments devoted to clinical needs, technical requirements, and research priorities. Section 8 is a workshop summary and Section 9 covers special sessions. There are three appendices: Appendix A is the workshop program, Appendix B lists the workshop participants, and Appendix C is the report bibliography.

Acknowledgments

A special debt of gratitude is due to the workshop sponsors:

* This report can also be found on the World Wide Web by starting at:

http://www.isis.georgetown.edu

and following the links to conferences and the Spine Workshop. Bound copies of the workshop report are available for $30 to U.S. addresses and $40 to other countries due to higher shipping costs. The report is 119 pages and includes 13 pages of color photos. Ordering instructions are on the web site, or the report editor can be contacted at: cleary@isis.imac.georgetown.edu

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Common Themes and Recommendations

From the Working Group reports, the following six themes have been identified:

1. **Spinal disorders** are a major public health problem and a potentially correctable source of disability. Surgical treatment, when indicated, produces variable outcomes that may be improved by less-invasive, image-guided procedures.
2. **Modeling, segmentation, and registration** are fundamental technical tools that still require major advances to be more clinically useful. These technical problems are important to many areas in image guidance, not just in the spine, but also in other clinical specialties. Validation is a significant issue here as well. It is interesting to note that, while progress has been made in addressing these problems and commercial systems incorporating some of this technology have appeared, many of the technical issues that dominated the discussion at this workshop are the same as those mentioned in previous workshops[4-6] on computer-assisted surgery.
3. **Improved image processing and display** is critical to advancing image-guided procedures of the spine and image-guided procedures in general. Several Working Groups commented that real-time image acquisition and display, in particular real-time three-dimensional (3D) rendering and fast, intraoperative, 3D imaging systems, would be extremely valuable in this respect.
4. **There is a significant communication and knowledge gap** between technical and clinical personnel. Each faction has its own vocabulary and specialized knowledge. While more people are becoming conversant with both areas, how to best bridge this gap and foster collaborative efforts is an important issue for further advancement of the field.
5. **Clinical outcomes studies** are important to help determine if these technological advances improve patient outcomes. Economic issues also need to be considered. While it is acknowledged that outcomes studies are difficult to design and carry out, they should be pursued and funding should be made available for them.
6. **Infrastructure issues**, such as reimbursement, liability concerns, and conflicts between specialties, may be as important as technical issues in advancing the field. Therefore, these issues must be addressed in addition to a focus on needed technical developments.

From these six common themes, as well as others mentioned in the Working Group Reports (Sections 2–7) and the Summary Presentation (Section 8), the following recommendations were made:

1. To hasten the development of **clinically useful applications of modeling, segmentation, and registration**, additional resources for research should be made available in these areas. These resources should be directed towards the development of medically relevant techniques, which may also require fundamental scientific advances.
2. **A common and open standard infrastructure** is needed for the next generation of image-guided operating rooms or interventional suites, to be used both for spine procedures and for all procedures in general. A request for proposals (RFP) should be issued to define this open standard, identify common elements, suggest possible architectures, and develop appropriate user interfaces. As part of this effort, NIH and other federal agencies should encourage partnerships between medical researchers and medical equipment designers and manufacturers to develop common elements for image-guided and minimally invasive surgery that include a research interface.
3. **Application testbeds** are needed to ensure clinical relevance, identify potential pitfalls,

and facilitate collaboration between technical and clinical personnel. The development of these testbeds is not supported by the current NIH R01 hypothesis-driven funding mechanism. Other funding mechanisms, such as the phased innovation award mechanism designed to encourage technology development and used in the recent request for applications on prostate cancer from the National Cancer Institute, should be created to fund these testbeds.

4. **Specific equipment and instrumentation** needs that are required to advance the field should be supported. For example, high-fidelity haptic interfaces, modular systems for spinal work and fast 3D visualization, and robotic instrumentation for surgery and therapy are prerequisites for advancing the field.
5. **Multidisciplinary training and education** should be supported, including programs that allow engineers and scientists to gain clinical knowledge and physicians to gain technical knowledge.
6. **A follow-up spine workshop** should be held in two or three years to track progress and re-evaluate the state of the field.

WORKING GROUPS

The Workshop consisted of plenary sessions and Working Group meetings. The plenary sessions were aimed at providing background for both clinical and technical areas. The Working Group meetings were to focus on the specific technical areas. Each Working Group had a technical leader (Ph.D.) and a clinical leader (M.D.). These leaders and each of the six groups' participants are listed in the Working Group reports.

The Working Groups were each charged with investigating a specific technology area. A general summary of the Working Groups' emphases are as follows:

Working Group 1: Operative Planning and Surgical Simulators. This group focused on preoperative planning, which will be increasingly used to define the best approach to the anatomy of interest, simulate the results of a surgical intervention, and evaluate the consequences of different approaches. The group also discussed surgical simulation for training and education as well as for preoperative planning.

Working Group 2: Intraprocedural Imaging and Endoscopy. This group discussed all of the imaging modalities that may be used during procedures, including the intraprocedural use of CT, MR, ultrasound, and fluoroscopy. As intraprocedural imaging becomes more common, the question of identifying the modality most appropriate for particular procedures will continue to arise. The trade-offs between cost, accuracy, and information provided were discussed. This group also considered the use of endoscopic images in spine procedures, and the potential for fusing endoscopic images with the 3D imaging capability of CT or MRI.

Working Group 3: Registration and Segmentation. This group focused on all aspects of registration including 3D/3D registration (such as CT to MRI), 3D/2D registration (CT to fluoroscopy), and registration for instrument tracking. While there has been a great deal of work done in registration and segmentation, the development of easy-to-use, robust, and automatic registration and segmentation algorithms is still an elusive goal.

Working Group 4: Anatomical and Physiological Modeling. This group discussed anatomical and physiological modeling as well as soft-tissue modeling, such as deformable models. The use of modeling in image-guided procedures is still in its infancy, and fundamental issues concerning the creation, use, and validation of models remain. Accurate and reliable models are key to advancing the state of the art in surgical simulation and operative planning, among other areas.

Working Group 5: Surgical Instrumentation, Tooling, and Robotics. This group considered surgical instrumentation, including cages and other devices for fusing the spine. Tooling includes the special-purpose devices needed to access the spine through percutaneous or minimally invasive techniques. In the future, robotic systems may be used to assist in these procedures. These robotic systems may include passive, semi-active, and active systems.

Working Group 6: Systems Architecture, Integration, and User Interfaces. The role of this group was to define the systems architecture for the image-guided spine procedure systems of the future. For example, how should the various technologies such as registration, tracking, and 3D visualization be integrated into a system that the clinician can use? What is the appropriate user interface for such a system (3D mouse, heads-up display, touch screen, voice-operated, eye tracker, etc.)? This group also discussed various technologies that were not covered by other groups, including image-guided surgery systems.

Workshop Rationale

When we first starting planning for the Workshop in the fall of 1997, the question arose as to why another workshop was needed. The reason is simple: workshops develop infrastructure and help lay the groundwork for the development of the field. For example, early workshops on image-guided therapies in 1991[5] and computer-assisted surgery in 1993[6] helped set research directions for the field. The 1993 computer-assisted surgery workshop was followed by an NSF-sponsored workshop on robotics and computer-assisted medical interventions in 1996.[4] At this point, research activity in the field is beginning to increase noticeably, as evidenced by specialty conferences and the appearance of dedicated journals. While these earlier workshops were general and included all clinical areas, we are now seeing the emergence of specialty workshops, such as the spine workshop which is the subject of this report. Other specialty workshops include the prostate cancer workshop in June 1999[§] and the several image-guided workshops convened by the National Cancer Institute and the Office of Women's Health in the Spring of 1999.

Image-Guided Procedures

Image guidance has been used in one form or another in various medical procedures since the introduction of X-rays. Recently, however, there has been a marked increase in interest in this field, which can be largely attributed to developments in volumetric imaging and increased computer power.[7] Volumetric imaging includes computed tomography (CT), magnetic resonance imaging (MRI), and 3D ultrasound, which are capable of producing a 3D representation of the human body. The memory capacity, processing capability, and relatively low cost of present-day computers enable the rapid analysis of these 3D data sets.

Image guidance, in the form of frameless stereotaxy, has been driven primarily by the neurosurgery community. Neurosurgery in the brain requires precise navigation through an anatomically complex and delicate organ. For neurosurgery, computer-assisted surgery (including image guidance) is an enabling technology that allows new techniques to be employed.[2] However, image guidance as currently used in the spine is primarily a safety measure for preventing iatrogenic injuries. The Workshop organizers hope that this meeting will be a first step in expanding the use of image guidance in spine procedures by identifying the relevant clinical areas, defining the technical problems, and proposing potential solutions.

SECTION 2: OPERATIVE PLANNING AND SURGICAL SIMULATORS
The Report of Working Group 1

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Overview: Definitions and State of the Art

This Working Group explored the requirements for pre- and intraoperative planning and simulation technologies that can be used in image-guided surgery of the spine. The first step was to define the terms: simulator and planner. Using the broadest definitions possible was thought to be important so as to avoid biased preconceptions toward the value of certain technologies currently available and known to our participants.

Simulators and Planners: Definitions

A **Simulator** is defined here as an interactive virtual environment used to improve human performance. Note that this definition does not require that a simulator be computer based. A simulator is virtual in the sense that it behaves in some ways

§ http://www.amainc.com/admetech/admetech.html

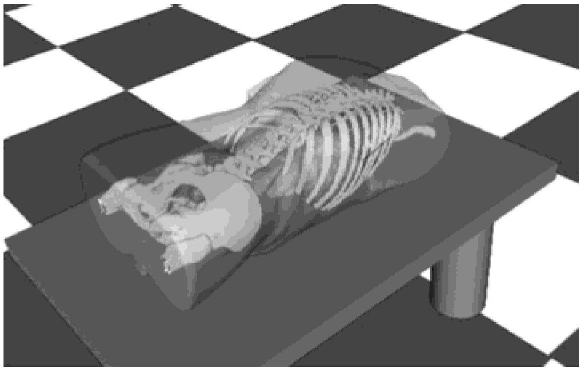

Figure 2-1: Three-dimensional visualization for surgical simulation (Courtesy of Daniel Blezek, Ph.D., and Richard Robb, Ph.D., Mayo Clinic).

equivalently to the real patient, but is not the real patient. Thus "sawbones," or plastic models of anatomy, would qualify as simulators by our definition. In addition, the simulator must permit interaction, because interactivity is necessary for learning and practicing perceptual motor skills. We also do not confine the role of simulators only to training, because they could also be used for planning.

A **Planner** uses tools, including simulation, to improve human performance on the patient-specific task at hand. There is overlap between simulation and planning, but neither is inherently a subset of the other. The essence of a planner is to provide assistance in performing a procedure on a specific patient.

State of the Art: Advances in Surgical Simulators to Date

Clinically, the state of the art in simulators for training is still at a primitive stage, and uses cadavers and sawbones for teaching purposes. The state of the art in planning takes several forms, including multi-modality radiological studies and interventional magnetic resonance imaging (MRI). Commercial image-guidance systems are available, but their utility in the spine is limited. Currently, these systems are used for pedicle screw sizing and basic trajectory planning.

The state of the art in computer simulation has advanced to a level of prototype partial task training. Specifically, only parts of research or commercially-oriented procedures can be demonstrated via computer simulation. For example, 3D computer graphics workstations and PCs permit surface models of moderate complexity, on the order of tens of thousands of polygons, at interactive update rates of 15 Hz or more. An example of 3D visualization is shown in Figure 2-1. Haptic interfaces with force feedback are commercially available. Most operate using three degrees of freedom (DOF), although six-DOF devices have recently been introduced, as shown in Figure 2-2. The physical modeling methods used to simulate tissue behavior and generate forces for the haptic display are still primitive, however. Methods in the literature are typically based on mass-spring-damper meshes, linear elastic finite elements, or a variety of non-physically based, ad hoc methods.

Clinical Needs: Common Tasks and Procedure-Specific Needs

Our Working Group separated image-guided spine procedures into two tasks that were common to all major procedures and others that were procedure-specific.

Common Tasks and Needs in Image-Guided Surgery

The first major common task of image-guided spine procedures is to identify the optimal trajectory for the procedure, which is a function of the anatomical level of the spine on which the procedure will focus. This task includes defining the starting and goal points of the intervention and identifying a working corridor that provides adequate access while minimizing the risk of damage to fragile tissues. The planner must provide the clinician with the ability to identify structures, and then to determine relationships on the global scale from which to plan a surgical approach and, on the fine scale, to verify adequate clearance between structures. Im-

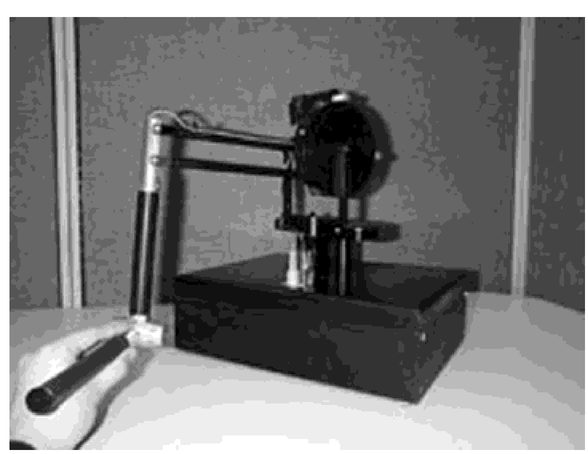

Figure 2-2: Six-degree-of-freedom force feedback device (Courtesy of SensAble Technologies).

ages are obtained well before the operation, which allows for a planning time-frame of anywhere from hours to weeks of off-line computations such as segmentation. However, intraoperative planning should provide sufficient speed and interactivity for performance of these tasks to be accomplished rapidly within a few minutes.

