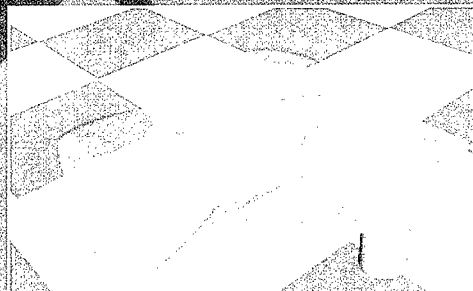


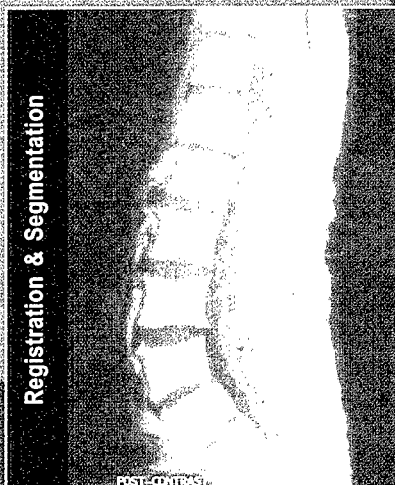
Technical Requirements for **Image-Guided Spine Procedures**



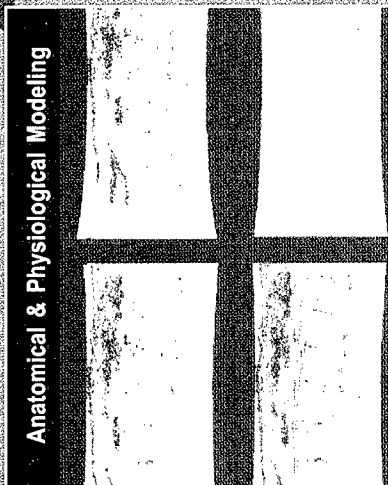
Operative Planning & Surgical Simulators



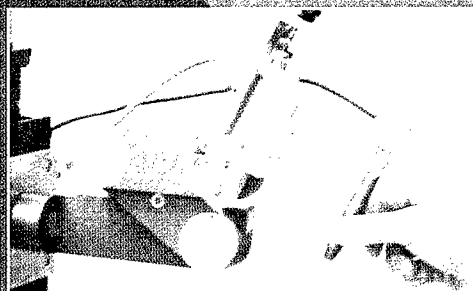
Intraoperative Imaging & Endoscopy



Registration & Segmentation



Anatomical & Physiological Modeling



Surgical Instrumentation,
Tooling & Robotics



System Architecture, Integration
& User Interfaces

**Workshop
Report**
17-20 April 1999

ISIS Center



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CONTRACTING ORGANIZATION: Georgetown University Medical Center
Washington, DC 20007

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Seong K. Mun, Ph.D.**7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)**
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Washington, DC 20007**8. PERFORMING ORGANIZATION
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The general objective of the Workshop was to determine the technical requirements for image-guided procedures in the spinal column, the spinal cord, and paraspinal region. The 70 Workshop participants were selected for their expertise in image guidance and related fields. The six Working Groups were:

1. Operative Planning and Surgical Simulators
2. Intraprocedural Imaging and Endoscopy
3. Registration and Segmentation
4. Anatomical and Physiological Modeling
5. Surgical Instrumentation, Tooling, and Robotics
6. Systems Architecture, Integration, and User Interfaces

From the Working Group reports, six summary recommendations have been compiled:

1. The development of clinically useful applications of modeling, segmentation, and registration should be supported.
2. A common and open, standard infrastructure is needed for the next generation of image-guided operating rooms or interventional suites.
3. Application testbeds are needed to ensure clinical relevance, identify potential pitfalls, and facilitate collaboration between technical and clinical personnel.
4. There are specific equipment and instrumentation needs required to advance the field that should be supported.
5. Multidisciplinary training and education is required.
6. A follow-up spine workshop to assess progress should be held in 2 or 3 years.

This material will also be available on the web through <http://www.isis.georgetown.edu> and the conferences link.

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Seong K. Mun, Ph.D.

PI - Signature

Date

TECHNICAL REQUIREMENTS FOR IMAGE-GUIDED SPINE PROCEDURES

WORKSHOP REPORT

17-20 April 1999
Turf Valley Conference Center
Ellicott City, Maryland

Organizing Committee:

Kevin Cleary, PhD, Georgetown University Medical Center, Program Director
James Anderson, PhD, Johns Hopkins Medical Institutions
Michael Brazaitis, MD, Walter Reed Army Medical Center
Gilbert Devey, BS, Georgetown University Medical Center
Anthony DiGioia, MD, Shadyside Hospital
Matthew Freedman, MD, MBA, Georgetown University Medical Center
Dietrich Grönemeyer, MD, Witten/Herdecke University
Corinna Lathan, PhD, The Catholic University of America
Heinz Lemke, PhD, Technical University of Berlin
Don Long, MD, PhD, Johns Hopkins Medical Institutions
Seong K. Mun, PhD, Georgetown University Medical Center
Russell Taylor, PhD, Johns Hopkins University

Report Editor:

Kevin Cleary, PhD
Imaging Science and Information Systems (ISIS) Center
Department of Radiology
Georgetown University Medical Center
2115 Wisconsin Avenue, N.W., Suite 603
Washington, DC 20007
Telephone: 202-687-8253
Email: cleary@isis.imac.georgetown.edu

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Front cover:

Upper left: Three-dimensional visualization used in surgical simulation. Courtesy of Daniel Blezek, PhD, and Richard Robb, PhD, Mayo Clinic. Full image appears on page 26.

Upper right: Interventional spine procedure in electron beam computed tomography scanner. Courtesy of Dietrich Grönemeyer, MD, Witten/Herdecke University. Full image appears on page 34.

Middle left: Spinal tumor showing associated mass of blood vessels similar to an arteriovenous malformation (AVM). Courtesy of Elizabeth Bullitt, MD, University of North Carolina. Full image appears on page 51.

Middle right: Elastic registration of spine images. Courtesy of Christos Davatzikos, PhD, Johns Hopkins University. Full image appears on page 59.

Lower left: Robot designed for "steady hand" microsurgery to extend human ability to perform micro-manipulation. Courtesy of Russell Taylor, PhD, Director, Computer Integrated Surgical Systems & Technology, an NSF-funded Engineering Research Center. Full image appears on page 69.

Lower right: Image-guided surgery system used in the operating room for cranial interventions. Courtesy of Richard Bucholz, MD, St. Louis University. Full image appears on page 76.

FOREWORD

This report presents the results of a Workshop on image-guided spine procedures, held April 17-20, 1999, in Ellicott City, Maryland. The purpose of the Workshop was to determine the technical requirements for image-guided procedures in the spinal column, the spinal cord, and the paraspinal region. The Workshop participants also considered what needs to be done to advance the state of the art in this field and develop clinically useful technology. This was done through a collaborative effort involving physicians, engineers, and scientists.

First of all, I would like to thank the Workshop sponsors: the National Science Foundation, the Army Medical and Materiel Research Command, the National Cancer Institute of the National Institutes of Health, The Whitaker Foundation, and Picker International & DePuy Motech AcroMed. Without their support, the Workshop would not have been possible.

A special debt of gratitude is owed to Gil Devey, who was the inspiration for the Workshop and a driving force in keeping everything on track. Gil's vision and practical experience kept the process moving during the 15-month gestation period. Seong Ki Mun was a key individual in ensuring the viability of the Workshop, and his leadership was essential throughout the planning period.

All of the organizing committee members deserve thanks, but I would like to particularly thank James Anderson and Russell Taylor, who were instrumental in shaping the Workshop program and selecting the participants. Michael Brazaitis, Matthew Freedman, Corinna Lathan, and Heinz Lemke participated in some of the early meetings and contributed their expertise.

At the Workshop itself, the student volunteers from Georgetown, Johns Hopkins, and Catholic University were essential in keeping things running smoothly, and spent a few late nights photocopying the Working Group summary slides for distribution the next day. Special thanks are due to Roselyn Yun, who served as the logistical coordinator. Audrey Kinsella helped organize, edit, and write portions of the final report, which has benefited greatly from her expertise.

Last but not least, I would like to thank all the participants, who eagerly tackled the task at hand, and worked hard throughout several long days. Without their enthusiasm and contributions, this report would not exist. This report is the product of many authors, and the contents do not necessarily reflect the position or policy of any of the sponsors.

Kevin Cleary, PhD
Workshop Program Director

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EXECUTIVE SUMMARY

The general objective of the Workshop was to determine the technical requirements for image-guided procedures in the spinal column, the spinal cord, and paraspinal region. The approximately 70 Workshop participants were selected on the basis of their expertise in image guidance and related fields. The Workshop consisted of plenary sessions and Working Group meetings. The six Working Groups were:

1. Operative Planning and Surgical Simulators
2. Intraprocedural Imaging and Endoscopy
3. Registration and Segmentation
4. Anatomical and Physiological Modeling
5. Surgical Instrumentation, Tooling, and Robotics
6. Systems Architecture, Integration, and User Interfaces

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

1. Spinal disorders, especially low back pain, are a major public health problem and potentially correctable source of disability.
2. Modeling, segmentation, and registration are fundamental technical tools that still require major advances to be useful.
3. Improved image processing and display, including real-time volumetric image acquisition and three-dimensional visualization, would be extremely valuable.
4. There is a significant communication and knowledge gap between technical and clinical personnel which needs to be bridged for further advancement of the field.
5. Clinical outcomes studies, while difficult, should be pursued.
6. Infrastructure issues, including reimbursement, liability concerns, and conflicts between specialties, need to be addressed along with technical developments.

From the Working Group reports, the following six summary recommendations have been compiled:

1. The development of clinically useful applications of modeling, segmentation, and registration should be supported.
2. A common and open, standard infrastructure is needed for the next generation of image-guided operating rooms or interventional suites.
3. Application testbeds are needed to ensure clinical relevance, identify potential pitfalls, and facilitate collaboration between technical and clinical personnel.
4. There are specific equipment and instrumentation needs that are required to advance the field that should be supported.
5. Multidisciplinary training and education is required.
6. A follow-up spine workshop to assess progress should be held in 2 or 3 years.

The report consists of ten chapters, beginning with an overview in Chapter 1 and the Workshop summary presentation in Chapter 2. The Working Group reports are given in Chapters 3-8. Special presentations, including a talk on "The Operating Room of the Future," and sessions on outcomes measures for spine interventions and the therapy teams of the future, are reported on in Chapter 9. The five appendices are grouped in Chapter 10.

CHAPTER 1: WORKSHOP OVERVIEW

1.1 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 paraspinal region. While the Workshop title indicated a focus on image-guided procedures, the Workshop 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 2/3 of whom were PhDs and 1/3 MDs, participated (see Figure 1-1 on page 5 for a group photo).