The second common task involves obtaining adequate perception of the anatomy of the spine. This means providing appropriate information to the clinician to support clinical decision-making in real time during the procedure. Two major elements are required to complete this task. The first is tissue discrimination, or identifying the type and characteristics of tissues so that damage to fragile structures can be avoided. Intraoperative imaging and/or registration with previously obtained and segmented images may provide this needed information. However, it is important in this instance to have precise information on the position of relevant structures which are relative to the current location. The second element focuses primarily on "location", or knowing where one is relative to the desired trajectory. This assessment requires obtaining global as well as local information.

Procedure-Specific Tasks and Needs in Image-Guided Surgery

This Working Group also identified procedure-specific needs for decompression, stabilization, and deformity correction procedures. The major need in decompression is to provide sufficient soft-tissue resolution to enable the surgeon to remove the minimum amount necessary while avoiding neural damage. In stabilization, better models and planning are needed to enhance the placement of instrumentation to achieve the optimal biomechanical performance of implants. Biomechanical models also need to be developed and integrated into planners to aid in deformity correction procedures. These models would be useful for analysis and prediction of the response of the tissue and implant to the procedure, including loads, deformation, and fatigue.

Technical Requirements for Planning and Simulation Tools

This Working Group organized the technical requirements based on the clinical tasks described in the previous section. These requirements relate to trajectory planning needs, interactive simulation during spinal surgery, and increased need for human factors research into the efficacy of tasks completed during image-guided surgeries.

Preoperative Requirements for Planning

To plan a trajectory necessary for a procedure, accuracy of about 1 mm is needed to distinguish important structures. The level of resolution in a simulation would ideally be about 10 times higher (or 0.1 mm) to achieve sufficient fidelity in geometrical and physical models. It would thus be desirable to have high-resolution data sets available for incorporation into simulators for later use in intraoperative planning.

The ability to segment soft tissues to distinguish bone from nerve structures and vessels is critical for both planning and simulation. Preoperatively, there is time to run segmentation off-line over a period of several hours up to weeks, but to be of use intraoperatively, the period must be less than about 5 minutes. Achieving these precision and time requirements is a high priority for enabling effective trajectory planning. Intelligent assistants to aid the clinician in planning, as well as intelligent tutors for simulation, will be useful, but depend first on the achievement of the resolution quality- and time-related priorities described above, and so are not as critically immediate an issue.

Requirements for Intraoperative Simulation

Issues Related to Perception and Visualization. There are additional technical requirements for achieving adequate anatomical perception during a procedure. The clinician must be able to distinguish tissue type and determine its current location within the anatomy. Three-dimensional image-to-patient/instrument registration, discussed in greater detail by Working Group 3, is very important in this regard. The information provided by preoperative and intraoperative imaging modalities must be integrated in an interactive manner that allows the clinician to readily alter viewpoints and edit plans. There is a great need for integrated modeling as well, so that the surgeon can predict the effect of treatment. This development needs to include mechanical models and supporting data to predict the effects of

- instrumentation in deformity correction,
- treatments on the courses of nerves and the resulting strain, and
- the interaction between bone and implants.

In simulation, haptic interfaces are still relatively in their infancy. There is a need for high-fidelity, six-degree-of-freedom devices with force feedback and physical models of instrument-tissue interaction to simulate full contact. Relevant data on soft-tissue viscoelastic properties must be obtained to support these models.

Issues Related to Cognitive and Human Factors. A subtle but important aspect of image-guided surgery is the manner in which surgical information is displayed and how the clinician interacts with these data. From the information provided to the surgeon, he or she must construct a 3D mental model of anatomical space and then use this model to plan a procedure. Completing the process effectively can be challenging. Even when a 3D data set is available, every viewpoint of the data provides different information. The clinician must therefore integrate multiple views to perform a complex and often highly precise action, such as the placement of pedicle screws. Enabling effective processing of, and interaction with, anatomical data received by surgeons during image-guided surgery is an area requiring much further study.

Although a fair amount is known about how people construct and represent knowledge of spatial information, there is still little known about the integration of spatial skills in solving complex problems. Human factors experts should study the role of spatial cognition in surgery, driven by task analyses, to determine the optimal means of presenting information if image-guided surgery is to meet its potential.

Need for Predictive Biomechanical Models. In addition to the general need for biomechanical modeling discussed above, there are specific technical development needs for effectively completing/improving specific procedures which use image-guided surgery. For example, the biomechanical effect of instrumentation in stabilization procedures for instability, deformation, and fractures is still poorly understood. Development of models of the interaction between the disk and nerves would improve the performance of disk herniation and disk/nerve root decompression procedures. Initially, gathering and collating empirical data from the experience of multiple clinical groups may help to predict the response of anatomical structures within the spine to loads on typical instrumentation configurations. Fully predictive biomechanical models would eventually aid in the placement of instrumentation. Finally, intraoperative imaging should be capable of distinguishing changes in soft tissue for the purpose of gauging the progress of a procedure. An example is checking the adequacy of tumor resection to ensure that all of the tumor has been removed.

Research Priorities

Table 2-1 summarizes and prioritizes the technical requirements needed for effective planning and simulation of image-guided surgery of the spine described in the previous sections.

Table 2-1. Research Priorities for Planning and Simulation Needs for Image-Guided Spinal Surgery

High Priority
- (*) Task analysis and cognitive modeling of human performance by human factors experts, with special emphasis on the role of spatial cognition in image-guided surgical spine procedures.
- (*) Development of high-fidelity haptic interfaces which can simulate anatomical models of varying complexity.
- (*) Development of visualization and interaction algorithms and modes to allow the clinician to alter viewpoints and interactively plan the procedure.
- Imaging tools with accuracy of 1 mm resolution for discrimination of structures needed for planning purposes.
- Image data sets with 0.1 mm resolution for simulation purposes.
- Segmentation algorithms for distinguishing bone from neural structures and vessels.
- Dynamic registration methods for intraoperative planning.
- Biomechanical models and data for deformity correction, effects on nerve location and strain, and bone-implant interaction.

Medium Priority
- (*) Prediction of spine and instrumentation response to loads, based on an empirical data library.
- (*) Development of automated aids for corrective instrumentation placement.

Lower Priority
- (*) Intelligent assistance for planning needs.
- (*) Intelligent tutoring for simulation purposes.
- Biomechanical models for predicting disk-nerve interaction.

(*) Asterisk identifies research priorities of special importance to planning and simulation. Other priorities are shared with one or more of the other Working Groups.

SECTION 3: INTRAPROCEDURAL IMAGING AND ENDOSCOPY
The Report of Working Group 2*

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Overview

Five imaging modalities that can be used to guide surgical and interventional procedures in the spine are discussed: computed tomography (CT), magnetic resonance imaging (MRI), X-ray fluoroscopy, ultrasound, and endoscopy. Each of these tools is described in terms of capabilities for real-time capture and display as well as in terms of relative costs.

Clinical Needs

A range of clinical/pathological conditions that are judged by this Working Group to be amenable to image-guided procedures of the spine (such as procedures of the ilio-sacral joint and vertebral fractures) are identified and ranked in importance, in terms of immediate impact and numbers of patients. Types and adequacy of imaging modalities currently used for spinal interventions are noted in three tables [not reproduced here].

Technical Requirements

No single imaging modality currently meets the clinical and technical needs for both diagnostic and therapeutic procedures of the spine. In this Working Group's *Future System Requirements for Image-Guided Spine Procedures*, five phases of development for requirements of a future, more inclusive, multi-applicable system for image-guided procedures are identified and described. Areas focused on include preoperative imaging needs, improved virtual navigation, and verification of tissue status, among others.

Research Priorities

Two aspects of priorities defined by this Working Group are:

1. Those related to technical development issues. The authors call for development of open and modular imaging systems, among other design needs.
2. Those which call for changing the infrastructure that is currently in place among those working in the area of spine procedures. The authors focus on needed changes in tasks and roles, particularly in the training needs of team members involved in image-guided procedures.

SECTION 4: REGISTRATION AND SEGMENTATION
The Report of Working Group 3

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* Editor's note: This chapter has been accepted for publication in Academic Radiology, and therefore only an executive summary is included here.

Overview: The Use of Imaging in Registration and Segmentation

Image-guided surgery is widely accepted as the standard of practice for many intracranial procedures. For a number of reasons, some related to technical difficulties, image-guided surgery is not yet generally used for spine procedures, even though such guidance could greatly enhance the current standard of practice. The purpose of this chapter is to analyze the technical requirements that are needed for manipulation of patient image data to help define criteria by which image-guided surgery can be used effectively for spine procedures.

Image-guided surgery may employ image data in any of three ways:

- First, preoperatively acquired images may be used for surgical planning, surgical simulation, or model creation. This procedure often extracts particular structures of interest from the image data.
- Second, images of the patient may be obtained directly during an operation for the purpose of helping to guide the procedure. These intraoperatively acquired images are often of lower quality or informational content than those obtained preoperatively, however.
- The third method of employing image data combines intraoperatively acquired images of lower informational content with higher quality, preoperatively obtained images. This procedure of combining images requires that the intraoperatively acquired images be placed within the same coordinate system as the preoperatively acquired images. Both sets of images must also be placed within the patient's coordinate system in the operating room, in addition to the coordinates of the surgical instruments used. For imaging procedures such as these to be of clinical utility, they must meet certain constraints of both time and accuracy. Furthermore, for imaging procedures such as these to obtain clinical acceptance, they must also undergo rigorous tests of validity.

This Working Group's report analyzes the technical requirements for **segmentation** and **registration** of medical images as applied to the particular problems associated with spine procedures.

Segmentation and Registration: Definitions

Segmentation is defined as the delineation and labeling of image regions as distinct structures. Segmentation is required to extract and define objects of interest from image data for anatomic differentiation, to create models, and to implement some forms of registration.

Registration is defined as the mapping of coordinates between any two spaces specifying volumetric images, the patient, or the instruments. Registration is required to map one image to another, and to map any image to the patient.

Clinical Needs: Issues in the Use of Image-Guided Spine Surgeries

Several of the approaches to surgery of the spine that are discussed below are applicable to the current level of technology. However, there is also a strong need for the development of practical, clinically useful, intraoperative 3D imaging systems, which the authors believe to be feasible in the next five to ten years. A number of research issues require close attention, as indicated below.

Issues of Accuracy and Speed

For the clinician, image guidance with an accuracy of 1–2 mm is required in order to avoid injuring the spinal cord while undertaking surgical procedures. Clinical requirements of registration speed vary according to the procedure performed. For some procedures, such as pedicle screw placement, it may be acceptable to wait 5 minutes until registration is undertaken. For other procedures, such as those performed under endoscopic guidance, registration must be performed within 10–20 seconds to allow the procedure to continue smoothly. In general, for intraoperative procedures, because delay is detrimental to the patient's welfare, the upper bound on allowable delay for technical processing of image data depends on the perceived clinical contribution of the information. The delay timeframe is usually in the range of seconds to a few minutes.

Four Categories of Spine Procedures

We define four categories of spine procedures for which the use of image-guided surgery appears promising in improving patient health outcomes. These categories are:

1. Instrumentation and percutaneous procedures
2. Resection of tumors and arteriovenous malformations (AVMs)
3. Treatment of spinal instability
4. Treatment of disc disease

Some instrumentation procedures, such as correction of scoliosis, would benefit both from direct image guidance as well as from creation of a preoperative model of the spine and tracking of intersegmental motion for predicting tension upon the spinal cord. Other types of instrumentation, such as pedicle screw placement, would substantially benefit from direct image guidance.

1. **Instrumentation and percutaneous procedures**
   Many percutaneous and almost all instrumentation procedures are currently performed either in the CT scanner or (most commonly) under fluoroscopic guidance. X-rays of a typical instrumented patient are shown in Figure 4-1. A high-speed, image-guided method of registering the therapeutic instrument with the patient and of accurately determining the instrument's trajectory with reduction of radiation exposure to the patient would be beneficial. Such advancements would affect large numbers of patients.
2. **Tumor resection**
   Removal of the majority of spinal tumors probably does not require special image guidance. However, image-guided surgery may be important for the removal of some large tumors which have extended into the chest or pelvis, and it is likely to be important to the treatment of almost all AVMs. For the latter, as well as for any highly vascular tumor, segmentation and symbolic description of the blood supply to the lesion and to the normal spinal cord would add significantly to current therapeutic standards, although only a relatively small number of patients would be affected. A typical spinal tumor is shown in Figure 4-2.
3. **Treatment of spinal instability**
   Spinal instability is a common problem. When instability occurs below the level of C2, surgical intervention is almost always required. For many patients, such as the one shown in Figure 4-3, image-guided surgery with registration of preoperative images to the patient would be beneficial for the same reasons that image guidance of instrumentation procedures would be useful.

   It should be noted, however, that some patients with unstable spines may exhibit abrupt translations of spinal segments during operative positioning or even during the procedure. Such pathological movement is difficult to model and predict. High-speed, 3D intraoperative imaging would provide the best method of managing such problems.