The Workshop was organized by the Imaging Science and Information Systems (ISIS) Center of Georgetown University Medical Center, the Department of Radiology of the Johns Hopkins Medical Institutions, and the Biomedical Engineering Program of The Catholic University of America. The Workshop was supported by the National Science Foundation, the U.S. Army Medical Research and Materiel Command, the National Cancer Institute of the National Institutes of Health, The Whitaker Foundation, and Picker International & DePuy Motech AcroMed.

This chapter begins by summarizing common themes and recommendations from the Workshop. Next, the Working Groups are presented, followed by the Workshop rationale, planning process, and execution. An introduction to image-guided spine procedures is given, along with the technology components for these procedures. The chapter concludes with a summary of the Working Group reports and a description of how the report is organized.

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.

1.2 COMMON THEMES AND RECOMMENDATIONS

There were a number of common themes that were identified during the Workshop, as well as some overall recommendations that have been synthesized from the meetings and Working Group reports. These broad themes and recommendations are presented here. Please note that in the Workshop summary presentation (Chapter 2) and Working Group reports (Chapters 3-8), recommendations are also made in specific areas.

The following themes have been identified:

1. **Spinal disorders** are a major public health problem and 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 workshops¹ 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.

¹ Three related workshops are:

1. Second International Workshop on Robotics and Computer Assisted Medical Interventions, June 23-26, 1996, Bristol, England.
2. Workshop on Computer-Assisted Surgery, Feb. 28 – Mar. 2, 1993, Washington DC.
3. Workshop on Imaging-Guided Stereotactic Tumor Diagnosis and Treatment, 1991.

From these themes as well as others mentioned in the Workshop's summary presentation (Chapter 2) and the Working Group reports (Chapters 3-8), the following recommendations are 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 proposal (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 (page 30); modular systems for spinal work and fast 3D visualization (page 44); and robotic instrumentation for surgery and therapy (page 68) 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 programs that allow 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.



Figure 1-1: Workshop Participants
(Courtesy of Georgetown University Photographer)

1.3 WORKING GROUPS

The Workshop consisted of plenary sessions and Working Group meetings. The Working Groups were each charged with investigating a specific technology area. The six Working Groups were:

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 tradeoffs 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 as to 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.

1.4 WORKSHOP RATIONALE, PLANNING PROCESS, AND EXECUTION

1.4.1 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 (Jolesz and Shtern 1991)² and computer-assisted surgery in 1993 (Taylor and Bekey 1993) 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 (DiGioia, Kanade, and Wells 1996). At this point, research activity in the field is beginning to increase noticeably as evidenced by specialty conferences and the appearance of dedicated journals.

² References cited in this way are included in the report bibliography in Appendix E.

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 1999³ and the several image-guided workshops convened by the National Cancer Institute and the Office of Women's Health in the spring of 1999.

1.4.2 Planning Process

As noted above, planning for the Workshop began in the fall of 1997, when the ISIS Center at Georgetown began to crystallize its interest in image-guided spine procedures. It was felt that organizing a Workshop was a good way to get a better understanding of this growing field. Funding was solicited from various agencies, and preparations were begun in earnest in the spring of 1998. The organizing committee met several times in the spring and summer of 1998 to define the program and suggest the participants. Invitations were sent in the fall of 1998, followed by the pre-Workshop questionnaire in December 1998. The Workshop was held April 17-20, 1999.

1.4.3 Execution

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 (PhD) and a clinical leader (MD). The Working Group leaders and participants are listed on the first page of the individual Working Group reports (Chapters 3-8).

The Workshop program is presented in Appendix A. The Workshop began with a reception on the evening of Saturday, April 17, followed by an organizing committee and Working Group leaders' meeting. The opening session was held the next morning and included clinical and technical overviews. Clinical presentations on spine interventions, trauma, tumors, deformity, and degenerative disease were given in the afternoon. The next day of the conference included technical talks and a session on outcomes analysis in the morning, and a panel on the therapy teams of the future in the afternoon. The final day was devoted to Working Group and conference summary presentations. The Working Group meetings were interspersed throughout the conference, with time also allocated for summary presentations following most of the meetings.

There were four Working Group meetings, each with a specific purpose, as follows:

- Meeting 1: Current Status. Review the state of the art in each Working Group's area.
- Meeting 2: Clinical Requirements. Define the clinical needs.

³ <http://www.amainc.com/admetech/admetech.html>

- Meeting 3: Technical Requirements. Based on clinical needs, define the technical requirements.
- Meeting 4: Summary. Prepare list of research priorities.

Working Group status reports were presented at three times to the entire audience, following Meetings 1; 2; and 3 and 4.

To move forward quickly during the Workshop, a great deal of preparation was done before the Workshop. In particular, a pre-Workshop questionnaire was sent to all the participants in December 1998. The questionnaire asked the participants to identify research issues and suggest relevant references. This questionnaire served to get all the participants thinking about the field and provided excellent background for the Workshop process. As part of the questionnaire, participants were asked to recommend three papers that were relevant to the field and a bibliography was generated. About 60 percent of the participants responded by March 1999, and the responses were used to help generate a 30-page pre-Workshop report. This report provided general background for each of the Working Groups, summarized the questionnaire responses, and included a bibliography. All of this effort served to acclimate the participants beforehand so that informed discussion could move ahead quickly at the Workshop.

A summary of the questionnaire responses is provided in Appendix C and the bibliographic references suggested by the participants are provided in Appendix D. The questionnaire itself and all of the responses are available on the web site:

<http://www.isis.georgetown.edu>

Follow the links to conferences and the spine Workshop.

1.5 IMAGE-GUIDED PROCEDURES

1.5.1 Introduction

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 (Viergever 1998). Volumetric imaging includes computed tomography (CT), magnetic resonance imaging (MRI), and three-dimensional (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 stereotaxi, 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 (Bucholz 1998). However, image guidance as currently used

in the spine is primarily a safety measure in 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.

While the Workshop title indicated a focus on image-guided procedures, the Workshop participants were encouraged to think more broadly and to include computer-assisted and robotically assisted spine procedures in their discussions. This broader focus can also be seen in the various topics discussed in the Working Group reports in Chapters 3-8.

1.5.2 Technology Components

Figure 1-2 shows a broad overview of the technology components of image-guided procedures. The figure consists of three major blocks: 1) diagnosis and preoperative planning; 2) procedure execution; and 3) postoperative assessment.

In diagnosis and preoperative planning, imaging technologies such as CT and MRI play an important role, including the identification of disease processes and pathologic tissue. Although surgical planning currently is usually done on two-dimensional (2D) images, 3D visualization, modeling and simulation technologies such as virtual reality are playing an increasing role in the planning process.

The surgical or interventional procedure often involves intraoperative imaging such as interventional MRI, CT, fluoroscopy, or ultrasound (US). For image-guided surgery, preoperative images are registered with the physical space of the patient, and tracking systems can provide updates of the position of the patient and the surgical instruments in the context of the preoperative image data set. For interventional procedures such as biopsy or vertebroplasty, fluoroscopy can be used to update the position of the catheter or needle in real-time. While the development of robotic assist systems is still in its early stages, they have the potential to provide greater control for precise positioning or path guidance.

Finally, postoperative assessment often involves imaging and related technologies. Outcomes analysis is increasingly being incorporated into procedures for improving clinical decision-making.

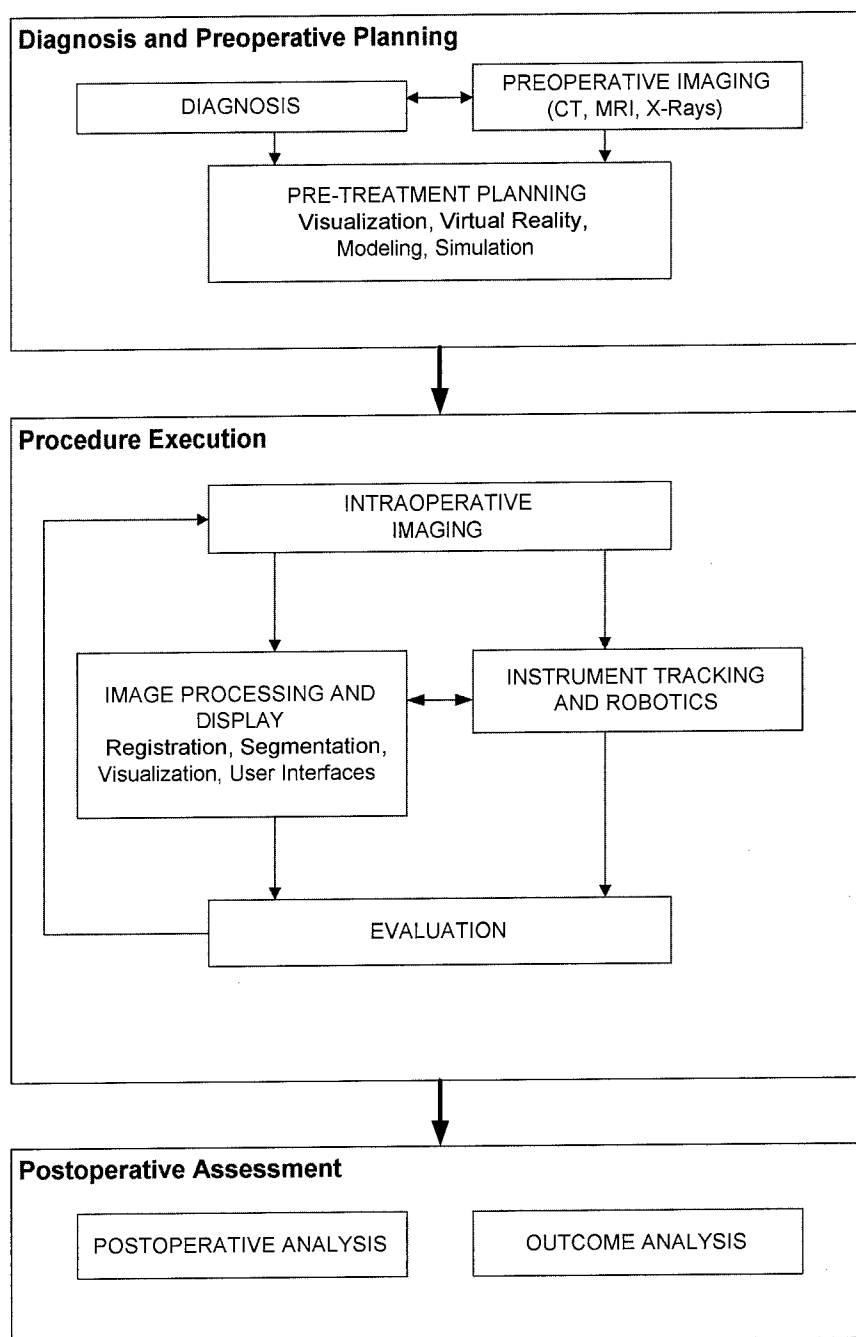


Figure 1-2: Technology Components of Image-Guided Procedures⁴

⁴ Diagram developed by Gerald Higgins, PhD, and Kevin Cleary, PhD

1.6 WORKING GROUP REPORT SUMMARIES

1.6.1 Working Group 1

In Working Group 1, operative planning and surgical simulators, a planner is defined as using tools, including simulation, to improve human performance on the patient-specific task at hand. A simulator is defined as an interactive virtual environment used to improve human performance. There is overlap between planning and simulation, but neither is inherently a subset of the other. The group felt that the state of the art in planning and simulation is still at a primitive stage, but the potential usefulness of planners and simulators is substantial.