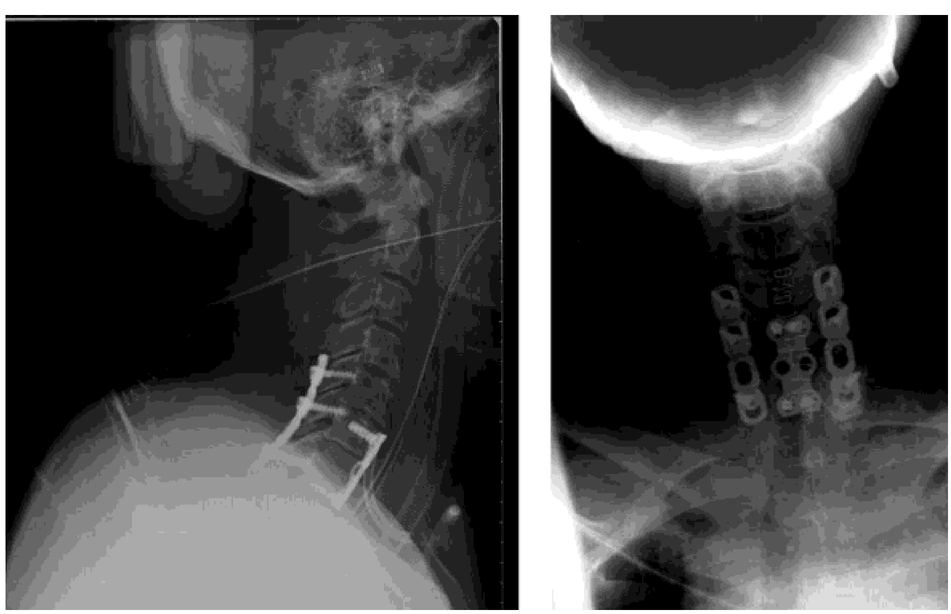

Figure 4-1: Surgical instrumentation (Courtesy of Elizabeth Bullitt, M.D., University of North Carolina). The patient has undergone both anterior and posterior cervical plating. Even minor errors in the angle of screw insertion can produce patient injury.

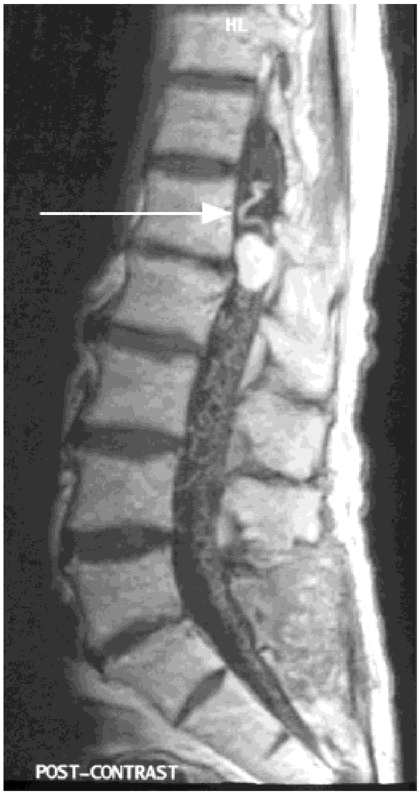

Figure 4-2: Spinal tumor (Courtesy of Elizabeth Bullitt, M.D., University of North Carolina). Note the associated mass of blood vessels similar to an arteriovenous malformation (AVM). Some of these blood vessels also supply the conus of the spinal cord (arrow).

4. **Disc removal**
   Standard, open operative methods of disc removal do not require special image guidance. However, new methods of endoscopic or percutaneous disc removal do. It is not yet clear, however, that these new methods are superior or equal to standard operative methods. Segmentation of disc from scar and of scar from nerve root would be highly valuable during disc removal by any method, however, in order to reduce the chance of nerve root injury. Intraoperatively, it is often difficult to find a disc fragment under a layer of scar tissue that is adherent both to the disc fragment and to the nerve root. Precise knowledge of the locations of both the disc fragment and of the nerve root would reduce the amount of exploration required and the possibility of nerve root injury.

Technical Requirements: Validation, Registration, and Segmentation

As in other medical imaging applications, the clinical needs involving image-guided surgeries of the spine, as described above, do not directly map to a well-defined engineering problem. The challenge for our Working Group was to address clinical needs in the context of well-formulated technical problems from which improvements would provide clinical benefits and identify realistic boundaries for the amounts of accuracy and speed required of such procedures. These technical problems include segmentation, registration, and a component-wise and overall system validation, as described below in order of perceived priority.

Validation

In the course of the Workshop, as well as during this Working Group's meetings, serious concerns were expressed about the need to validate existing imaging systems. Estimates regarding the accuracy with which the surgical instrument can be placed were varied. Furthermore, procedures for the overall validation of the system or its components were not unambiguously defined. Thus, research efforts to address validation issues in the spine are of highest priority. Specifically, the measurements of

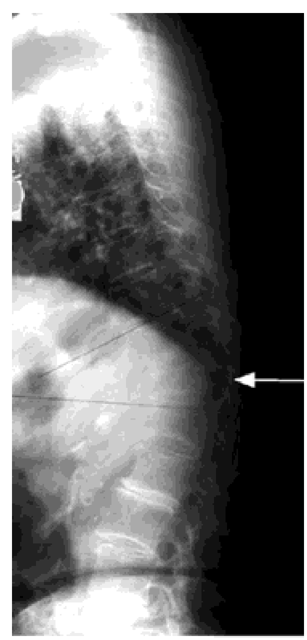

Figure 4-3: Spinal instability (Courtesy of Elizabeth Bullitt, M.D., University of North Carolina). This patient has a typical thoracic compression fracture (arrow) with kyphosis and angulation of the spine. Surgery was required.

accuracy/precision, robustness/stability, reliability/reproducibility, and, finally, clinical utility (e.g., as measured by time required, extent of user interaction, surgical value, etc.) are most significant.

Furthermore, there is a need for the compilation of a database which includes a variety of measurements, including an absolute standard for validation assessment. From this database, existing and future registration algorithms can be compared effectively. The generation of this database is an item of high priority, and it should consist of diagnostic and therapeutic images with embedded fiducials as the "gold standard".

Registration

Registration involves aligning distinct coordinate systems that are available from volumetric, preoperative images (typically CT, or CT and MRI), patients, instruments, and intraoperative images. Our Working Group classified registration techniques into three categories, as follows:

1. 2D image-3D image registration
2. 3D image-patient/instrument registration
3. 3D image-3D image registration.

From a clinical perspective, preoperative planning usually involves 3D image-3D image registration, while intraoperative procedures may rely on either 2D image-3D image and 3D image-patient/instrument registration. If interventional MRI/CT is available, then intraoperative procedures can rely on 3D-3D imaging attained by registering intraoperative lower-quality images with higher quality preoperative images.

Each of these registration techniques is described in our Working Group's perceived order of significance.

2D Image-3D Image Registration. A typical example of 2D image-3D image registration is the registration of intraoperative fluoroscopic images (2D) with preoperative CT data sets (3D). Since 3D intraoperative imaging is not currently widely applicable (nor believed to be so in the near future), we view 2D image-3D image registration as a high-priority research area. In addition, for certain procedures, the direct registration of preoperative fluoroscopic images with intraoperative MR images would alleviate the requirement of acquiring CT data.

Our Working Group identified three areas where technical improvements in this image registration category were needed: accuracy, speed, and ease of integration in a clinical protocol.

3D Image-Patient/Instrument Registration. The 3D image-patient/instrument registration procedure brings the coordinate system of the patient, as measured by the instrument, in registration with the coordinates of the patient in the 3D preoperative image. Currently, this procedure is accomplished by "point pair" matching, in which anatomical landmarks are selected interactively and the two coordinates are registered and constrained by the matched landmarks. Since the "landmarks" (examples being spinous processes and medial edge of facet) are not defined by pinpoint accuracy, but rather have finite extent, the accuracy of the registrations that are obtained via this method is limited.

Alternatively, some systems use measurements from the surface of the bone to generate a "cloud of points", which are then registered to surfaces extracted from preoperative images. Unfortunately, the variations in the distribution of generated clouds of points lead to inaccuracies in the measurements. There is, however, the potential to generate the uniformly distributed cloud of points via laser, ultrasound, video, or video/stereo sensor technologies to achieve better accuracy.

A second drawback of the systems based on "cloud of points" is that, because only the accessible/visible portion of the bone is measured, small inaccuracies in matching this portion to extracted surfaces lead to large inaccuracies in the "blind" or inaccessible portion of the vertebrae. The clinical implications related to these substantial inaccuracies are obvious.

Our Working Group suggested the use of ultrasound (US) as the modality having the greatest potential to address this particular problem. Examples might include placing US patches on the belly of the patient, or even using the bone itself as the US transmitter! It was also suggested that constructing a surface model from the cloud of points first and then matching the two surfaces will incorporate more of the geometrical structure in the matching process, thus constraining it and leading to more accurate registrations.

3D Image-3D Image Registration. The 3D image-3D image registration is valuable when, in several of the types of spine procedures currently undertaken, both CT and MR images are acquired. The intraoperative use of MR images in conjunction with fluoroscopic images requires that there be a preoperative registration of these two modalities. In addition, this registration process, when combined with fusion, leads to better presentation of the data needed for preoperative planning. In the future, when interventional 3D imaging becomes widely available, 3D image-3D image registration will be needed to augment the lower-quality intraoperative image with the higher-quality preoperative image(s).

Particular technical requirements of this process are assessed as follows:

- Requirements for speed are not as stringent for preoperative registration as for intraoperative ones; however, delays need to be in minutes and not hours for practical reasons.
- The extent of user interaction should not exceed more than a few minutes.
- Accuracy is, as with other registration types, a significant concern.

Segmentation

The generally shared view of this Working Group was that segmentation of preoperative and intraoperative images is typically required primarily as a means for providing surface-based registration methods. However, in several distinct areas, segmentation represents an important "stand-alone" problem.

First, in some applications, anatomical structures need to be differentiated, as in preoperative surgical planning to correct an arteriovenous malformation (AVM) or in differentiating disc from scar tissue. Second, segmentation is required for building anatomical and physiological models needed for biomechanical modeling, a topic addressed by Working Group 4. These models would then be used for simulation and training purposes. Third, segmentation is needed as a step towards building digital, or electronic, atlases of the spine which depict not only typical spinal anatomy, but also its relative geometry and alignment, as well as typical variations in anatomy.

For spinal surgery, segmentation will be most commonly useful when applied to bony structures. Other structures are also significant in some cases, however. Examples include definition of the spinal cord during scoliosis surgery, vascular structures during resection of AVMs, and some tumors. Figure 4-2 showed a complex case of an AVM and tumor involving the spinal cord. Segmentation of the various structures with definition of the blood supply of the cord and tumor would have been of great help intraoperatively during this procedure.

In summary, segmentation seems likely to be useful in the following clinical areas:

1. In definition of the boundaries of bony surfaces in order to help guide instrumentation procedures such as pedicle screw placement or scoliosis surgery. Accurate segmentation combined with registration of the patient to the preoperative CT scan could, in such cases, prevent mis-insertion of a screw into neural structures.
2. In definition of the vascular territories of vessels feeding highly vascular tumors or AVMs. Knowledge of the structures supplied by an individual vessel could help prevent interruption of an artery that, unknown to the surgeon, supplies the spinal cord as well as the lesion.
3. In the delineation of disc, scar, and neural tissue in order to reduce the amount of exploration required and the chance of tearing the dura during "redo" disc operations.
4. In definition of structures used for both 3D-3D and 2D-3D registration.
5. In the creation of biomechanical spinal models and atlases of spinal anatomy.

It also should be noted that segmentation is neither required nor the best approach for several other types of clinical problems. For example, the majority of tumor removals and "first-time" disc removals by open operation require neither image guidance nor segmentation. Although surgery on a grossly unstable spine would benefit from image guidance, such guidance would probably best be approached through direct, 3D intraoperative imaging. Nevertheless, the number of procedures that would benefit from segmentation either directly or indirectly (through use of segmentation as a prelude to registration) is significant.

Research Priorities

This list summarizes the research priorities we view as important to image-guided spine surgery. We view all items in this list as important.

1. Long-term goals

   Development of intraoperative, fast, 3D imaging systems of reasonable cost that allow easy patient access with preservation of a sterile field; that can cover a large volume while providing high detail; and that limit the current problems of radiation (CT) or fringe field (MR).

2. Shorter-term goals
   a) Emphasis on validation of methods, with establishment of accepted criteria for evaluation of registration methods, creation and use of a standard database with embedded fiducials, and measurements of accuracy/precision, robustness/stability, reliability/reproducibility as well as of surgical utility (the time and user interaction required).
   b) Development of accurate, intraoperative 3D-2D image registration (e.g., registration of intraoperative fluoroscopic images with a preoperatively acquired CT scan, or registration of endoscopic images with a preoperative MR scan). Deformable registration will be required in many cases.
   c) 3D image-patient/instrument registration. Ultrasound may have potential in this area, possibly by placing patches on the abdomen or even by using the bone itself as the ultrasound transmitter.
   d) 3D image-3D image registration, particularly in regard to CT-MR registration. As the patient position may be different during each procedure, deformable registration may be required. Issues of speed and the extent of user interaction that is required are important.
   e) Segmentation for delineation of bony surfaces during instrumentation procedures, differentiation of tissues (e.g., disc versus scar), biomechanical model building, and the creation of atlases of spinal anatomy which depict elative geometry and alignment.

SUMMARY

Spinal surgical procedures can significantly benefit from image-guided surgery, which is currently widely accepted for intracranial procedures. Our Working Group addressed the technical requirements for the use of image-guided procedures in the context of clinical needs in surgery of the spine. The highest priority item is the development of procedures for the evaluation of an overall system and its components. The development of widely accepted clinical systems requires improvements in accuracy, speed, extent of user interaction, and ease of integration in a clinical protocol, which in turn demands the design of technical innovations for registration.

SECTION 5: ANATOMICAL AND PHYSIOLOGICAL MODELING
The Report of Working Group 4

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OVERVIEW: THE ANATOMICAL AND PHYSIOLOGICAL MODELING PROCESS

The anatomical and physiological modeling development process includes

- model representation,
- image segmentation and registration (both to atlases and real-time adaptations),
- model construction,
- visualization and image display,
- simulation,
- plan optimization, and
- validation and adaptations to the systems.

Integration of each of these processes will play a critical role in the development of comprehensive models.