The needs for image-guided spine procedures were separated into two tasks that were common to all major procedures and others that were procedure specific. The first common task is to identify the optimal trajectory for the procedure and the second is obtaining adequate anatomic perception. Procedure-specific tasks in decompression, stabilization, and deformity correction were also discussed.

Research priorities were identified, and high priority areas included task analysis and cognitive modeling, the development of high fidelity haptic interfaces, and the development of visualization and interaction algorithms for planning purposes.

1.6.2 Working Group 2

In Working Group 2, intraprocedural imaging and endoscopy, a review of current imaging modalities for image-guided spine procedures is given. The modalities are: computed tomography, magnetic resonance imaging, X-ray fluoroscopy, ultrasound, and endoscopy. This description is followed by a list of clinical/pathological conditions judged to be candidates for image-guided spine procedures. These include degeneration of the facet or ilio-sacral joints, herniation of intervertebral discs, vertebral fracture, inflammation, and tumor resection/treatment.

The role of the various imaging modalities listed above is summarized based on whether imaging is being performed for diagnosis or therapy. Future system requirements for image-guided spine procedures are discussed in terms of preoperative imaging requirements, virtual navigation requirements, interventional guidance requirements, other design requirements, and verification of therapy/tissue status. Research needs are then prioritized, including technical challenges, infrastructure issues, and other related factors.

For technical challenges, the greatest priority need is the development of a modular concept, starting with the integration of mobile CT, fluoroscopy, endoscopy, and navigation equipment. The next greatest priority is an open, modular, integrated MRI/fluoro-CT system for spinal work. Other priorities include increased tip accuracy and definition, multi-modality image fusion for navigation, fast volumetric 3D rendering, rapid tissue discrimination, small multi-modality endoscopic systems, the development of verification probes, and reducing the size of tomographic systems.

1.6.3 Working Group 3

Working Group 3 reported on registration and segmentation development needs. Their report begins with an overview of how image data are employed in image-guided surgery: preoperatively for planning, simulation, or model creation; intraoperatively to help guide the procedure; and a combination of preoperative and intraoperative images. Registration is then defined as the mapping of coordinates between any two spaces specifying volumetric images, the patient, or the instruments. Segmentation is defined as the delineation and labeling of image regions as distinct structures.

Clinical needs are then discussed, including requirements for accuracy and speed. Spine procedures for which image-guided surgery appears promising include instrumentation procedures, resection of tumors and arteriovenous malformations (AVMs), percutaneous procedures, the treatment of spinal instability, and, possibly, disc disease. Technical requirements are outlined in the areas of validation, registration, and segmentation.

Finally, research priorities are summarized, with the most important long-term goal being the development of intraoperative, fast, 3D imaging systems. Shorter term goals include an emphasis on validation, the development of intraoperative 3D-2D image registration methods, 3D image-patient to instrumentation registration, 3D image-to-image registration, and segmentation for various purposes.

1.6.4 Working Group 4

This Working Group focused on issues in anatomical and physiological modeling. While modeling has many different meanings with respect to image-guided surgery, in this report the focus was on anatomical/physiological and biomechanical data sets that provide the opportunities to influence the outcomes of spine procedures. Modeling of the spine for this purpose is a formidable task that is in its infancy of development.

The most important clinical need is increased realism in the models and simulations. Technical requirements include segmentation for discriminating heterogeneous soft tissue components, soft tissue modeling, and patient-specific models.

Research priorities for model development 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.

1.6.5 Working Group 5

Working Group 5 focused on preventive care of the spine, as the aging of the U.S. population has significant implications for spine care. The largest single complaint leading to spinal interventions is low-back pain. Preventive programs will require large scale delivery of certain procedures, particularly injections, for diagnosis and treatment.

It is believed that the development of special instrumentation and tooling, along with robotic systems, can contribute to the accuracy, efficiency, and safety with which such procedures can be carried out. Infrastructure needs include making visualization, registration, and data fusion standard procedures in the operating room or interventional suite. Funding for systems research and development is needed to develop and evaluate prototype delivery systems.

1.6.6 Working Group 6

Working Group 6 focused on the development of effective tools for image-guided surgery of the spine. Clinical needs include issues related to registration procedures and input of data, network requirements, graphical user interfaces, information sources, and outcomes studies. Technical requirements in imaging, including ultrasound, endoscopy, fluoroscopy, and intraoperative tomography, were identified. Technical needs in registration and intraoperative data integration were also discussed. The highest research priority that was identified by this group was a focus on creating mechanisms for describing vertebral motion and registration accuracy via intraoperative data.

1.7 REPORT OVERVIEW

The remainder of the report is organized as follows. The next chapter is the Workshop summary presentation given by Michael Vannier, MD. This summary is followed by the Working Group reports in Chapters 3-8. Each Working Group report includes a capsule summary "At a Glance" page, an overview, and reports on clinical needs, technical requirements, and research priorities for each topic. In Chapter 9, special presentations are reported, including a talk on the operating room of the future, and sessions on outcomes measures for spine interventions and the therapy teams of the future. Appendix material includes the Workshop program, a list of participants, a summary of the questionnaire responses, the bibliography suggested by the participants, and the references cited in this report.

CHAPTER 2: WORKSHOP SUMMARY PRESENTATION

Image-Guided Spine Procedures

Technical Requirements Planning

Overview and Summary

Michael W. Vannier, MD
University of Iowa

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.

Contents

- Planning objective and process
- Significance of the problem
- Background
- Needs and opportunities
- Strategy
- Detailed recommendations
- Recommendations specific to spinal surgery
- Summary

2.1 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 2-1) 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.

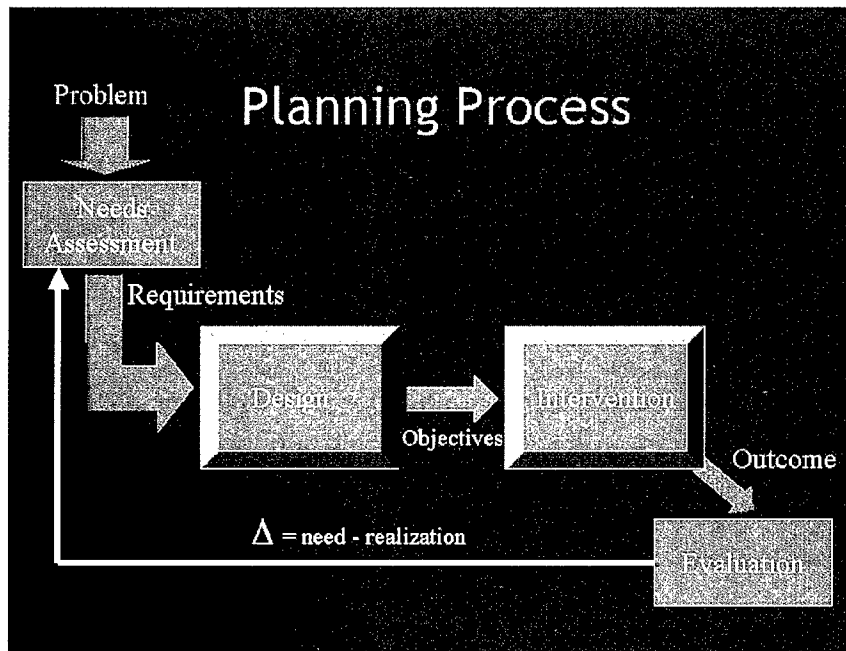


Figure 2-1. Workshop Planning Process

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.

The Workshop is organized into six Working Groups, each of which has a specific area of concentration (Figure 2-2). 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 2-2: 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?

2.2 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 (Deyo 1998).

However, there are cases when surgery is indicated. According to Deyo, 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 (Wipf and Deyo 1995).

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 the overall efficiency be improved.

2.3 BACKGROUND

The image-guided spine surgery process is complex. As shown in Figure 2-3, 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.

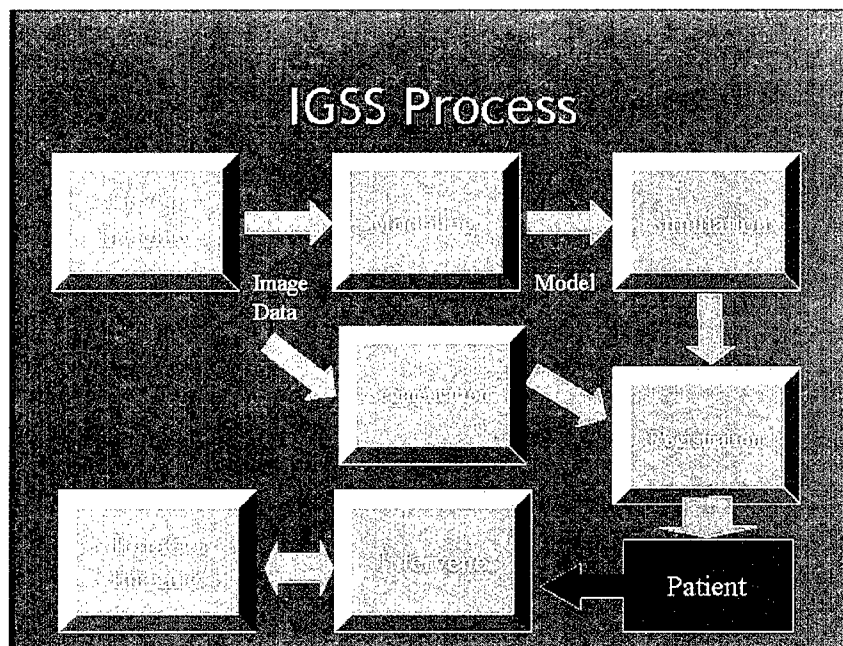


Figure 2-3: Image-Guided Spinal Surgery Process Diagram

Whom do we want to serve? There are many 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 surgery systems (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 published in Spine in 1995 (Boos and Rieder et al 1995) 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 disc 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 discs) 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.

2.4 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.

2.5 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.

2.6 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 of 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.

2.7 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

2.8 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.

CHAPTER THREE AT A GLANCE: OPERATIVE PLANNING AND SURGICAL SIMULATORS
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Overview

Advances in pre- and intraoperative planning and virtual reality-based simulation of image-guided surgery of the spine are indicated by the authors. However, applications of the technology for spine procedures are currently, in a word, limited.