Innovative, computationally efficient methodologies must be developed which integrate rigid-body modeling with deformable modeling and reconstruct (redefine) the model owing to the effects of these external influences. Physiological modeling of the interface between the soft and hard structures that are present in the spine is another important task. Eventually, all of these models need to be patient-specific models. This construction will require successful mapping from models to patient-specific data sets. For initial model development, research should focus on soft-tissue modeling, segmentation of heterogeneous tissue components, basic biomechanical properties, and proper alignment and positioning of component parts.

Modeling: An Overview

All image-guided spine procedures require some form of pretreatment planning. The planning process aims toward translating, integrating, and coupling preoperative computer-constructed models and therapy plans with intraoperative actions. The desired goal of this planning is to better understand both normal and disease or injury processes and to optimize care and management of the patient.

The degree of complexity of the pretreatment planning process can vary considerably. Planning efforts can range from creating simple visualizations of image data sets to developing highly sophisticated models and execution plans that may require augmentation of the surgeon's eye and/or facilitating physician interaction with multiple data sets and the use of patient-specific simulations. Close assessment of anatomical and biomechanical or physiological models of the patients is central to the planning process.

Modeling and Image-Guided Therapy

The term "modeling" has many different meanings with respect to image-guided therapy. For the purposes of this chapter, modeling will focus on the development and/or use of anatomical/physiological and/or biomechanical data sets that provide opportunities to predict, evaluate, simulate, validate, develop, and enhance the outcomes of surgical or other therapeutic image-guided spine procedures. The modeling process may involve integration of multiple forms of both anatomical and functional image data sets with anatomical atlases, biomechanical data, and computational algorithms. In addition, this interactivity requires obtaining and integrating information regarding the physical properties of surgical and therapeutic instruments, and of sensor input data that are needed to predict the interactions of the surgeon and instruments with various tissues.

Modeling of the spine and paraspinal region for the above applications, such as prediction and validation, is a formidable task and one that is in its infancy of development. A true understanding of how such models can be used either in training or pretreatment planning cannot ignore the complex interactions of biomechanics and physiology or pathophysiology prior to, during, and following the therapeutic intervention. Our understanding of outcomes requires that we first understand the basics of modeling the normal spine and paraspinal region. The development of useful models will require validation of the visual and physical parameters as well as the acceptance of and value to the physician end-user.

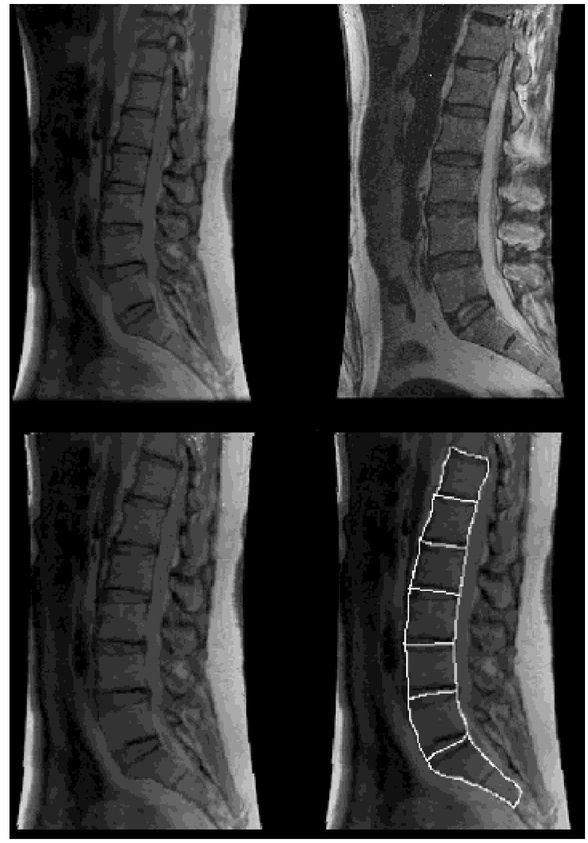

Figure 5-1: Elastic registration of spine images (Courtesy of Christos Davatzikos, Ph.D., Johns Hopkins University). The images in the top row are midsagittal MR sections from two different individuals. The bottom left shows an elastic deformation of the model (top left) to the target (top right). The bottom right shows an overlay of the bottom left image with an outline of the target, indicating a good registration at all levels of the spine.

The Registration Process of Modeling

A fundamental issue that arises when using anatomical models is that these models must somehow be adapted to the individual anatomy of a patient. Information that is associated with these models is then automatically transferred to the patient's images. This process is achieved via registration, which in its simpler form is rigid, and in a more complex form is deformable, perhaps even incorporating physical properties of anatomical structures.

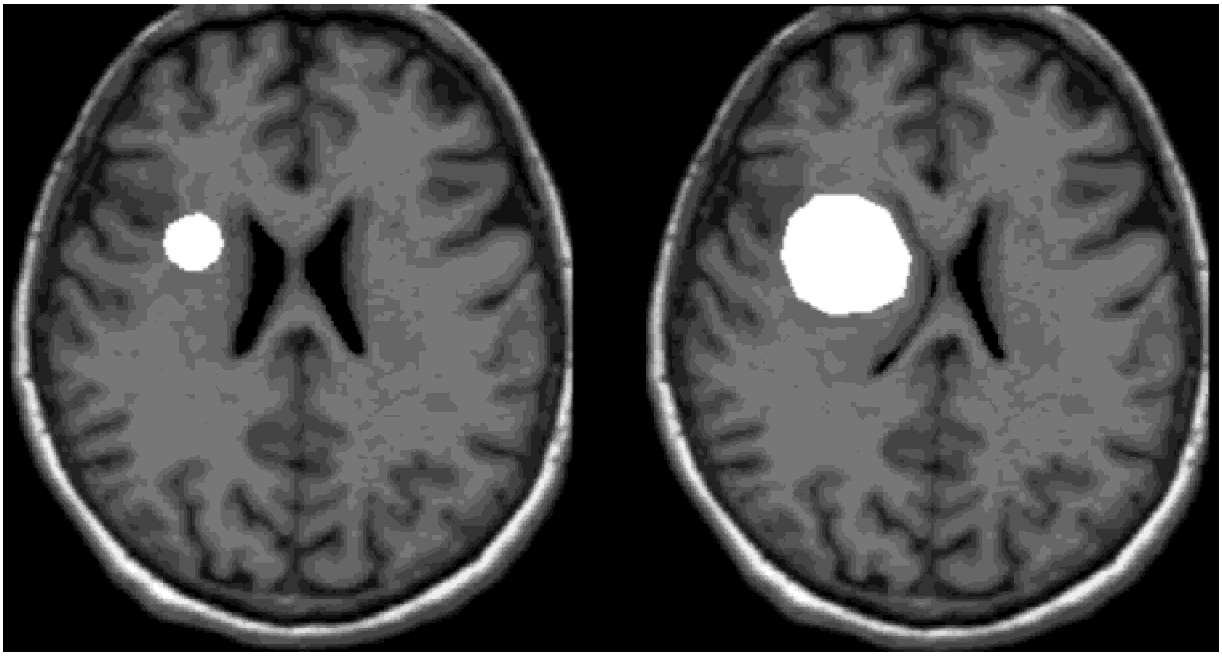

Figure 5-2: Finite element simulation of tumor growth in the brain (Courtesy of Christos Davatzikos, Ph.D., Johns Hopkins University). Left: MR image of a normal subject. Right: Simulation of the soft tissue deformation.

Registration models should initially focus on transforming image data to rigid or nondeformable models, with deformable models and soft tissue modeling being of second priority. Real-time registration of intraoperative images with atlases and preoperative models are necessary for performing effective image guidance and obtaining accurate intraoperative data. Initial work in the modeling process should concentrate on those preliminary procedures that require simpler registration methods, such as rigid bodies interfaced with elastic spring modeling approaches (the discrete element analysis technique). Rigid-body modeling involving registration and fusion of data is much better established than soft-tissue modeling. Second-generation work should concentrate on more advanced procedures that involve articulating flexible or deformable tissues such as the intervertebral disc and paraspinal ligaments, and nervous system soft tissue.

An example of elastic registration of spine images is shown in Figure 5-1.

The Deformable Modeling Process. Deformable modeling is a complicated process owing to the difficulties of adequately representing the deformations of different soft tissues. Deformable registration is still in a preliminary development stage. It involves shape modeling and reliance on deformable atlases using physical models and statistical shape models. Many methods for undertaking deformable modeling have been developed during the past several years, including snakes, which use energy functions to represent the static shapes of contours (or surfaces in 3D) and which deform until they reach their minimum energy. Dynamic deformable models represent both shapes and motions of contours. When both internal and external forces reach a balance, the contours (or surfaces) come to rest at their final locations.

Finite element methods (FEMs) that are capable of handling large deformations are one of the most commonly used approaches in the computation of physically based representations of deformable modeling. In addition, probabilistic deformable models combine the characteristics of both prior and sensor models in terms of probability distributions.

An example of a finite element simulation of tumor growth in the brain is shown in Figure 5-2. The same techniques could be applied to the spine.

The Physiological Modeling Process. Physiological modeling includes the dynamic functional aspect of the deformation of soft tissues. These models also apply to sensor interaction with tissues, tissue resistance and other properties, and functional imaging registration, e.g., positron emission tomography (PET) with anatomical imaging such as computed tomography (CT) or magnetic resonance imaging (MRI). Physiological information could include electromyelogram (EMG), MRI tagging, nuclear magnetic resonance (NMR) metabolism spectroscopy, and Doppler ultrasound imaging.

Compared to anatomical modeling, physiological and biomechanical modeling have not been as extensively studied. Modeling these functional parameters is even more challenging than that of anatomical deformable modeling because, in most cases, it is possible to acquire only indirect measurements of a physiological process. A physiological activity usually varies over time, which makes quantification difficult. As such, a challenging issue in physiological modeling is the accurate acquisition and identification of biomechanical information, which includes mechanical properties of soft tissue and its interaction with surrounding tissues.

Finally, dynamic anatomical and physiological modeling should include the influence of muscle contractions and respiratory and vascular pulsations on the spinal structures. Innovative, computationally efficient methodologies must be developed which integrate rigid-body modeling with deformable modeling and reconstruct (redefine) the model owing to these external influences. This development will make the virtual model physiologically and functionally accurate.

Clinical Needs

The importance of anatomical and physiological modeling becomes more apparent as increased attention is being given to the development of less-invasive procedures that reduce health care costs and do not sacrifice quality of health care delivery. Advances in modeling will rely not so much on molecular approaches but instead on basic integration of image data sets and physiological/biomechanical data of both the bone and soft-tissue components. We are just in the beginning of this process and all of the correct questions and needs have not been clearly defined. However, the ultimate clinical requirement must be that outcomes or improvements in treatment be predicted before the therapy is provided.

This Working Group felt strongly that the proper use of anatomical and physiological or biomechanical models could result in improved outcomes. Improvements can be accomplished by using preoperative models to guide intraoperative actions that will minimize tissue damage or enable more specific interventions. The most important clinical need is improving the ability to achieve increased realism in the models and simulations.

To meet this need, there has to be a much better understanding of pathogenesis and analysis of factors affecting loads on the spine and connective tissue in both normal and pathological tissues. New information gained from the use of these new models must complement information derived from clinical cases and provide information about the biomechanics of surgical planning. We may know very little about modeling soft-tissue organs such as the brain, but we know even less about an area as complex as the spine.

To advance modeling efforts we need to:

- Gather a vast amount of anatomical and physiological information, particularly about the spine.
- Compile information regarding adequate biomechanical models of muscles under normal and abnormal stress.
- Develop physiological models and modeling of the interface between soft and hard tissues that are present in the spine.
- Gather more data regarding the effects of loading on the spine and basic information about muscle functions.
- Develop models that quantify the relationship between spinal damage and clinical symptoms, which in some cases is poorly understood.

Six research focuses for physiological modeling were identified by this Working Group. The process of modeling the spine and paraspinal regions must start with simple models of normal anatomy and physiology, but the long-term goals should be the design of:

1. Patient-specific models.
2. Practical implementation and realistic approximation methods.
3. Successful mapping from models to data sets.
4. Validation parameters defined by both clinicians and engineers, a goal which is essential at every step in model development.
5. An accurate model incorporating phenomena such as spine motion dynamics.
6. Computational efficiency and validation measurements and parameters.

Although several potential clinical applications were discussed by this Working Group, including spinal fusion and fixation procedures, vertebroplasty, and discectomy, the group felt that the most common procedures, and possibly those most amenable to modeling, were related to spinal stabilization applications and correcting spinal deformity that is either idiopathic or post-traumatic in nature. Three areas of immediate clinical need include:

1. Positioning of components.
2. Biomechanical modeling of bone-ligament-muscle components, including modeling of the material properties of bone, mineral content, and structure and fatigue strength of the elements.
3. Consideration of wear patterns, aging, range of motion analyses, remodeling, and disease-related factors.

The models must be modular, interchangeable, and patient specific. In all cases it is important to validate and determine error margins in the developed models. The Working Group also gave high priority to training-based models that included visualization components and measurements, outcomes analyses, and testing of physicians' skill level and experience. The Working Group recommended that the biomechanical models be multi-segmental, cover the entire spine, and include significant soft-tissue components of ligaments and muscle forces and the relative physiological parameters. Finally, the group recognized that the models must reflect the effects of surgery, including modification with instrumentation, bone removal, and fusion procedures.

Technical Requirements

Seven technical requirements for advancing work in anatomical and physiological modeling of the spine were identified by this Working Group:

1. Further research into spinal modeling development needs. Technical requirements for modeling of spine procedures are not dissimilar from those associated with other areas of the body, except that in many cases they are more difficult. Modeling of the spine and paraspinal soft tissue introduces problems related to segmentation of multiple, heterogeneous tissue components, including bone, muscle, ligaments, vascular structures, and neural components. The anatomical relationships between these components are complex and poorly understood with respect to model development.