Clinical Needs

Common tasks and needs in image-guided spine procedures are identified as:

- enabling identification of the optimal trajectory for the procedure
- obtaining adequate perception of the anatomy of the spine
- meeting the needs of procedure-specific requirements for procedures such as decompression, stabilization, and deformity correction

Technical Requirements

Three required research needs should focus on:

1. Parameters for the development of effective tools for pre- and intraoperative perception and visualization, based on the aforementioned clinical needs.
2. The role of cognitive and human factors in image-guided surgery.
3. Predictive biomechanical models which can assist in, for instance, the placement of instrumentation during spine procedures.

Research Priorities

Thirteen Research Priorities are identified by the authors, each assigned a degree of priority, from high to low. A table listing these priorities is presented on page 30.

The full report of this Working Group appears on pp. 25-30.

CHAPTER 3: OPERATIVE PLANNING AND SURGICAL SIMULATORS

... The Report of Working Group 1

AUTHORS

Frank Tendick, PhD, University of California San Francisco (Technical Leader)
David Polly, MD, Walter Reed Army Medical Center (Clinical Leader)
Daniel Blezek, PhD, Mayo Clinic
James Burgess, MD, Inova Fairfax Hospital
Craig Carignan, PhD, University of Maryland
Gerald Higgins, PhD, Ciemed Technologies
Corinna Lathan, PhD, The Catholic University of America
Karl Reinig, PhD, University of Colorado

3.1 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 equivalently to the real patient, but is not the real patient. Thus "sawbones," or plastic models of anatomy, would qualify as a simulator 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 3-1. 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 3-2. The physical modeling methods 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.

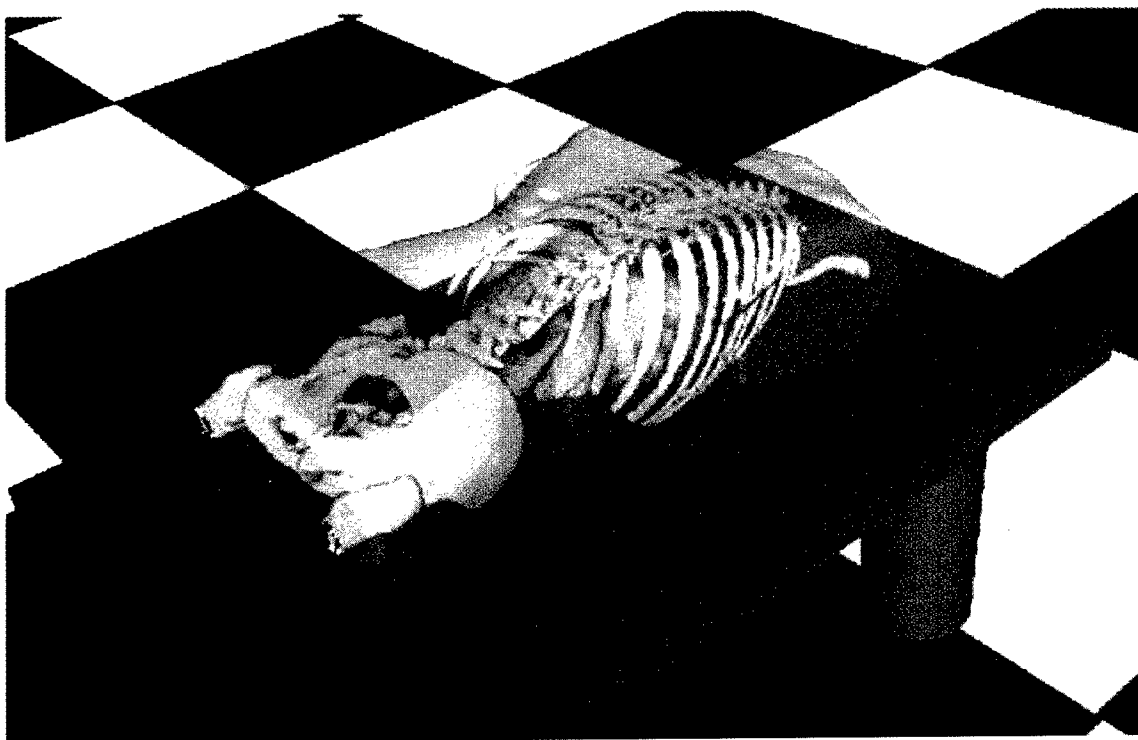


Figure 3-1: Three-Dimensional Visualization for Surgical Simulation
(Courtesy of Daniel Blezek, PhD, and Richard Robb, PhD, Mayo Clinic)

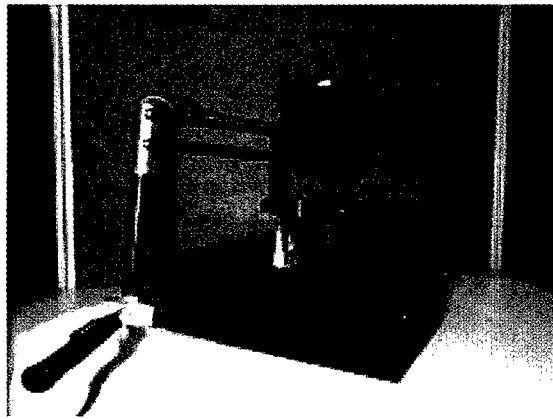


Figure 3-2: Six Degree of Freedom Force Feedback Device
(Courtesy of SensAble Technologies)

3.2 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. Images are obtained well before the operation, which allows for a planning timeframe 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 of 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.

3.3 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 to achieve sufficient fidelity in geometrical and physical models, or 0.1 mm. 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 are high priorities 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. 3D image-to-patient/instrument registration, discussed in greater detail by Working Group 3 (page 52), 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.

3.4 RESEARCH PRIORITIES

Table 3-1 summarizes and prioritizes the technical requirements needed for effective planning and simulation of image-guided surgery of the spine described in the previous sections.

High Priority

- (*) Task analysis and cognitive modeling of human performance, to be undertaken 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

Table 3-1: Research Priorities for Planning and Simulation Needs for Image-Guided Spinal Surgery

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

CHAPTER FOUR AT A GLANCE: INTRAPROCEDURAL IMAGING AND ENDOSCOPY

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 Tables 4-1 to 4-3 on page 40.

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" (page 41), five phases of development for requirements of a future, more all-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.

The full report of this Working Group appears on pp. 33-45.

CHAPTER 4: INTRAPROCEDURAL IMAGING AND ENDOSCOPY

... The Report of Working Group 2

AUTHORS

Jeffrey L. Duerk, PhD, Case Western Reserve University (Technical Leader)
Dietrich Grönemeyer, MD, Witten/Herdecke University (Clinical Leader)
Benedicte Bascle, PhD, Siemens Corporate Research
Laurence Clarke, PhD, NIH Office of Imaging Technology
Martin Deli, BS, Witten/Herdecke University
Gilbert Devey, BS, Georgetown University Medical Center
William Herman, BS, Food and Drug Administration
Barbara Hum, MD, Georgetown University Medical Center
Yongmin Kim, PhD, University of Washington
Arthur Rosenbaum, MD
Vance Watson, MD, Georgetown University Medical Center
S. James Zinreich, MD, Johns Hopkins Medical Institutions

4.1 OVERVIEW

In the past 20 years, advancements in imaging procedures, coupled with improvements in minimally invasive surgical techniques, have led to significant strides toward reducing patient morbidity and mortality. These advancements have been most widely developed in orthopedic and abdominal surgical applications. Recent work indicating advancements in image-guided spine procedures has been much more limited, however. Neurosurgical guidance via endoscopy and interventional MRI, and development for procedures of the spine, have been noted at only a few centers of excellence.

The challenges for successfully adapting and creating technology for image-guided spinal procedure are vast; the opportunity, however, is greater. This chapter will focus on technological development involved in intraprocedural imaging of the spine, including endoscopy. The current tools available for image-guided procedures of the spine will be summarized. A section on clinical applications that could be amenable to image-guided surgical procedures of the spine will follow. Three tables are then presented which denote the relative importance of imaging modalities (such as computerized tomography and magnetic resonance imaging) in spine procedures, including disc disease; spinal tumors; and instability, deformation, and fracture. These tables will be followed by a summary of the role of current tools in meeting the technical and clinical demands in image-guided spinal imaging. Concluding segments prioritize the technical issues of importance as well as identify and prioritize the infrastructural changes that are needed in the development of image-guided spine procedures.

4.2 IMAGING MODALITIES FOR IMAGE-GUIDED SPINE PROCEDURES

Imaging modalities currently used for image-guided procedures of the spine include computed tomography (CT), magnetic resonance imaging (MRI), X-ray fluoroscopy, ultrasound (US), and endoscopy. Each of these technologies is described below in terms of capabilities for real-time capture and display.

COMPUTED TOMOGRAPHY (CT)

There are five types of computed tomography (CT) systems available and used today in intraoperative spine procedures. All provide excellent contrast between bone and soft tissues and a high ability to localize the tip of interventional instruments. Operational information on each of these five systems is described as follows.

1. **Electron beam CT** systems acquire multiple images in real time by deflection of an electron beam into fixed anode material. Essentially, the electron beam CT is a large electron gun. Primary advantages of the electron beam CT are its rapid acquisition time, low radiation dose, versatility, and ability to achieve 8 parallel slices without table movement. The gantry, or patient opening, is very large. Unfortunately, the reconstruction time is long and the price of the system is high. An electron beam CT intervention is shown in Figure 4-1.



Figure 4-1: Interventional Procedure in Electron Beam CT Scanner
(Courtesy of Dietrich Grönemeyer, MD, Witten/Herdecke University)

2. **Fluoroscopic CT** systems' advantages include real-time capability for imaging, reconstruction and display, procedure targeting, and localizing the interventional tool. The patient access is quite good. However, the X-ray dosage for the patient and physician is high. Furthermore, fluoroscopic CT systems are expensive.
3. **Spiral CT** systems use a moving patient table and a continuously rotating X-ray tube to acquire image data that spirals through the cross-section of the patient. Most of the currently sold CTs are equipped with this feature. The speed for the acquisition of a true 3D image volume is good. The capital and maintenance costs of these systems are high, however.
4. **Older CTs**, typically of the non-spiral type, are widely available and new, non-spiral CTs are relatively low cost. Their disadvantages include a slower 2D and 3D acquisition time when compared to spiral scanners. Older systems use a higher X-ray dosage, and many of them provide modest to poor imaging quality.
5. **Mobile CT** systems are portable, using a combination of battery and wall outlet energy sources. They allow tremendous flexibility in operating room siting and have the ability to be integrated easily with other modalities at relatively low radiation doses. Unfortunately, they have lower image quality, decreased tube capacity, and provide slow acquisitions. Specific challenges involve providing adequate image registration when attempting integration with other modalities and overcoming maneuverability limitations which result from their great weight. A photograph of a mobile CT in use in the operating room is shown in Figure 4-2.

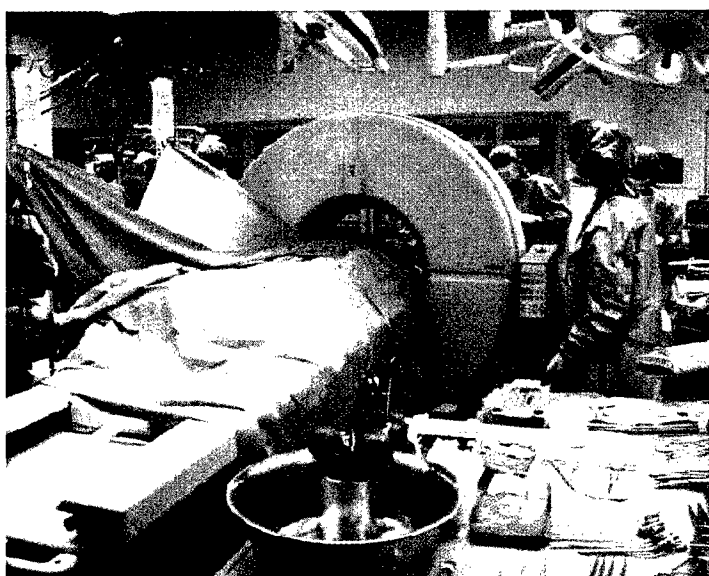


Figure 4-2: Mobile CT System in Operating Room
(Courtesy of Kevin Cleary, PhD, Georgetown University)

MAGNETIC RESONANCE IMAGING (MRI)

As with the use of CT technology, there are a number of magnetic resonance imaging (MRI) systems which may prove useful in image-guided spine procedures. However, unlike CTs, MRI systems are able to achieve excellent soft tissue contrast (via a variety of relaxation phenomena) in arbitrary scan plane orientations without the use of ionizing radiation. MRI technology is also able to achieve special contrasts, such as semi-quantitative thermal visualization. Limitations of MRI technology include:

- The as-yet unaddressed safety issues within the fringe field (and hence the need for specialized tools and other MRI-compatible equipment)
- Insufficient tip accuracy
- Poor definition of bony structures
- A variety of potential artifacts which can be generated
- High cost

In addition, there are no real-time MRI scanners currently available. The scan protocols used at different institutions are highly variable, which limits the ability to perform comparative analyses.

Specific types of MRI systems are among the following:

1. **Open MRI systems (0.06 to 0.35T).** Advantages include: good patient access, resolution sufficient for guidance in low-risk areas, and, most recently, automated scan plane definition. An example of this type of system is shown in Figure 4-3 and Figure 4-4.
2. **Open MRI systems (0.5T [e.g., GE SPI]).** Advantages are the same as above for patient access, resolution, and scan plane definition. There is modest agreement that there is a slight improvement in image quality over lower field systems, but this assessment has not been confirmed. Disadvantages include high cost and restricted physician access for spine procedures.
3. **Closed MRI (0.5T to 2.0T).** Advantages include faster and better image quality and the ability to acquire spectroscopic data at the expense of virtually no patient access, reduced patient acceptance, limited access for surgical instruments, and high cost.

X-RAY FLUOROSCOPY SYSTEMS

X-ray fluoroscopy systems provide excellent visibility of bone, real-time imaging over a large field of view, widespread accessibility, high portability, and low cost. The primary limitations are the high dosage of radiation for the patient and physician, poor soft-tissue discrimination, only two-dimensional information acquisition display, and consequent problems resulting from the display of overlapping tissues.

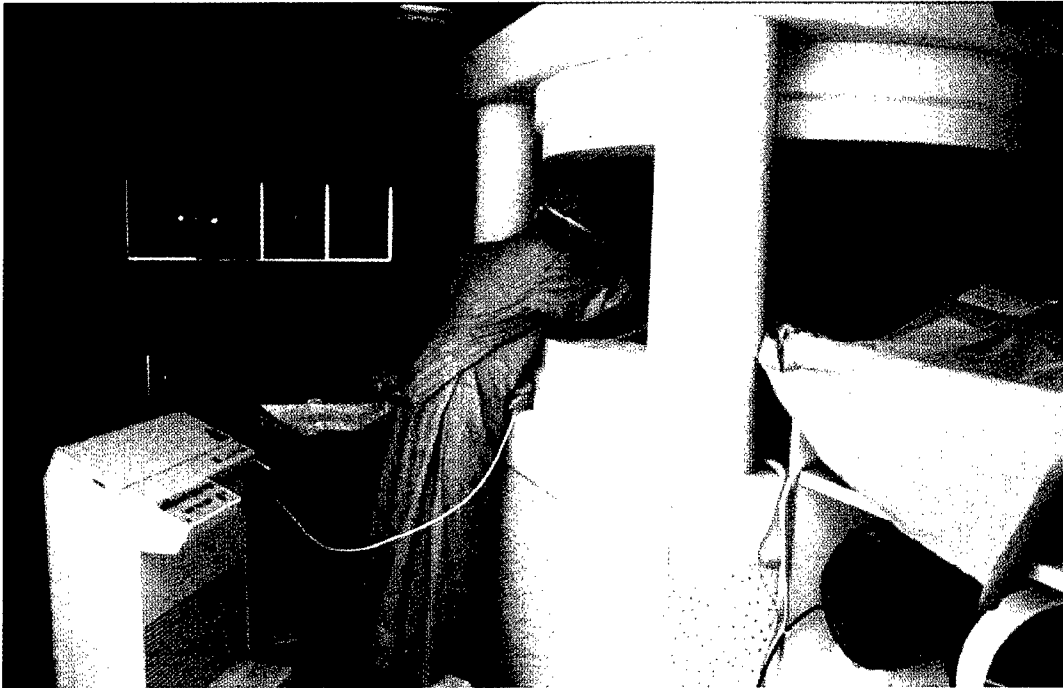


Figure 4-3: Procedure in Toshiba Access Open MRI
(Courtesy of Dietrich Grönemeyer, MD, Witten/Herdecke University)



Figure 4-4: Intraoperative MRI – Close-up View
(Courtesy of Dietrich Grönemeyer, MD, Witten/Herdecke University)

ULTRASOUND (US)

Diagnostic ultrasound (US) systems' increasingly important role in intraoperative spine imaging has resulted from the recognition of ultrasound's many advantages. Ultrasound images are obtained in a real-time manner on inexpensive, small, and portable equipment. Its history and role in the operating room is well accepted. While 3D image acquisition systems are now being demonstrated, an additional advantage of ultrasound is that images are obtained without the use of ionizing radiation. Unfortunately, the image quality is poor when compared to CT, MRI, and fluoroscopy. In addition, adequate use is highly dependent on the skills of the operator. Discrimination via imaging between tissue types within the spinal cord is limited, and intraoperative access is often required.

ENDOSCOPY

Endoscopic imaging systems typically rely on some type of video system for image display. The technology offers several advantages. For instance, no radiation dose is required for image acquisition, the images being obtained from the visible portion of the electromagnetic spectrum. In addition, endoscopy provides real-time images of the true anatomy via readily available, inexpensive hardware. The primary disadvantage of the technology is that endoscopic images show only surface information within a limited field of view. This imaging is, furthermore, achieved only by introducing endoscopic probes invasively into the patient. An example of an EBCT scan of an endoscopic procedure is shown in Figure 4-5.

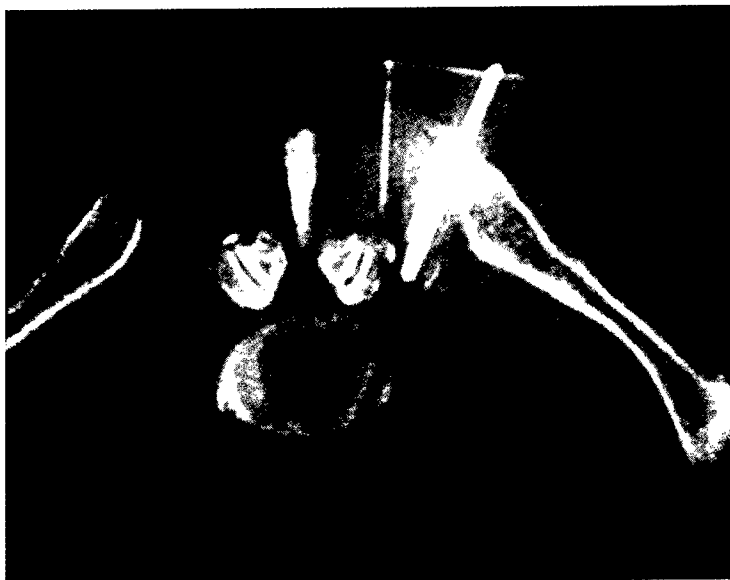


Figure 4-5: Electron Beam CT Scan of Endoscopic Procedure
(Courtesy of Dietrich Grönemeyer, MD, Witten/Herdecke University)

4.3 CLINICAL/PATHOLOGICAL PROBLEMS AMENABLE TO IMAGE-GUIDED SPINE PROCEDURES

A number of clinical/pathological conditions were judged by our Working Group to be amenable to image-guided procedures of the spine. These conditions include procedures of the facet joints (both acute and chronic/degenerative), procedures of the ilio-sacral joint (both acute and chronic/degenerative), procedures involving the intervertebral discs (prolapse, protrusion: acute, chronic, sequestration, mass herniation), vertebral fracture (due to trauma, osteoporosis, tumor), inflammation (disc, vertebral body, or both), and tumor resection/treatment (vertebral body with/without disc/cord involvement, with or without involvement of the adjacent soft tissue).

There are two ways in which the *Importance* of these clinical conditions can be prioritized. One is in terms of immediate impact on the health of an individual patient. The other is in terms of the total numbers of patients, who would benefit through improved quality of life. Using the immediate impact on health definition, tumor, fracture, inflammation, disc herniation and then facet joint procedures would be ranked highest to lowest. When prioritized by numbers of patients, the highest to lowest ranking would be as follows: facet joint procedures, fracture, disc herniation, and then tumors, as described in Figure 4-6.