2. Further understanding of physiological and biomechanical properties related to the spine. Of even greater difficulty than understanding complex anatomical relationships within the spine is the modeling of muscle physiology and biomechanical properties related to the spine. Currently, little information is available regarding the constraints of soft-tissue components in the paraspinal region. The influence of functional parameters such as gravity, abdominal muscular support, age, variations in intradiscal pressures, kinematics, and various loading and weight-bearing parameters need to be considered. Modeling of the interactions of these parameters will be extremely difficult.

- Model representation
- Image segmentation and registration (both to atlases and real-time adaptations)
- Model construction
- Visualization and image display
- Simulation and animation
- Plan optimization
- Validation and adaptations to the systems

Figure 5-3: Required technical components of the model development process.

3. Multi-modality imaging registration techniques for spinal surgical procedures. Functional imaging studies related to muscle strain and stress using MRI tagging may be of value, but little research has been done in most areas of the body, with the exception of the heart. Automatic image segmentation techniques need to be developed for discriminating between the heterogeneous soft-tissue components. Multi-modality image registration techniques need to be implemented for enabling registration of preoperative images with real-time intraoperative images. Finally, respiratory and even vascular pulsation motion-related issues need to be addressed for enabling registration of preoperative and intraoperative image data.

4. Identification of technical requirements needed for developing models for image-guided surgery. Steps within this development process were identified by our Working Group, as listed in Figure 5-3.

In addition to addressing each of the steps suggested in Figure 5-3, our group recommended that there also be a hierarchical organization of problems that can be addressed for each stage of technical development. Currently, a limited number of developments are underway in model simulation of areas of the human body. One of these is orthopedic/arthroscopy simulator systems which are being developed for studying interventions of the knee and shoulder. This Working Group was not aware of any major developments in simulation systems for use in spinal interventions.

5. Development of algorithms to track tissue deformation. Tissue deformation is a major technical problem in surgery of the spine. Other technical areas in need of development include real-time performance and research into both non-linear deformation and identifying characteristics of anisotropic materials. Some of these issues are closely related to the development of physiological and biomechanical modeling of soft tissues. A compromise between finite element mesh resolution and the achievable complexity of current biomechanical models is unavoidable due to the demanding computational resources. More efficient algorithms need to be developed for better understanding the deformation of non-linear viscoelastic tissue models, collision detection between deformable bodies, and computation of contact forces or pressures between deformable bodies. Integration of both anatomical and physiological modeling will become a key issue in this field. Validation of all of the technical developments is critical as each progresses.

6. Development of algorithms to compute muscle activity and roles in spinal stability. Muscle contractions and co-activation is yet another major research issue that needs to be developed. Muscle groups provide active control and dynamic forces to the paraspinal regions, which provide spinal stability. Several optimization algorithms have been developed to compute the roles of different muscles in static postures, but have had very limited success in practice (if any). Innovative approaches are needed to address muscle co-activation and the roles of muscles, soft tissues, and vertebral bones in stabilization of the spine. Integration of the above research findings will play a crucial role in the design of the comprehensive model(s) needed for image-guided spine procedures.

7. Additional requirements of models for image-guided spinal surgical systems. Models that are developed for work on the spine should be generalized, but they should also be individualized and adaptable to individual patient factors such as age, sex, history, and patient-specific anatomy. The systems must be practical and include real-time performance standards. In addition, these imaging systems must be designed with a hierarchical organization of problems that can be addressed at each stage of the technological development. Tissue mechanical properties must also be included in model development.

Research Priorities

The following research priorities were suggested by this Working Group:

1. Initial model development should focus on clinically relevant problems of deformity and spine stabilization.
2. Anatomical models should focus on shape construction and the proper alignment and positioning of component parts.
3. Biomechanical properties are critical and considerable work needs to be done to better understand the interaction of heterogeneous soft-tissue components and bony structures.
4. Initial model development must incorporate data on wear patterns, age, stress, and load bearing.
5. Initial model development must reflect the effects of surgery or other interventions.

For initial model development, research should focus on soft-tissue modeling, segmentation of heterogeneous tissue components, basic biomechanical information such as kinematics, forces, and tissue stresses, as well as the proper alignment and positioning of component parts. Physician interaction and validation studies must be a part of the evolution of the models at every stage of development.

SECTION 6: SURGICAL INSTRUMENTATION, TOOLING, AND ROBOTICS
The Report of Working Group 5

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Preventive Care of the Spine: An Overview

Our Working Group particularly considered the consequences of an aging U.S. population, which we believe has significant implications for care of the spine in the near future. Currently, the single largest presenting complaint leading to spinal interventions is lower back pain. Direct costs might be estimated at $14 billion annually, with the additional annual cost of failed surgeries at perhaps $5 billion. These costs may be expected to rise.

As our population ages, *preventive* programs will require large-scale delivery of certain procedures, particularly injections. Diagnosis and prevention will be considered together here as the relevant procedures, with similar technical requirements. Efficient and extremely safe delivery of these procedures is needed; otherwise, preventive care will not be appealing to those who need it.

CLINICAL NEEDS

Our Working Group identified and assessed three image-guided spinal interventions which can effect improved outcomes for patients with lower back pain. These include needle procedures for nerve root decompression; better visualization for interventions focused on compression fractures; and minimally invasive techniques to destroy tumor in the spine.

USE OF IMAGE-GUIDED SURGERY IN NEEDLE PROCEDURES FOR NERVE ROOT DECOMPRESSION

Compression of the nerve roots or spinal cord is a common problem. It can be congenital or the result of Paget's disease, degenerative disease, spondylosis, ligamental ossification, fractures, tumors, and other causes. Compression is a painful condition that may require intervention, or "bony decompression". The current standard of treatment is an open decompression procedure. Currently, less-invasive treatments have not proven effective.

Image-guided surgery (IGS) or robotic techniques can, however, contribute to both the efficiency and safety with which needle procedures used for diagnosis or treatment of compression may be carried out. Decompression of the nerve root or cord is accomplished by removing tissue that places pressure on the neural element. Accurate targeting reduces the (small) chance that sensitive structures can be inadvertently damaged. It can also improve the speed with which a needle procedure can be accomplished.

Examples of robotic systems that might be applied to image-guided spine procedures are shown in Figures 6-1 and 6-2. The first figure shows a new-generation remote center-of-motion robot developed at the Johns Hopkins University. This robot is designed for "steady hand" microsurgery to extend human ability to perform micromanipulation. For image-guided spine procedures, a device like this might be used to assist in needle placement while ensuring that dangerous regions such as the spinal canal are avoided. The second figure depicts a robotic system for precise needle insertion under radiological guidance. The system has been applied to kidney biopsy and presents a modular structure comprising a global positioning module, a miniature robotic module, and a radiolucent needle driver module.

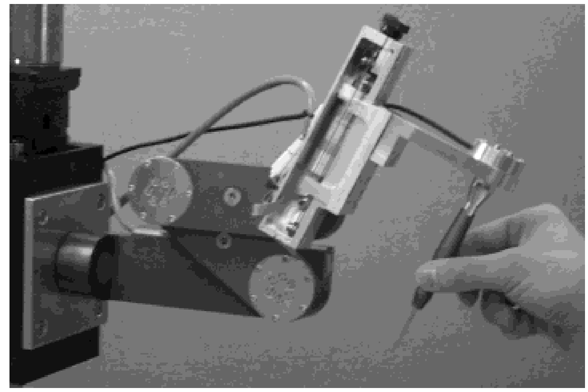

Figure 6-1: Steady hand robot (Courtesy of Russell Taylor, Ph.D., Johns Hopkins University).

Accurate targeting, which can be facilitated by IGS, is perhaps even more important for achieving accurate diagnostic results. A primary tool of diagnosis for the cause of pain is the injection of anesthetic or steroids in or near (within about 1 mm of) a sensory nerve. For a variety of reasons, not least the placebo effect, at least two — and often

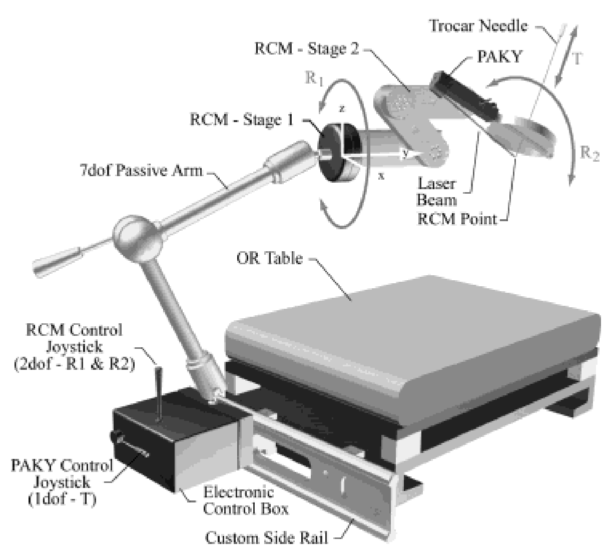

Figure 6-2: PAKY needle insertion robot (Courtesy of Dan Stoianovici, Ph.D., Johns Hopkins Medical Institutions).

more — injections are needed. Reliable diagnosis thus depends on reliable targeting of the injected material. Diagnosis is greatly facilitated if one can count on successive injections being delivered to the same location on the nerve.

In order for significant societal investment to be made in preventive programs for spinal pain, outcomes validation studies are required. Controlled studies are needed to determine the accuracy and efficacy of these needle delivery programs and to determine their preventive significance.

Another Application for Image-Guided Surgery: Compression Disk Fractures

Compression of the nerve root is also a widespread problem, and can result from herniated, prolapsed or protruded, extruded, or sequestered discs. Compression fractures number some 500,000/year, and probably are orders of magnitude larger in number if we consider cases in prevention as well. A large fraction will require operative intervention. Clinical issues which can benefit from IGS techniques are those which assist in identifying how much cement to use, where to put it, and how to control where it goes.

The state of the art in discectomy includes microdiscectomy, nucleotomy, micro-endoscopic discectomy, and laser ablation. These interventions are effective for many types of disc procedures and can be performed almost on an outpatient basis.

Another Application: Tumor Reduction

Here one wishes to remove the tumor in order to help the body to maintain its immunological effort. The idea is to destroy (or "munch") most of a tumor, deposit a tumoricidal agent, and do this with minimally invasive technology. Spinal tumors are almost always located in the vertebral bodies, and the tumors are generally of soft material. This application represents somewhat more sophisticated techniques than does a needle procedure. What is needed is a minimally invasive "muncher" guided by IGS. Such a tool will be discussed at greater length below.

One Area of Possible Improvement Using IGS: Stabilization and Fusion

Stabilization involves the use of metallic implants and is performed to eliminate motion, usually for fusion of segments in the spinal region. Stabilization can be required due to incidence trauma, for tumor removal, or to assist with fusion. Fusion is typically done as follows:

1. Removal of disc and/or facets and/or bony end-plates.
2. Addition of grafting material.
3. Stabilization using a mechanical construct such as a cage, rods, or plates fixed to the vertebrae with wires, plates, cortical bone screws, pedicle bone screws or hooks, or a combination of these.

The state of the art in stabilization and fusion requires the invasive introduction of screws and other hardware. It is simply much easier to introduce plates and screws and to fasten them in an open operation, although some clinicians have been investigating ways to accomplish these tasks in a minimally invasive manner.

Most attempts at minimally invasive implantation of screws and needles for stabilization currently require frequent use of fluoroscopy, which uses ionizing radiation. Sophisticated new instrumentation and techniques such as computer-aided surgery (CAS) will have to be developed for percutaneous stabilization. This can be accomplished, it is thought, by using CAS or new imaging methods such as the open CT or open MR.

Fusion has been made easier and much less invasive owing to the introduction of cages, but long-term results are not yet known. Cages are not appropriate in all cases as they do not provide the same degree of stabilization that is provided by conventional fusion procedures.

Technical Requirements

Imaging

The state of the art in guiding needle procedures is represented by manual fluoroscopic and CT guidance. We noted that interventional radiologists perform biopsies with CT guidance, doing so iteratively by positioning a needle and sliding the patient in and out of the CT scanner. This process is labor-intensive and slow. We considered a number of alternative IGS technologies to facilitate needle procedures (and similar interventions such as the "muncher").

Optically tracked tools correlated with CT data sets (of which Sofamor Danek's StealthStation® is an example) duplicate an open procedure more slowly and, perhaps, more accurately. However, we did not find significant benefit in this technology for facilitating needle procedures. What is needed is a minimally invasive technique, and one for which the registration process is rapid, convenient, and accurate.

Ultrasound has been available for use in spine trauma interventions for 15 years or so. It has never been accurate enough and, we believe, has been more or less abandoned. It is labor-intensive to use; it needs a dedicated technologist to produce good images, because ultrasound imaging often has a lot of variability; and its use is not straightforward. Ultrasound pictures are also difficult to interpret. While this may change with recent developments in ultrasound, it is currently not used very much in the spine.

Fluoroscopy has many advantages, allowing intraoperative imaging and intraoperative registration. IGS techniques (as opposed to manual fluoroscopy) would also minimize radiation exposure for both patient and surgeon. A disadvantage of fluoroscopy, however, is that image quality can be problematic, especially in cases of low bone-density and of obesity. These problems might be alleviated by a fluoroscopic overlay on preoperative CT images.

The use of IGS in, for instance, compression procedures will require the development of more effective imaging. It is extremely difficult to work in tight recesses of the spine without having the advantage of high-resolution, unambiguous images. Our Working Group examined several options, including use of the intervascular MR coil, frameless stereotaxy (which was dismissed as not providing needed accuracy or up-to-date images), and foraminoscopy.