- Facet joint disease affects millions of patients per year, and the management of the chronic pain associated with this disease incurs societal costs over multiple years. Currently, injection of anesthetic blocks is performed via X-ray image guidance. Anesthetic blocks and chemical or thermal ablation, inside or outside the joint, is performed under CT or MRI guidance at only a few treatment centers in the U.S.
- Fracture of the vertebral body occurs approximately 500,000 times/year in the U.S., with many individuals experiencing multiple fractures. Paraplegia, hemiplegia, and death can occur. Image-guided treatment options include semi-blind pedicle screw insertion, interbody fusion, and vertebroplasty.
- Disc herniation affects approximately 350,000 people/year in the U.S. The disease may begin with chronic pain and progress to neurological deficits, paralysis/paraplegia/hemiplegia, and death if the herniation occurs high in the cervical spine. Image-guided treatment options include chemonucleolysis, or nucleolysis via laser or radiofrequency energy deposition.
- Tumors within the spine, including those involving the cord and also those involving adjacent soft tissue are not as common as other pathological conditions. Treatment options include: surgery (pedicle screw, interbody fusion, etc.), vertebroplasty, thermal ablation for metastatic and benign tumors (hot, cold), radiation therapy (e.g., brachytherapy), drug injection, and nidus excision.
- Conditions involving inflammation are often treated via percutaneous needle-based procedures, including biopsy, drainage, and local injection of drugs.

Figure 4-6: Numbers of Spine Procedures in the U.S. — A Prioritized List

4.4 DISEASES OF THE SPINAL CORD AND THE CURRENTLY PREFERRED TREATMENT MODALITIES

The role of the various imaging modalities in spine disease is based on whether imaging is being performed for diagnosis or therapy. Three tables presented below indicate the suitability of CT, MRI, fluoroscopy, and endoscopy in a variety of pathological conditions of the spine.

DISC DISEASES		
	DIAGNOSIS	THERAPY
CT	++	+++
MRI	+++	+
Fluoroscopy	+	++
Endoscopy	0	++

Table 4-1: Imaging Modalities for Disc Diseases

SPINAL TUMORS		
	DIAGNOSIS	THERAPY
CT	++	+++ (drug distribution)
MRI	+++	+++ (thermotherapy)
Fluoroscopy	+	++
Endoscopy	0	+++ (intraspinal)

Table 4-2: Imaging Modalities for Spinal Tumors

INSTABILITY, DEFORMATION, AND FRACTURE		
	DIAGNOSIS	THERAPY
CT	++	++
MRI	+++	+
Fluoroscopy	+	+++
Fluoroscopic CT	++++	++++
Endoscopy/US	0	++ (endoscopy for the removal of bone fragments)

Table 4-3: Imaging Modalities for Instability, Deformation, and Fracture

TABLE KEY:

- ++++: extremely suitable
- +++ : good suitability
- ++ : suitable
- + : poor suitability
- 0 : not suitable

4.5 FUTURE SYSTEM REQUIREMENTS FOR IMAGE-GUIDED SPINE PROCEDURES

No single imaging modality currently meets the clinical and technical needs for both diagnostic and therapeutic procedures of the spine, as indicated in Tables 4-1 to 4-3. Because of existing technical limitations, members of our Working Group foresee the opportunity to define the requirements that a future system for image-guided procedures of the spine should provide. Five phases of development are involved: 1) preoperative imaging; 2) virtual navigation; 3) interventional guidance; 4) documentation procedures, including other design requirements; and 5) verification of therapy/tissue states. Each of these phases is described below.

Preoperative Imaging Requirements. Prior to actual image guidance, the preoperative imaging should provide good soft tissue contrast (as currently attained with MRI) in addition to bony contrast (as is accomplished with X-ray-based modalities). It is desirable to achieve 3D volumetric imaging in addition to vessel imaging, and to have the ability to co-register CT/MRI/endoscopic information for navigation. (Registration is the subject of the report by Working Group 3 on page 47.)

Virtual Navigation Requirements. To achieve successful virtual navigation which allows effective interventional procedure planning, a platform that is integrated with the imaging device must provide accurate cross-correlation between preoperative image data and the current patient position. This correlation may be achieved via some type of external or anatomical fiducial co-registration and warping registration. A data pinpointing device may identify anatomical locations such as the spine vessels, nerve roots, iliac crest, colon, or kidney in complementary preoperative data and align these to the patient's current orientation. To be most useful, the virtual navigation's data must be updated as quickly as possible, but not exceeding 20 seconds; and these data must be accurate within 2 mm or better for interventional guidance planning.

Interventional Guidance Requirements. To achieve successful image-guided procedures in the spine and to advance the field beyond current capabilities, it will be necessary to achieve the following requirements: a 1 mm tip accuracy in-plane in CT or MRI over a 200 mm field of view (FOV) at 2-3 mm slice thickness during an acquisition which provides greater than one image/second. We foresee the system being a combined MRI/CT fluoroscopy system which provides the soft tissue and bony tissue contrasts that are necessary at various phases of most intraoperative procedures of the spine.

Examination of Tables 4-1 to 4-3 indicates that while MRI is quite successful to date in diagnosis, it plays only a small role in intraoperative/therapeutic spine procedures, for which the more rapid CT scans and the higher device tip accuracy are available. Future MRI systems will likely utilize new materials and new scan techniques to minimize the magnetic susceptibility artifacts which currently limit tip accuracy. Improvements in image acquisition time will ultimately depend on the magnetic field strength for the MRI component of the system. At 0.5T and above, Maxwell field terms which limit echo-planar imaging (EPI) on lower field systems may be sufficiently low to permit EPI.

Alternatively, new work in real-time steady-state imaging may make these methods more desirable due to improvements in the images' signal-to-noise ratio, artifact reduction, and contrast resolution, when compared to EPI.

Other Design Requirements for Systems of the Future. To permit a robust array of intraoperative surgical procedures, it will be imperative to design a combined MRI/CT fluoroscopy system which is maximally open, for reasons both of patient acceptance and improved physician access. Currently, systems are limited to approximately 40 cm access over about a 120° rotation (vertical field MRI) and 45 cm on either side of the patient table. It is important to realize that the image FOV will only need to be approximately 200 mm, thus relaxing design constraints imposed by current systems which were intended to be used for interventional and diagnostic procedures throughout the body.

In addition, methods that are currently in development to correct for both magnetic field non-uniformity distortions of the image plane and gradient non-linearity distortions may prove to be effective enough to further relax geometric design constraints which currently impose a rigorous geometry to the MRI component of a spine imager of the future. It is anticipated that issues regarding deflection of the electrons during travel from the cathode to the anode of the X-ray component of the system will be minimized by shielding, but this process should be evaluated as well. It is important to point out that the combined MRI/fluoro-CT system imagined for future spinal surgery is not intended to resemble the existing Philips Gyroscan equipped with a C-arm fluoroscopy system at the end of an extended patient table; instead this system will be integral to the shared imaging volume.

During the therapeutic approach to the spine, the MR and X-ray CT images must be able to provide at the very least a 1-2 mm spatial resolution. The integrated fluoroscopic/CT and/or MR imaging must be fully integrated with the preoperative data registration system. That is, the software and hardware to perform preoperative image registration to the patients' current image data sets must be integral components of the system. There should be no external stand-alone workstations. Furthermore, the system should operate from a single console: MRI and fluoroscopic/CT imaging are to be performed from a single computer interface. In essence, the system will provide a "one table solution." Our Working Group estimated that the system would need to be priced at approximately \$800,000 to achieve market penetration into most academic centers in the U.S. (approximately 200).

Verification of Therapy/Tissue Status. Because image-guided spinal surgery may involve a variety of pathological conditions and a variety of therapies, it is imperative that the surgical system provides sub-second control and feedback information. As technology advances, it may be possible to use imaging, modeling, and other tools to determine the status of ongoing therapies (e.g., thermal ablation). It would be desirable to automatically assess the treatment margin via images and the tissue biology via modeling until other confirmatory methods are developed for the 3D volume.

For intraoperative imaging, we foresee the use of a "verification" probe (technology yet to be developed) that provides additional physical parameter information of the tissue underlying the probe tip. The tip location would be shown on acquired images, while output from the probe would provide information on indicators such as pH, pO₂, pCO₂, or other biochemical markers; material stiffness or density; or, for tumors, identification of the underlying tissue as either normal or pathologic. To date, this information cannot easily be measured by imaging. MRI methods exist or are in development that can measure only pH (via spectroscopy), temperature, stiffness, and a few other physical parameters of tissues.

4.6 RESEARCH NEEDS: PRIORITIZATION OF TECHNICAL ISSUES

Technical imaging requirements for future image-guided spine procedures will be varied among physicians. While certain requirements, such as a combined MRI and CT/fluoroscopy system, would be shared by all spine interventionalists, other requirements will be different. For this reason, it is the recommendation of this Working Group that the system should be designed from a *Modular Concept*, allowing integration of MR, fluoroscopy, and image guidance in a basic configuration to a more sophisticated system that integrates mobile CT, fluoroscopy, endoscopy, and navigational components.

It is important to stress that the system needs to have greater patient/physician access than that provided by existing MRI or CT systems. An optimal open modular MRI/fluoro-CT system for spinal work would have an open MRI *AND* CT gantry. The software would perform multimodality image fusion (MR, CT), endoscopy, and angiography (MR, CT, fluoroscopy) for navigation to the target tissue and during navigation provide approximately 1 mm tip accuracy and tip definition in displayed images. The acquired 3D image volume must be acquired rapidly and allow 3D rendering. In addition, more research is needed to determine the acquisition parameters that are necessary to achieve not only the spatial and temporal resolution requirements for image-guided spine procedures, but also the tissue contrast requirements. Little work has been done to date to address the image contrast needs of the spine interventionalist during the procedure.

The physically small, open, one-table solution which includes probes for providing additional information (namely, the "verification probe") will be an important tool to future spine interventionalists, with the following caveats. The cost and efficacy of the system must enable widespread availability; and the system needs to include ergonomically designed and functional devices. It cannot be overemphasized that the imaging, navigation, and planning system is to be fully integrated into a single "box." A summarized list of the Technical Requirements is provided in Figure 4-7.

1. **Modular concept (as a first step):** Integration of mobile CT, fluoroscopy, endoscopy, navigation, and therapeutic equipment
2. **Optimized operation theater (as a second step):** Optimal, open modular MRI/fluoro-CT system for spinal therapies
3. Increased tip accuracy and tip definition
4. Multi-modality image fusion for navigation
5. Fast volumetric 3D rendering
6. Rapid tissue discrimination over the 3D volume
7. One-table solution
8. Open CT gantry
9. Small multi-modality endoscopic systems
10. Development of verification probes
11. Reduced size of tomographic systems

Figure 4-7: Prioritized List of Technical Challenges for Future Imaging Systems

4.7 RESEARCH NEEDS: PRIORITIZATION OF INFRASTRUCTURE CHALLENGES

Our Working Group is convinced that infrastructure-related issues will play a critical role in development issues that are related to the design and use of image-guided surgical tools. "Infrastructure," for our purposes here, refers to the underlying facilities (physical and personnel) and resources that must be in place for successful attainment of image-guided procedures of the spine.

Changes in routine tasks and roles will need to be planned. Most importantly, training will be required of all image-guided spinal procedure team members. Physicians, technicians, and engineers will initially all need to define, learn, and gain experience in working as part of a new, interdisciplinary team. Secondly, in the future, we foresee the growth of new professions, including nurse/technologist, radiological surgeons, and surgical radiologists. This change, in effect, represents a set of professionals that is skilled in multiple disciplines. In addition, the administration of data, patients, personnel, equipment, and operating rooms must be centralized under one line of authority. These elements are summarized in Figure 4-8.

1. Training: physicians, technicians, engineers
2. New profession: nurse/technician, medical engineer, radiological surgeon/surgical radiologist
3. Administration of data, patient, personnel, machines, and OR
4. Sterility

Figure 4-8: Prioritized List of Elements of a New Required Infrastructure

A number of other important items must be addressed at some point during the development of new technology and new clinical procedures, as noted in Figure 4-9. A compelling case must be made to the major medical imaging vendors justifying capital expenditures for research and development of the proposed systems. Once completed, a continuing dialog between the vendors and their development partner institutions is needed to ensure that the capital and maintenance costs for these systems are not excessive. We estimate that a cost of approximately \$800,000 would be tolerable, in addition to approximately a 10% annual maintenance fee. The justification for vendors to commercialize prototype systems and for institutions to purchase them will be based on outcomes studies that demonstrate cost efficiency and clinical efficacy. As noted above, a great deal of the administration of the image-guided facilities for the spine will need to be the responsibility of a single entity. This arrangement will likely require care in ensuring that institutional politics are handled diplomatically, with an emphasis on consensus building. The worst outcome would be that the system, for either practical or political reasons, is not accepted by disciplines other than those in control of the facilities.

1. Costs: capital (R&D) and maintenance
2. Reimbursement
3. Outcomes analysis
4. Institutional politics
5. Acceptance by other disciplines

Figure 4-9: Prioritized List of Other Factors Related to Technical Developments

4.8 SUMMARY

The availability of intraprocedural imaging and endoscopy of the spine will increasingly help to perform safe and efficient minimally invasive therapies. New technical equipment, clinical procedures, and professions have to be developed to optimize the value of image guidance for the health of the patient and the reduction of medical expenses.

CHAPTER FIVE AT A GLANCE: REGISTRATION AND SEGMENTATION
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Overview

Registration maps the coordinate systems involved in spine procedures, including the images, patients, and/or instruments. Segmentation delineates and labels image regions. The uses of imaging in the registration and segmentation aspects of spinal procedures are identified by the authors, who note that, while image guidance is not yet widely used for spine procedures, such guidance could greatly enhance the current standard of practice.

Clinical Needs

A strong need for developing practical, clinically useful intraoperative 3D imaging systems is indicated by the authors. Four categories of spine procedures where image-guided surgery appears promising are defined: 1) instrumentation and percutaneous procedures; 2) tumor resection; 3) treatment of spinal instability; and 4) disc removal.

Technical Requirements

Three technical problems which require research are prioritized by the authors, as:

1. Validation. Compilation of a database is needed which primarily includes an absolute standard for validation assessment of accuracy and precision of instrument placement.
2. Registration. Three types of image registration are identified; and particular technical improvements required of each are noted, such as those related to improved accuracy and speed of imaging procedures.
3. Segmentation. Specific problems related to the need to differentiate anatomical structures (as in preoperative surgical planning to correct AVMs) are discussed.

Research Priorities

Development of procedures needed for the evaluation of an overall image-guided surgical system and its components was the most highly prioritized need. The key long-term goal is the development of fast intraoperative 3D imaging systems; while shorter term goals include development of techniques for validation of registration methods and 3D-based registration techniques.

The full report of this Working Group appears on pp. 47-55.

CHAPTER 5: REGISTRATION AND SEGMENTATION

... The Report of Working Group 3

AUTHORS

Benjamin Kimia, PhD, Brown University (Technical Leader)
Elizabeth Bullitt, MD, University of North Carolina (Clinical Leader)
Lou Arata, PhD, Picker International & DePuy Motech AcroMed
Gene Gregerson, MS, Visualization Technology, Inc.
Alan Liu, PhD, National Institutes of Health
Yanxi Liu, PhD, Carnegie Mellon University
Murray Loew, PhD, George Washington University
Nassir Navab, PhD, Siemens Corporate Research
Y. Raja Rampersaud, MD, University of Toronto
Joseph Wang, PhD, The Catholic University of America
William Wells, PhD, Harvard Medical School and Brigham and Women's Hospital
Terry Yoo, PhD, National Library of Medicine
Jianchao Zeng, PhD, Georgetown University Medical Center
Qinfen Zheng, University of Maryland

5.1 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 chapter 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.

5.2 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 time frame 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 5-1. 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.

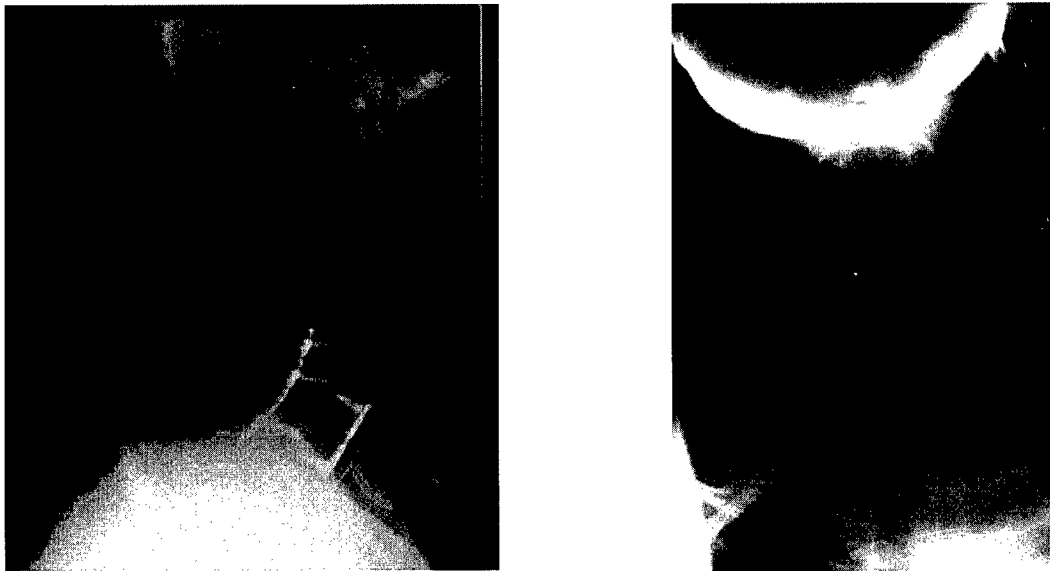


Figure 5-1: Surgical Instrumentation

(Courtesy of Elizabeth Bullitt, MD, 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.

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 5-2.

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 that shown in Figure 5-3, 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 to predict. High-speed, 3D intraoperative imaging would provide the best method of managing such problems.

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.

5.3 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.



Figure 5-2: Spinal Tumor
(Courtesy of Elizabeth Bullitt, MD,
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).

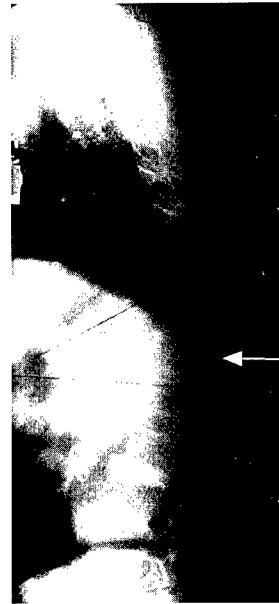


Figure 5-3: Spinal Instability
(Courtesy of Elizabeth Bullitt, MD,
University of North Carolina)

This patient has a typical thoracic compression fracture (arrow) with kyphosis and angulation of the spine. Surgery was required.

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 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, compilation of a database is needed 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, and
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 from 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 coordinate 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 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 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 in the next chapter. 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 5-2 on page 51 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 misinsertion 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 is the best approach for several other types of clinical problems. For example, the majority of tumor removals and of "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.

5.4 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
 - a) 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 data base 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 relative geometry and alignment.

5.5 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.

CHAPTER SIX AT A GLANCE

ANATOMICAL AND PHYSIOLOGICAL MODELING

Overview

Modeling for use in image-guided spine procedures requires development of anatomical/physiological and/or biomechanical data sets that provide opportunities to predict, evaluate, simulate, validate, develop, and enhance the outcomes of procedures. The modeling processes are discussed at length, although it is noted that the use of modeling in image-guided procedures is still in its infancy.

Clinical Needs

The importance of anatomical and physiological modeling has become better appreciated as health care trends move toward development of less invasive clinical procedures. The clinical needs that require research are:

- identifying procedures that are most amenable to modeling, such as procedures related to spinal stabilization and spinal deformity correction;
- defining the components of the models. Needed features that are identified by this Working Group are: modularity, interchangeability, and patient-specific models.

Technical Requirements

Seven requirements were identified by the authors and include:

- Further research into spinal modeling development needs
- Further understanding of spine-related physiological and biomechanical properties
- Development of algorithms to track tissue deformation

Research Priorities

The authors identify five priorities, all of them focused on model development involving:

1. Clinically relevant problems of deformity and spine stabilization
2. Shape construction and proper alignment and positioning of component parts
3. Better understanding of biomechanical relationships involving interaction of heterogeneous soft tissue components and bony structures
4. Incorporation of data on wear patterns, age, stress, and load bearing
5. The effects of surgery or other interventions

The full report of this Working Group appears on pp. 57-65.

CHAPTER 6: ANATOMICAL AND PHYSIOLOGICAL MODELING

... The Report of Working Group 4

AUTHORS

James Anderson, PhD, Johns Hopkins University C.I.S.S.T. Engineering Research Center (Technical Leader)

Ron Kikinis, MD, Brigham and Women's Hospital (Clinical Leader)

Andrew Bzostek, MS, Johns Hopkins University C.I.S.S.T. Engineering Research Center

Ed Chao, PhD, Johns Hopkins University

Christos Davatzikos, PhD, Johns Hopkins University C.I.S.S.T. Engineering Research Center

Matthew Freedman, MD, MBA, Georgetown University Medical Center

Martha Gray, PhD, Massachusetts Institute of Technology

Noshir Langrana, PhD, Rutgers University

Greg Mogel, MD, U.S. Army Medical Research and Materiel Command

Thomas Whitesides, MD, Emory University

6.1 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 of 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 and value to the physician end-user.

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.

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 6-1.