Guidance

We polled the three clinicians in our Working Group on their preferred mode of guidance: Should an IGS system (1) simply indicate the current target of entirely hand-held tools (real-time video overlay), or should it (2) involve a positioner for guidance ("robot line-up"), or should it (3) more actively perform the insertion? One clinician opted for #1 (video overlay) while two clinicians preferred physical guidance ("robot line-up"). No one expressed any interest in a robot more actively involved than that. The clinician that opted for video overlay expressed a lack of trust in robotic positioners, which one could imagine might be allayed over time and with advancements in the field.

Endoscopic Tools: Disk Removal "Muncher"

What is currently available for endoscopic disk removal is a rigid tool known as a "muncher." This is inherently a linear tool: its path can be obstructed by bone or anatomical structures. The actual surgery to access the tunnel that the nerve traverses is extremely tight and instrumentation required to perform nerve procedures must be extremely dexterous.

Improvements are therefore needed in both the visualization of the nerve and tools which can navigate around obstacles (i.e., bite away the bone). The tool needs to have a mobile tip once it is positioned correctly. Specifications for such a tool are as follows:

- 1-cm range of motion
- capability for suction: volume of material removed is 1 to 10 cm^3
- grasping forceps
- perhaps a drill or burr for taking out pieces of bone
- low force-level requirements
- CT-like navigation down to the foramen is required, then visual guidance is needed
- needed tool tip angles may be 30 degrees for disk removal, but 90 degrees would provide additional capabilities
- tool body could be up to 10 mm in diameter, narrowing to 4 mm for the part that would enter a disk, and narrowing further to about 2 mm at the tip.

Improved instruments for spinal procedures, notably in endoscopic visualization, will be necessary to achieve advancements in spinal interventions.

Research Priorities

Although bone morphogenetic proteins (BMPs) and gene therapy will become more and more important in treating the spine over the next several years, they will never obviate the need for intervention. These materials will precipitate rapid and stable fusion, but precise instrumentation will be required to deliver the materials to the appropriate locations in the spine. These biologically active materials will require minimally invasive intervention (similar to that being envisioned for vertebroplasty) for delivering the agents to the appropriate locations.

There was a definite consensus in our Working Group that the future lay in a marriage of biological treatments and minimally invasive systems to deliver the agents to the location accurately. One example might be a development like an "injectable bone screw", which could solve a problem by enabling the surgeon to locate a screw percutaneously and inject an agent rather than introduce one.

However, in terms of determining biomedical research priorities, we feel that advancement of the instrumentation, biologically active materials, and IGS for delivery all need to be studied simultaneously. The following priorities are critical:

1. To achieve this advancement, infrastructure needs include making the visualization and registration systems, and data fusion, become standard procedures in the OR. We need to undergo a sizeable shift in focus from surgical "carpentry" to information-intensive surgery.
2. For these technologies to be deployed, NIH and other innovative research/support institutions need to do much more focused work on systems research and development. This Working Group believes that if we want to couple IGS to biologicals, we have to invest in the delivery systems. Merely to be able to study the effect of the biologicals, we need to do controlled delivery of the image-guided procedures.

SECTION 7: SYSTEM ARCHITECTURE, INTEGRATION, AND USER INTERFACES
The Report of Working Group 6

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IMAGE-GUIDED SURGICAL SYSTEMS FOR THE SPINE: CURRENT LIMITATIONS AND CHALLENGES

Image-guided surgery has, to this point, been predominantly applied to intracranial procedures. Most cranial guidance systems consider the skull and brain to be rigid structures for which a single, rigid transform can suffice for registration of image data. Even for cranial interventions, this assumption is incorrect, as the brain is neither homogeneous nor rigid. In addition, few guidance systems allow intraoperative information retrieval and modification of the preoperative images based on this intraoperatively acquired information. These issues must be addressed for image-guided surgery of the spine to be accurate.

The spine can be considered (as a first approximation) as a series of rigid bones connected by flexible structures. Unless the patient is immobilized within a rigid constraint during imaging and interventions, the relative positions of the vertebrae cannot be assumed to be the same as when any preoperative scans were obtained. This variability necessitates the capability to either capture additional data intraoperatively or to perform multiple spatial and temporal registrations.

Beyond issues of lesion targeting, image-guided systems for spinal procedures must be developed to allow for treatment of a variety of structural disorders. These procedures will range from simple disk removal to correction of gross deformities which require exposure of several spinal levels. Image-guided spinal systems must either track multiple objects and depict their relative position and angulation, or permit intraoperative imaging of these structures to produce an accurate model of the spine as it exists within the operating room.

CLINICAL ISSUES: DESIGNING AND BUILDING FUTURE IMAGE-GUIDED SYSTEMS

The overall goal of this Working Group was to envision effective tools for image-guided surgery of the spine. The group felt that a valuable approach would be to develop an architecture that could incorporate advances in localization, registration, display techniques and targets, and trajectory definition into systems which have demonstrated their clinical usefulness and significance. Mechanics of this image-guided system involve capturing information about the spine during the intervention that is required for accurate intervention, and presenting that information in a time interval and manner that is appropriate for the intervention. These interventions may be disk procedures, spinal instrumentation, procedures for the biopsy and ablation of cancer, surgery for gross deformity, or needle procedures. A typical image-guided surgery system used in the operating room for cranial interventions is shown in Figure 7-1.

Figure 7-1: Image-guided surgery system in operating room (Courtesy of Richard Bucholz, M.D., St. Louis University).

The user interface for this system, which presents axial, sagittal, coronal, and 3D views, is shown in Figure 7-2. A similar system can be used for spine interventions, such as the placement of pedicle screws.

There are a variety of specific clinical needs that must be addressed in order to advance the development of image-guided surgery of the spine. Among these clinical needs are issues related to registration procedures and input of data; network requirements; graphical user interface (GUI) architecture; acquisition and classification of surgical-related information sources and data; and accumulation of valid data for comparative patient health outcomes studies. Each of these clinical issues will now be described briefly.

Registration Procedures and Input of Data. A specific clinical need for improved flexibility in registration procedures and for the input of data (measured signals, 2D images, and 3D image sets) was identified by the Working Group. To satisfactorily meet this clinical requirement, the design of surgical image guidance systems will have to be more open. They will need to be connected to a data network and be able to transfer data from hospital databases and from diverse information sources directly to the operating room.

Network Requirements. The process of image-guided surgery is an example of a mission-critical system, just like the internal network of a modern airplane. The pilot relies upon the plane's network to provide information on a real-time basis about the position of control surfaces, engine functions, plane location, and guidance information. Similarly, patient safety and positive surgical outcomes depend on rapid, secure, and stable data transfer to and from the interventionalist. The systems should be able to initiate and terminate individual data streams and set bandwidth and communication priorities for individual data streams.

Adjustable Graphical User Interfaces (GUIs). One difficulty in defining system architecture, integration, and graphical user interfaces (GUIs) stems from the fact that the development of the system must be closely coupled to the preferences of the operating surgeon. Advances in technology will require new surgical techniques, just as new surgical techniques place demands on existing technology, which promotes the development of new technology. Against the backdrop of this rapid developmental cycle, surgeons must be comfortable in their mastery and control of the devices used during a procedure. As surgeons vary greatly in their approach to technological innovation, each development may be accepted and/or used quite differently by different surgeons and specialists. Some surgeons desire greater technical control over the system and some want to use it as a "point and shoot" mechanism.

In addition, systems may be used for different functions, and indeed not all are meant to be multifunctional. A system used for discectomies will not require the same functions as one used for the correction of gross deformity. Although there cannot be specialized systems for each type of procedure, a system should instead have a selection

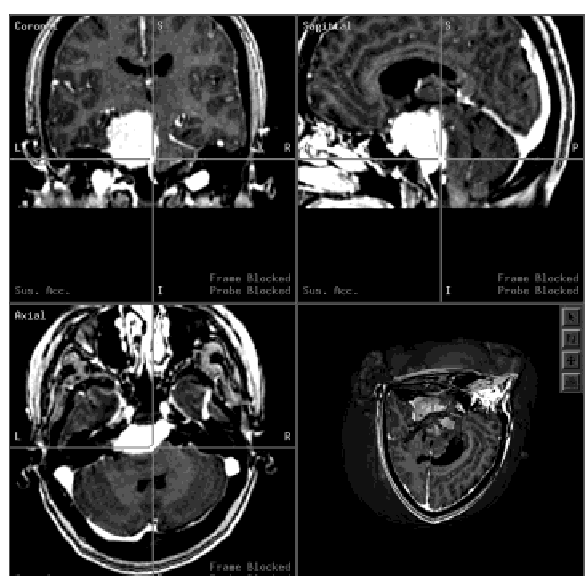

Figure 7-2: Image-guided surgery system user interface (Courtesy of Richard Bucholz, M.D., St. Louis University).

mechanism from which the surgeon can alter the amount and type of information displayed and be able to tune in and out specific data streams as needed.

While there is considerable appeal in allowing flexibility of system function to enable surgical technique and to support differing desires of surgeons, there is also a danger in aiming toward "too flexible" a system. Such flexibility makes it extremely difficult to posit valid comparisons across procedures and between surgeons. As these systems develop, clinical study design needs to address the issue of controlling systems' flexibility in order for valid comparisons to be made across sites.

Information Sources: Acquisition and Classification Systems for Surgical-Related Data. There are two classes of input to image-guided surgery systems — preoperative and intraoperative. Preoperative data are traditionally comprised of tomographic image sets; however, surgical plans and historic data on prior cases should also be part of the input data stream. Intraoperative data should include intraoperative images (both three- and two-dimensional) as well as electrophysiological and mechanical information. Other data sources — such as biomechanical studies, comparisons of surgical instrumentation characteristics, and patient-specific data (for example, a history of smoking, concomitant disease, and other factors) — should also be incorporated and available to make the system a true information appliance. Mechanical data, such as how the spine responds to specific forces, are very important in determining what can be achieved with surgery and how to best achieve it.

Accumulation of Outcomes Study Data. With the broad acceptance of image-guided surgery system development, there is considerable anecdotal evidence that such systems improve surgical interventions by reducing morbidity and allowing more complete resections. However, careful prospective comparisons with conventional surgical techniques have not been made. Concomitant with the development of image-guided spinal surgery techniques, methods for assessing process effectiveness should be developed to provide a mature and established methodology to demonstrate clinical efficacy. As a result of creating an established baseline for comparisons, truly valid outcomes studies would then be possible.

Technical Requirements for Imaging Systems' Design and Integration Processes

Intraoperative Imaging Modalities and Development Needs

Using the four types of imaging systems that are currently employed intraoperatively during spinal surgeries — namely, ultrasound, endoscopy, fluoroscopy, and intraoperative tomography — our Working Group focused on the technical requirements for enhancing these current technologies and the procedures used for image-guided spinal surgery.

1. **Ultrasound** is a real-time (30 frames per second, 1 frame latency), gray-scale imaging stream. If color Doppler is employed to examine blood flow, then the system must be capable of displaying color. By providing 3D localization and trajectory information, localization data from the ultrasound images can be extracted noninvasively. However, given the reflective nature of ultrasound images, basic research is needed on methods to make this registration process feasible.
2. **Endoscopy** is also performed in real time. It, too, is inherently true color, which effectively triples the bandwidth requirements of this imaging technology. If the endoscopic data are to be used quantitatively, image-guided surgery systems must allow for on-line distortion correction.
3. **Fluoroscopy** provides real-time, gray-scale, highly resolved, and therefore large images. However, since the distortion inherent to fluoroscopic devices is position dependent, the guidance system must be able to correct the resulting distorted images. Recently, a commercial fluoroscopy-based image-guided surgery system has been introduced, as shown in Figure 7-3.
4. **Intraoperative Tomography: CT/MRI.** Use of this technology requires high-speed imaging and data transfer. The requirements are highly procedure-dependent. Conventional picture archiving and communications servers (PACS) are generally not fast enough for intraoperative use. As a result, to use intraoperative imaging effectively, a new standard for local transfer needs to be developed to circumvent the slowness of current PACS standards.

Figure 7-3: FluoroNav™ fluoroscopy-based image-guided surgery system (Courtesy of Medtronic—Surgical Navigation Technologies).

Registration

In addition to examining particular changes and improvements of current imaging technologies, our Working Group also examined technical requirements for registration of the spine. As spinal vertebrae move relative to each other during the course of surgery, frequent spatial and temporal registrations must be performed by the image guidance system. Three types of registration are described:

1. **Transcutaneous Registration.** Percutaneous procedures such as biopsies and injections might benefit from a method of transcutaneous registration, one that may be tracked and/or uses three-dimensional ultrasound. The image guidance system must then support the image processing needed to extract necessary information for registration assessment and tracking.
2. **2D-to-3D Registration.** Intraoperative ultrasound, laparoscopy, and intraoperative fluoroscopy are all two-dimensional imaging modalities. These 2D images should be reformatted to be related to 3D data sets, such as computed tomography. Three-dimensional position information can be obtained from two views and should be supported by the system.
3. **Temporal Registration.** The frequency of repeat registration and allowable time for registration is procedure-dependent. Temporal registration time is most critical in surgical procedures for tumor and deformity, but should be a basic component of any spinal guidance system.

Intraoperative Data Integration

Preoperative planning can be crucial to the success of the surgery, especially in cases of deformity. The integration of a preoperative plan with an intraoperative reality using some of the data streams indicated above can speed the surgery and allow for better agreement between desired configuration and accomplished tasks.

Acquisition and assessment of intraoperative data and integration of these data into surgical planning and procedures are important technical requirements for image-guided surgery of the spine. Guidance systems should be viewed as information appliances. If standards are developed which allow measurement devices in the operating room to talk to and interact with the guidance system, this intraoperative data can be used to optimize the intervention. These data may be presented visually, as shown in the sample 3D visualization of a brain tumor in Figure 7-4. These data can include:

1. Thermal data for radio frequency ablation and cryoablation.
2. Neurophysiological data such as evoked potentials.
3. Mechanical data measure elements which can be used to modify biomechanical models with patient-specific information. In addition, such processes can allow for the quantification of the rigidity of spinal instrumentation.

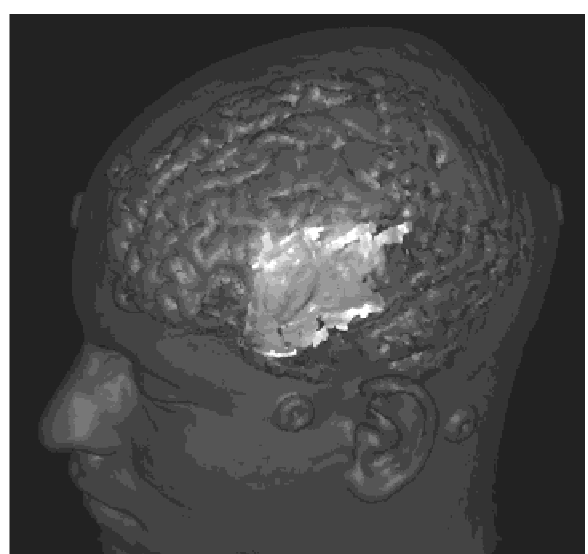

Figure 7-4: 3D tumor visualization (Courtesy of Richard Bucholz, MD, St. Louis University).

4. Pathological data identifying the tumor type and distribution that may impact the nature of the procedure being performed.

Feedback of Information to the Interventionalist

The capability for providing intraoperative data to the interventionalist is a critical technical requirement of surgical imaging systems. Design issues that were raised in this regard by our Working Group were:

1. Feedback of data during surgical procedures on the spine is necessary. Surgical guidance systems are based on the concept of display of position. In spinal surgery, perhaps more than any other type of surgery, the feedback of the position of connected structures is of critical importance.
2. The mode of data display should be flexible and available as needed. As the systems evolve into information appliances, the handling of data flowing into the system and the selective display of that information are vital intraoperative processes. System design should allow for the flexible display of information and control over data sources and operative effectors.

Research Priorities

Several priorities for intensive research were identified within this group:

- High-speed networks (and image transfer standards for effective use of these networks), should be developed and placed immediately in research centers to facilitate the use of imaging in the operating room.
- Research into the development of user-configurable graphical user interfaces should be supported, and the ergonomics of system-surgeon interaction should be carefully pursued.
- Registration techniques must be simplified, and enabled using low-cost techniques such as fluoroscopy or ultrasound.
- Intraoperative navigational systems should be developed with an open interface to facilitate their transformation into information appliances capable of acquiring and displaying information from diverse data sources, including imaging sources.
- Intraoperative inter-vertebral motion and the effect of this motion upon registration accuracy is poorly understood, and is critical for creating effective image-guided systems for surgery of the spine. An animal model for the testing of spinal image guidance systems should be developed to study this motion.

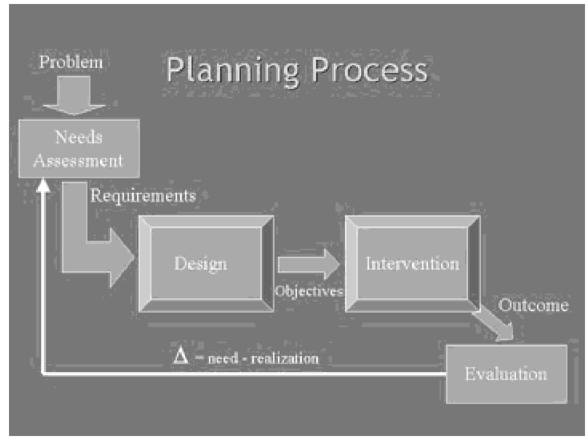

Figure 8-1. Workshop planning process. The planning process includes needs assessments, design and application of an intervention, and evaluation of the results, which refines and adapts future needs to the changing environment.

SECTION 8: WORKSHOP SUMMARY PRESENTATION

By Michael W. Vannier, M.D.†
University of Iowa

Contents

† Editor's note: Dr. Vannier served as the Workshop rapporteur and was tasked with the job of summarizing the Workshop on the last day. This chapter is his summary talk. His presentation described the conference objective and process, the significance of the problem, some background, needs, opportunities, and overall recommendations.

Planning Objective and Process

The objective of the conference is to determine the technical requirements for image-guided procedures in the spinal column, spinal cord, and paraspinal region. The planning process (Figure 8-1) begins with a needs assessment, which included a pre-Workshop questionnaire and the formation of Working Groups.

This process is intended to design, develop, deploy, and evaluate new systems that will be useful in spinal interventions, which will need to be validated through outcomes assessment. The ultimate goal, of course, is improved clinical outcomes for spinal disorders, especially low-back pain.

The Workshop is organized into six Working Groups, each of which has a specific area of concentration (Figure 8-2). In *planning and simulation* (Group 1), the purpose is to choose the best strategy from the various interventions possible, as well as to optimize the intervention chosen. *Intraoperative imaging and endoscopy* (Group 2) deals with collecting data; *registration and segmentation* (Group 3) with preparing the data; and *modeling* (Group 4) with organizing knowledge in the context which is ultimately more useful. *Instrumentation, tooling, and robotics* (Group 5) assist in the intervention itself, while *systems architecture and user interfaces* (Group 6) is concerned with the integration of these components.

Group	Purpose
1. Planning and simulation	Choose best alternative (optimization)
2. Imaging	Collect data
3. Registration and segmentation	Prepare data
4. Modeling	Organize knowledge
5. Instruments and robots	Intervene
6. System architecture	Integrate

Figure 8-2. Working Groups and Purpose.

There are several general questions regarding image-guided spinal interventions that should be answered in this report. First of all, whom are we trying to serve? What do we want to do? Why do we want to do it, and why is it important? How will this be accomplished? How will we know if we've got it right or not?

Significance of the Problem

To underscore the importance of the topic addressed here, consider the following summary of an overview of low-back pain by one of the nation's leading experts in outcomes analysis of interventions related to low-back pain:

> Up to 80 percent of all adults will eventually experience back pain. Its possible causes are multifarious and mysterious. Why some people experience it is as hard to understand as why many others don't. Fortunately, treatment options are improving, and they usually involve neither surgery nor bed rest.[3]

However, there are cases when surgery is indicated. According to Deyo,[3] surgical consultation with CT or MR imaging is indicated for patients with persistent or progressive neurological deficits or persistent sciatica with nerve root tension signs. Also, acute radiculopathy with bilateral neurologic deficits, saddle anesthesia, or urinary symptoms is suggestive of cord compression or cauda equina syndrome and requires urgent surgical referral.[8]

Based on the medical literature and a needs assessment, a problem statement for Image-Guided Spinal Interventions can be formulated as follows:

> Low-back pain is a prevalent and potentially correctable source of disability. Surgical treatment, when indicated, produces variable outcomes that may be improved by less-invasive, image-guided procedures. Reduced overall disability, lower cost of treatment, fewer complications, and less variability in outcomes may be realized by using image-guided technology.

Based on the problem statement, we developed specific goals for image-guided spine procedures. It is essential that treatment be individualized, that the techniques employed have the promise to optimize interventions, that variability be reduced, and that the overall efficiency be improved.

Background

The image-guided spine surgery process is complex. As shown in Figure 8-3, components of the process include preoperative imaging, data preparation including modeling and segmentation, simulation (if applicable), then registering sources of data and applying these to the intervention on the patient. The interventions are monitored, corrected, or extended, according to the results of intraoperative imaging.

Whom do we want to serve? There are many

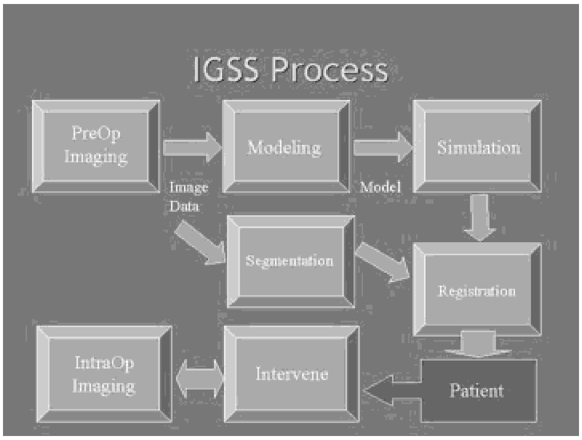

Figure 8-3: Image-guided spinal surgery process diagram.

constituencies that are affected by spine abnormalities and the interventions to treat them. Each has different needs and motivations. These constituencies include the patients and their families, the clinicians who treat spinal disorders, as well as employers and insurance companies who are affected by the productivity loss and financial consequences of persons who experience low-back pain. Patients want pain relief, and for chronic pain they want long-term relief.

These needs lead us to a vision for what we would like to achieve; namely, that low-back pain treatment with image guidance improves outcomes while reducing overall variability, costs, and complications. This yields benefits for patients, physicians, employers, and the public at large.

Low-back pain is a major concern in spinal interventions because it is so common, but the scope of abnormality in the spine is vast and has bearing in many different clinical areas.

Our shared vision is:

> Low-back pain treatment with image guidance improves outcomes while reducing overall variability, cost, and complications. Benefits accrue to patients, payors, employers, and the public at large.

The scope of disease and abnormality in the spine is vast and includes trauma, deformity, degeneration, neoplasm, and other disorders. Images are often available, especially preoperatively, in 2D and 3D for spinal abnormalities, but the images themselves do not depict function. In particular, pain and disability are not shown on the images. While the anatomy is well delineated on the images, particularly the bony geometry, pain and disability are usually evaluated subjectively.

There are many imaging modalities available, and they have overlapping and unique capabilities, which will continue to evolve. There are several possible interventions for many conditions, including surgical alternatives, and many of the interventions are not well standardized.

Surgical procedures for image-guided spinal surgery (IGSS) are either anatomic, ablative, or augmentative. The anatomic procedures correct the "cause"; ablative procedures destroy pain pathways; and augmentative procedures modulate pain transmission. IGSS, in general, could be useful in the spine and has already proven its value in selected procedures such as pedicle screw insertion. However, these systems must be made more real-time and interactive. Since a completely integrated system is likely to be much more useful than a partial implementation, the benefits of these systems may not be fully realized until an integrated system is available.

It is important to emphasize that all spine surgery is image-guided, whether there is a direct or indirect use of images in the operating room. Preoperative imaging is clearly the standard of care, and typically includes plain radiographs supplemented by myelography, CT, and MRI. Cost constraints discourage using multiple modalities, and so usually a single modality such as a CT or MRI scan is employed.

With regards to low-back pain, the structural abnormalities in the spinal images themselves and those found *in vivo* are not equivalent. Both structural abnormalities and low-back pain are prevalent, but their correlation is not high. The predictive value of imaging in low-back pain is also imperfect, but for different reasons. It is not clear that interventions that improve appearance in imaging will reduce or eliminate symptoms; thus the images are not that valuable as a predictor of outcomes. Patient selection to receive a given treatment and outcomes measurement across populations is an understudied area.

An article in *Spine*[1] reported on the diagnostic accuracy of MRI, work perception, and the psychosocial factors in identifying symptomatic disk herniations. This prospective study involved patients (study group) with symptomatic disk herniations and asymptomatic volunteers (control group) matched for age, sex, and work-related risk factors.

The researchers found that for a risk factor-matched group of asymptomatic individuals, disc herniation had a substantially higher prevalence (76%) than previously reported in an unmatched group. They concluded that MR images in individuals with minor disc herniations (i.e., protrusion, contained disks) are not a causal explanation of pain because many asymptomatic subjects (63%) had comparable morphologic findings. Thus, in this example, imaging is limited in its diagnostic predictive value for spinal abnormalities.

For evaluating IGSS system performance, there is almost no quantitative information available. This lack of measurements makes comparison of experience from various groups difficult. It is not clear that there are any standardized ways of treating the same disease between groups. Again, we see that a high degree of variability and uncertainty exists. The outcomes are not well defined; non-technical, societal factors strongly influence the results and may be more significant than surgical factors.

On the other hand, we have a tremendous amount of operational knowledge, and a good deal of technology is already available. We have detailed knowledge of anatomy, including an atlas in electronic form. We have expertise in biomechanics, material properties, and kinematics and dynamics. There are many imaging modalities available, including intraoperative systems. Surgical instruments, appliances, and prostheses are all well developed.

Image-guided spinal surgery (IGSS) procedures are classified as: decompression (largest volume of cases), stabilization (high volume of procedures), and deformity correction (highest risk of undesirable outcomes).

To accomplish IGSS, there are four major tasks: diagnosis, planning, intervention, and evaluation. Diagnosis includes detection and characterization as well as outcomes prediction and prognosis estimation. Planning includes a first-guess approximation, simulation (and optimization), treatment selection, and often involves image segmentation and labeling. Intervention requires registration, localization and orientation, and intraprocedural navigation with and without real-time updates. Finally, evaluation is done to assess immediate and subsequent late outcomes.

NEEDS AND OPPORTUNITIES

Image-guided spinal surgery (IGSS) is performed to satisfy unmet needs of spine surgery. However, there are many alternatives and we must identify the best of several feasible alternatives. Spine abnormalities involve highly prevalent disease(s) with multiple presentations and etiologies. There are major costs to society when less effective and efficient treatment is used. Many treatment options are available, but individualization (selection and outcomes) is less predictable. Variability is high in IGSS.

Variability in IGSS refers to patient, disease, procedure, device, and operator characteristics. Each of these entities contributes to a perceived need for individualization on a case-by-case basis. This is a fundamental observation that applies to IGSS.

The barriers to wider use of IGSS are the absence of proven technology and economic value. From the technology standpoint, there is no clear evidence that IGSS works in a majority of cases. This technology is rapidly evolving and integrated systems are not widely available. Multicenter IGSS trials are seldom reported. From the economic and public health policy perspective, the principal barriers to IGSS are its added cost, which is not specifically reimbursed in many cases. Since the methods are experimental in many cases, the proof of benefit is absent for most applications. There is a general lack of randomized, controlled, multicenter clinical trials of IGSS methods and technology.

We seek to improve outcomes, both immediate and short-term, through pain reduction and by rapid return to work. In the long term, we seek freedom from chronic as well as acute pain in these patients, with lower overall disability. Restoration and maintenance of structural integrity (for destructive pathologic processes, especially metastases) are important in some cases. From the economic and public health policy standpoint, treatment outcomes should be predictable, while IGSS would ideally minimize complications (improve safety) and lower costs (to payor, government, employer, etc.).

In general, we aspire to reduce the variability in outcomes, reduce total costs, and assure the best possible results with the fewest complications in individual cases. We observe that most variability is due to a few sources and surgeons are susceptible to information overload when too much information is presented through a suboptimal user interface.

From the surgeon's perspective, we should offer newer IGSS interventions such as interstitial heating, cryotherapy, and accessories such as the Mammotome™ (vacuum biopsy/removal). These technologies promise better utility, convenience, and efficiency with fewer limitations (errors). IGSS can provide more certainty, thereby increasing the surgeon's confidence, which is consistent with fundamental surgical precepts. IGSS promises to facilitate accommodation of individual differences by unblinding the operator. IGSS may avoid complications and complete the procedure as planned in the largest number of cases.

STRATEGY

We defined technical requirements for further development of image-guided spinal surgery in the following six categories:

1. Planning and simulation
2. Guidance and localization
3. Monitoring and control
4. Instruments and systems
5. Evaluation
6. Training and career development

Our recommendations for each of these categories are given in the next section, followed by recommendations that are specific to spinal surgery.

DETAILED RECOMMENDATIONS

Planning and Simulation

- Better definition of tumor and other surgical target margins or boundaries utilizing various medical imaging techniques is needed (correlating with spatially registered histology to estimate the capabilities of the various imaging modalities in defining the boundaries for various anatomical regions).
- Development of real-time image-processing techniques, particularly rapid methods of model creation, three-dimensional rendering, and accurate segmentation of anatomic tissues for various imaging modalities.
- Research in surgical planning and simulation, particularly trajectory planning for needle placement, the basic surgical application of trajectory planning today.
- Improvement, via more complex, automated technologies, of current registration or image fusion methods for different medical imaging modalities, especially video-based and laser-scanning techniques with prospectively created models.

Guidance and Localization

- Development of flexible and untethered sensors to provide anatomical fiducial marks or information on the position of needles, catheters, and surgical instruments for tracking of instruments or for fusing patient and image coordinate systems.
- Development of computational systems and algorithms to enable "instantaneous" reconstruction, reformation, and display of the image data so as to enable real-time following of a physician's actions during a procedure (e.g., advancing a catheter or needle).

Monitoring and Control

- Definition of the temporal resolution required for various image-guided therapeutic procedures, taking into consideration the physical characteristics of the specific imaging modalities and the dynamic properties of the monitored procedures, specifically for multislice volumetric monitoring.
- For MRI, development of new pulse sequences designed specifically for therapeutic applications rather than diagnostic applications. A particularly important need is the development of highly temperature-sensitive pulse sequences to enable monitoring of "heat surgery."
- Investigations to correlate the factors affecting energy deposition or abstraction (e.g., pulse duration, pulse energy, and power spectrum) with histological and physiological changes in the tissue and resulting image changes. The purpose of this correlation is to determine mechanisms of thermal damage and the biophysical changes that take place during various thermal surgical procedures such as interstitial laser therapy, cryoablation, and high-intensity focused ultrasound treatment. Such investigations need to be undertaken for various anatomic regions and medical conditions for which such therapy might be appropriate.
- Investigation of the range of medical conditions amenable to treatment with minimally invasive techniques that are made possible by expanded capabilities for visualization during a procedure via the various medical imaging modalities.

Instruments and Systems

- Although prototypical MRI systems have been created that provide direct and easy access to the patient, more research and development is required to further optimize the geometric configuration of these systems. Similar requirements are appropriate for the other imaging modalities, particularly CT.
- For MRI-guided biopsy and therapy, magnet-compatible needles and other equipment using

materials that do not cause image distortions in a magnetic field need to be identified and developed. Accessible and easy-to-use guidance systems are required to perform localization or biopsy of lesions detected by MRI alone.

- Development of high-performance 2D detector arrays for CT and other X-ray imaging modalities are needed, as are less-expensive 2D transducer arrays for ultrasound. Appropriate means for acquiring, reconstructing, and displaying the data are also required.
- Improved methods of inexpensively shielding the magnetic field to enable inexpensive retrofitting of existing MRI systems for use in current operating rooms need to be developed.
- There is a need for integrating imaging methods with therapeutic procedures, including feedback systems between data display devices and image information, computer-assisted image-controlled surgical tools, robotic arms, and instruments.
- Creation and development of new instruments and tools to accomplish new tasks enabled by the availability of image-guided therapy, especially specialized surgical tools such as MRI-guided therapy.

Evaluation

- Develop *in vitro* and *in vivo* models for evaluation and measurement.
- Define relevant outcomes/effects standards for human applications of image guidance systems.
- Inaugurate translational clinical trial mechanisms and support for biomedical imaging sciences and engineering.
- Develop and foster adoption of clear regulatory guidelines.

Training and Career Development

- Develop multidisciplinary curricula focusing on "invention" and creativity, aimed at discerning and overcoming roadblocks between disciplines.
- Train professionals in medical physics, applied mathematics, computer science, biomedical imaging science, and biomedical engineering to develop basic methods, and link their training with translational clinical research programs.
- Develop multidisciplinary training sites, and include corporate partners and a mix of NIH, NSF, and industrial support for the implementation of such programs.

Recommendations Specific to Spinal Surgery

Research should focus on:

- Biomechanical evaluation of structural stability, load capacity, and movement
- Bone-implant and disk-nerve interaction
- Imaging in the presence of metal
- Separation of scar from tumor and normal tissue (tissue characterization)
- Spine-specific atlases and instruments
- Systems, techniques, and equipment designed (in part) and validated by spine surgeons for spine surgeons

Summary

In summary, recommendations for image-guided spine surgery are made that encompass treatment selection and optimization; real-time 3D imaging; integration of imaging and therapy for seamless, flexible systems that monitor progress on-line; and outcomes evaluation of translational research through standards, metrics, regulatory issues, and reimbursement perspectives. In addition, there are recommendations for multidisciplinary training and the formation of academic/industrial/government consortia to work towards realizing these needed developments in image-guided spine surgery.

SECTION 9: SPECIAL SESSIONS

Three special sessions were presented during the Workshop: a keynote talk titled "The Operating Room of the Future," and panels on "Outcomes Measurement for Spine Interventions," and "Therapy Teams of the Future." These sessions are summarized here by Barbara Hum (first session) and Audrey Kinsella (sessions 2 and 3). For more details, see the full report on the Web as noted in Section 1.

- **The Operating Room of the Future.** According to Dr. Don Long, this operating room requires the coordination of numerous functions, many of which are now available but are not as readily accessible as they should be. The new design should be modular, where centrally located, high-end imaging modalities such as computed tomography (CT) and magnetic resonance imaging (MRI) will be at hand for intraoperative use. Other components of the room include:

- an easy-to-maneuver patient transport system;
- improved optics;
- robotic assistance for hand support and instrument control; and
- enhanced virtual reality capabilities.

All of these features are much needed to increase precision and enhance the outcomes of surgical procedures performed on the spine.

- **Outcomes Measurement for Spine Interventions.** Both clinical and technical measurement of patient health outcomes were scrutinized in this session led by Drs. Richard North and Daniel Clauw. Measures for spinal interventions have changed over time, they note. Currently, clinical outcome reportage of spinal interventions may rely on patients' assessments of "success", and technical outcome reportage on clinicians' views. Achieving consensus among these two groups may be an elusive goal.

Gathering adequate measurement data about the procedures and patients' response is, however, the key requirement needed for improving the quality of spinal interventions. Drs. North and Clauw reviewed the generic clinical outcomes measurement tools that are currently in use, such as the McGill questionnaire, and the shortcomings of each as they apply to patients who have undergone spinal interventions. They recommend the following procedures for outcomes researchers:

- Use more than one outcome measurement tool to obtain a more complete picture of results
- Understand the differences in outcomes measurements (e.g., generic or body-part-specific tools) and the varied results that can be expected from the different tools.

The presenters also reviewed technical outcome measurement procedures, noting that analysis has become a good deal more complex than simply asking the question: Did the device work? Expectations of "successful" interventions are higher, and differ from the strictly technical assessments of positive outcomes used in the past.

It is a challenge, the speakers concluded, to keep current about what is or can be correctly measured and what data are needed to render a complete picture of patient health outcomes from, say, a spinal intervention. Nevertheless, gathering adequate outcomes measurement data about the procedures and patients' response is the key requirement needed not only for documenting what was accomplished, but for improving the quality of spinal and all clinical interventions.

- **Therapy Teams of the Future.** A panel of engineers, scientists, and physicians discussed this topic. The panelists were Drs. Heinz Lemke, James Anderson, Martha Gray, Richard Bucholz, Ron Kikinis, and Thomas Whitesides.

Creating these teams, it is thought, can encourage multidisciplinary collaboration between engineers, scientists, and physicians. Development of these teams will be a critical step toward meeting the challenges of exponential growth of new and sometimes complex technologies that are now being experienced in health sciences and technology development.

Multidisciplinary education is necessary, the panel members said, if programs are to prepare students to meet the challenges posed by this growth. The panelists shared information about their institutions' programs in clinical and engineering problem-solving tasks shared by their students. Less independent and more interactive modes are critical in multidisciplinary programs, they noted.

The training process was described by the panelists in some detail, with a note that multidisciplinary team training is not akin to "cross training." Engineers are not being trained to become spine surgeons, for instance. Rather, clinicians can be taught the principles of engineering, engineers the principles of medicine. Modular curricula development is also a part of the program planning and delivery, so that different levels of sophistication can meet learners' varied needs on an as-needed basis.

The most important goal of these therapy team training programs, as suggested by the participants in this session, is to broaden students' exposure to multidisciplinary problems. This means facilitating

- constant interaction among clinicians, scientists, and engineers;
- exchanges between institutions and from institutions to industry (one speaker noted: "The best way to transfer technology is to transfer people.");
- group problem-solving venues.

Each of these means of exposure can, it is suggested, help each learner appreciate how realistic his or her expectations should or can be about technologies and clinical applications; and how they can best contribute to the multidisciplinary, problem-solving team effort.

APPENDIX A: WORKSHOP PROGRAM

The full program can be found on the Web as noted in Section 1.

Day 1 (Sunday)

0830–1200 Overview & vision

0840–0930 Clinical state-of-the-art: Dietrich Grönemeyer, M.D.

1010–1030 Spine surgery in the 21st century: Don Long, M.D.

1040–1100 Coupling information to action: Russell Taylor, Ph.D.

1140–1155 Advanced technology direction for U.S. Army Medical R&D: Conrad Clyburn, Greg Mogel, M.D.

1200–1330: Lunch and Working Group meeting 1: Define the current status in image-guided procedures of the spine for your Working Group.

1415–1530 Diseases/procedures

1415–1430 Interventions: John Mathis, M.D.

1430–1445 Trauma: John Kostuik, M.D.

1445–1500 Tumors: Elizabeth Bullitt, M.D.

1500–1515 Deformity: David Polly, M.D.

1500–1530 Degenerative disease: Richard North, M.D.

1600–1700 Working Group presentations by technical leaders

1800–1900: Dinner and Working Group meeting 2: Clinical requirements. Using clinical areas identified in questionnaire, discuss how image guidance might be applied.

Day 2 (Monday)

0830–0930 Working Group presentations by clinical leaders

0930–0940 Deformable modeling: Christos Davatzikos, Ph.D.

0940–0950 Display technology: Heinz Lemke, Ph.D.

0950–1000 Accuracy issues: Neil Glossop, Ph.D.

1030–1040 Intraoperative CT: Frank Feigenbaum, M.D.

1040–1050 Open MRI for spine procedures: Eric Woodard, M.D.

1100–1145 Special session on outcomes analysis: Daniel Clauw, M.D.; Richard North, M.D.

1200–1330: Lunch and Working Group meeting 3: Technical requirements. Based on the clinical requirements developed in meeting 2, define the technical requirements for these applications and brainstorm potential solutions.

1415–1530 Therapy Teams of the Future (special session)

Panel chair: Heinz Lemke, Ph.D.

Speakers/panel members: Martha Gray, Ph.D.; James Anderson, Ph.D.; Richard Bucholz, M.D.; Ron Kikinis, M.D.; Tom Whitesides, M.D.

1830–2030 Group dinner: sponsor presentations

NSF: Sohi Rastegar, Ph.D.

NIH/NCI: Larry Clarke, Ph.D.

Picker International & DePuy Motech AcroMed: Lou Arata, Ph.D.

Day 3 (Tuesday)

0830–1100 Working Groups present reports

1100–1200 Summary speaker and discussion: Michael Vannier, M.D.

1200–1300 Group lunch

1300–1500 Working Group leaders outline reports

1500 Depart

APPENDIX B: WORKSHOP PARTICIPANTS

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APPENDIX C: REPORT BIBLIOGRAPHY

Note: A list of approximately 85 references for related reading as suggested by the workshop participants is available on the Web site.

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