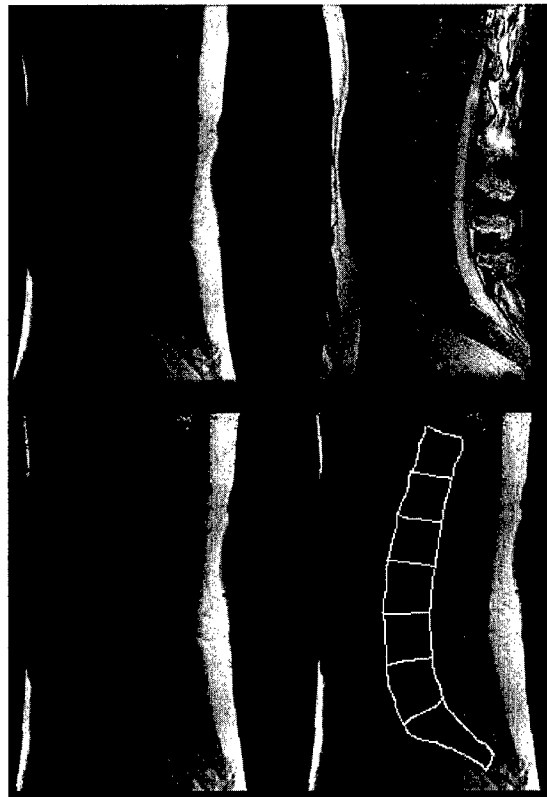


Figure 6-1: Elastic Registration of Spine Images
(Courtesy of Christos Davatzikos, PhD, Johns Hopkins University)

The images at 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 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 6-2. The same techniques could be applied to the spine.



Figure 6-2: Finite Element Simulation of Tumor Growth in the Brain
(Courtesy of Christos Davatzikos, PhD, Johns Hopkins University)

Left: MR image of a normal subject. Right: Simulation of the soft tissue deformation.

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 such as positron emission tomography (PET) with anatomical imaging such

as computed tomography (CT) or magnetic resonance imaging (MRI). Physiological information could include electromyogram (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 be physiologically and functionally accurate.

6.2 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 and possibly the procedures 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 and 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.

6.3 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.

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 6-3.

- 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 6-3: Required Technical Components of the Model Development Process

In addition to addressing each of the steps suggested in Figure 6-3, 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 towards

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.

6.4 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.

CHAPTER SEVEN AT A GLANCE: SURGICAL INSTRUMENTATION, TOOLING, AND ROBOTICS

Overview

The significant need to address the problem of lower back pain, currently the single largest presenting complaint in the U.S., is stressed in this Working Group's report.

Clinical Needs

This Working Group identified and assessed three image-guided spinal interventions, including needle procedures for nerve root decompression; interventions for compression fractures; and minimally invasive techniques to destroy tumors in the spine.

Technical Requirements

The state of the art in guiding needle procedures is represented by manual fluoroscopic guidance. Imaging systems that are currently available for spinal interventions, such as ultrasound, are reviewed by the authors. Guidance systems and endoscopic tools are similarly assessed with a good deal of attention paid to the disk removal "muncher," an endoscopic tool.

Research Priorities

These are advanced by the authors as follows:

- Research must not proceed in an isolated fashion, this Group stressed; instead, the study of instrumentation, biologically active materials, and image-guided systems should be studied simultaneously.
- More visualization and registration systems ought to become standard in the OR, the authors note, in effect shifting the activity from surgical "carpentry" to information-intensive surgery.

The full report of this Working Group appears on pp. 67-73.

CHAPTER 7: SURGICAL INSTRUMENTATION, TOOLING, AND ROBOTICS

... The Report of Working Group 5

AUTHORS

Michael Peshkin, PhD, Northwestern University (Technical Leader)
John Mathis, MD, Lewis Gale Medical Center (Clinical Co-leader)
John Kostuik, MD, Johns Hopkins Medical Institutions (Clinical Co-leader)
Fred Barrick, MD, Inova Fairfax Hospital
Norman Caplan, MS, Johns Hopkins University C.I.S.S.T. Engineering Research Center
Neil Glossop, PhD, Traxtal Technologies
Randy Goldberg, MS, Johns Hopkins University C.I.S.S.T. Engineering Research Center
Nobuhiko Hata, PhD, Brigham and Women's Hospital
Michael Loser, PhD, Siemens Medical Engineering
Michael Murphy, PhD, Louisiana State University
Russell Taylor, PhD, Johns Hopkins University C.I.S.S.T. Engineering Research Center

7.1 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.

7.2 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, ligament 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 Figure 7-1 and Figure 7-2. 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 micro-manipulation. 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.

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 on or near (within about 1 mm) a sensory nerve. For a variety of reasons, not least the placebo effect, at least two and often 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 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.

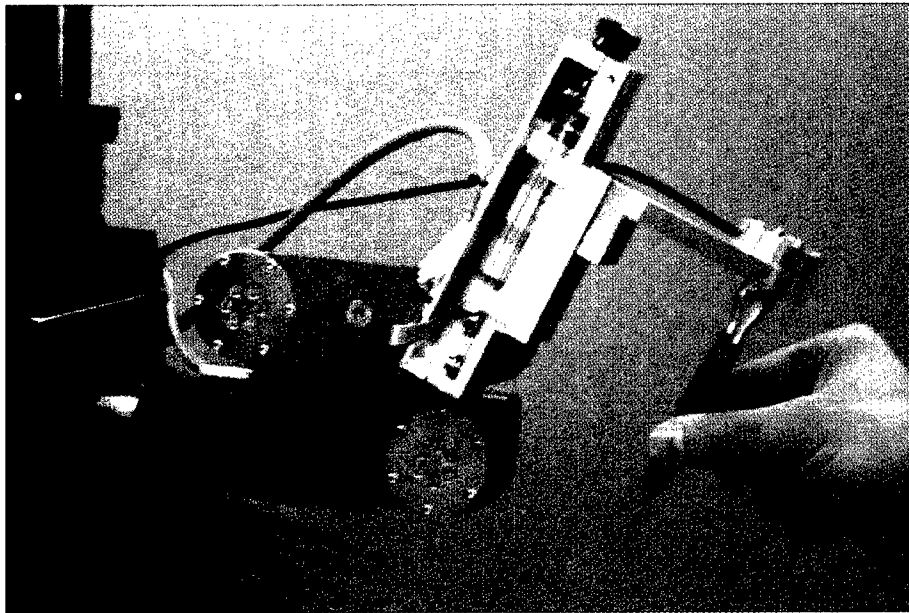


Figure 7-1: Steady Hand Robot
(Courtesy of Russell Taylor, PhD, Johns Hopkins University)

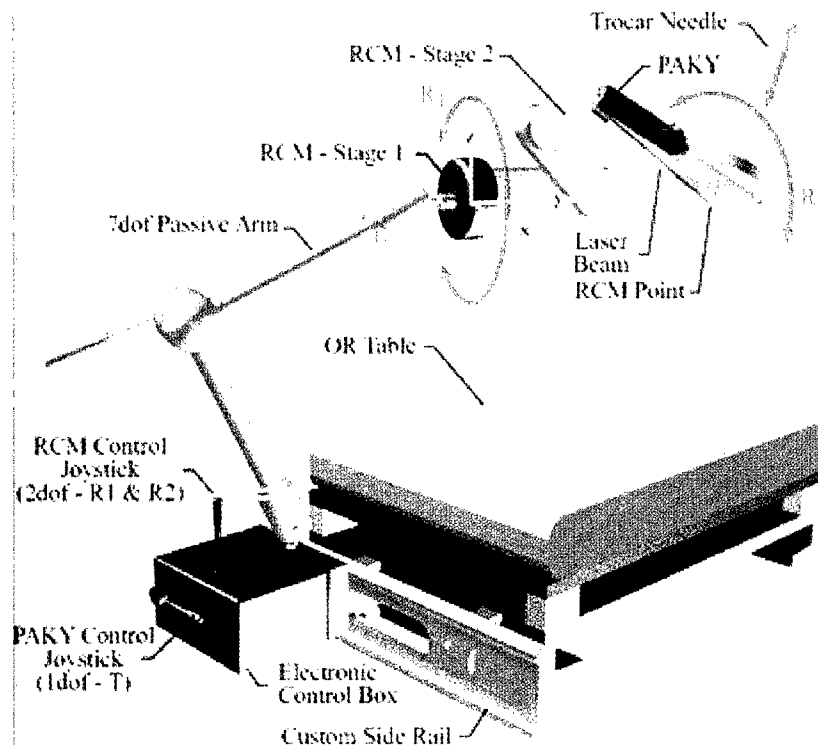


Figure 7-2: PAKY Needle Insertion Robot
(Courtesy of Dan Stoianovici, PhD, Johns Hopkins Medical Institutions)

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 into 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.

7.3 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 for 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 stereotaxi (which was dismissed as not providing needed accuracy nor 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 handheld 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 transverses 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 1 to 10 cm³
- 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 of it that would enter a disk, 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.

7.4 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.

CHAPTER EIGHT AT A GLANCE: SYSTEM ARCHITECTURE, INTEGRATION, AND USER INTERFACES

Overview

The overall goal of this Working Group was to envision the system architecture needed for image-guided spine procedure systems in the future. Current limitations and challenges for spine procedures are reviewed.

Clinical Needs

Five clinical issues that must be addressed to advance the development of image-guided surgery of the spine are identified. These issues are related to:

- Registration procedures and input of data
- Network requirements
- Adjustable graphical user interfaces (GUIs)
- Information sources for surgical-related data
- Accumulation of outcomes study data

Technical Requirements

Technical requirements related to improvements in intraoperative procedures are identified for specific types of imaging systems (ultrasound, endoscopy, and so on), for registration procedure types (needle, temporal, and 2D to 3D), and intraoperative integration. Another critical technical requirement is an improved capability for the interventionalist to receive feedback of spine data from the image-guided system, which should have a flexible user interface.

Research Priorities

To create effective image guidance systems for surgery of the spine, intraoperative data which describe vertebral motion and registration accuracy are of the highest research priority. Other research priorities include the development of: high speed networks (and image transfer standards for effective use of these networks); simplification of registration techniques; user configurable graphical user interfaces (GUIs).

The full report of this Working Group appears on pp. 75-82.

CHAPTER 8: SYSTEM ARCHITECTURE, INTEGRATION, AND USER INTERFACES

... The Report of Working Group 6

AUTHORS

Robert Galloway, PhD, Vanderbilt University (Technical Leader)
Richard Bucholz, MD, St. Louis University (Clinical Leader)
Jae Jeong Choi, MS, Georgetown University Medical Center
Kevin Cleary, PhD, Georgetown University Medical Center
Sarah Graham, MS, Johns Hopkins University C.I.S.S.T. Engineering Research Center
Heinz Lemke, PhD, Technical University of Berlin
Richard North, MD, Johns Hopkins Medical Institutions
Monish Rajpal, MS, Johns Hopkins University C.I.S.S.T. Engineering Research Center
Ramin Shahidi, PhD, Stanford University
Ann Sieber, RN, Johns Hopkins Medical Institutions
Laura Traynor, BS, University of Utah
Michael Vannier, MD, University of Iowa

8.1 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.

8.2 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 timed 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 8-1. The user interface for this system, which presents axial, sagittal, coronal, and 3D views, is shown in Figure 8-2. A similar system can be used for spine interventions, such as the placement of pedicle screws.

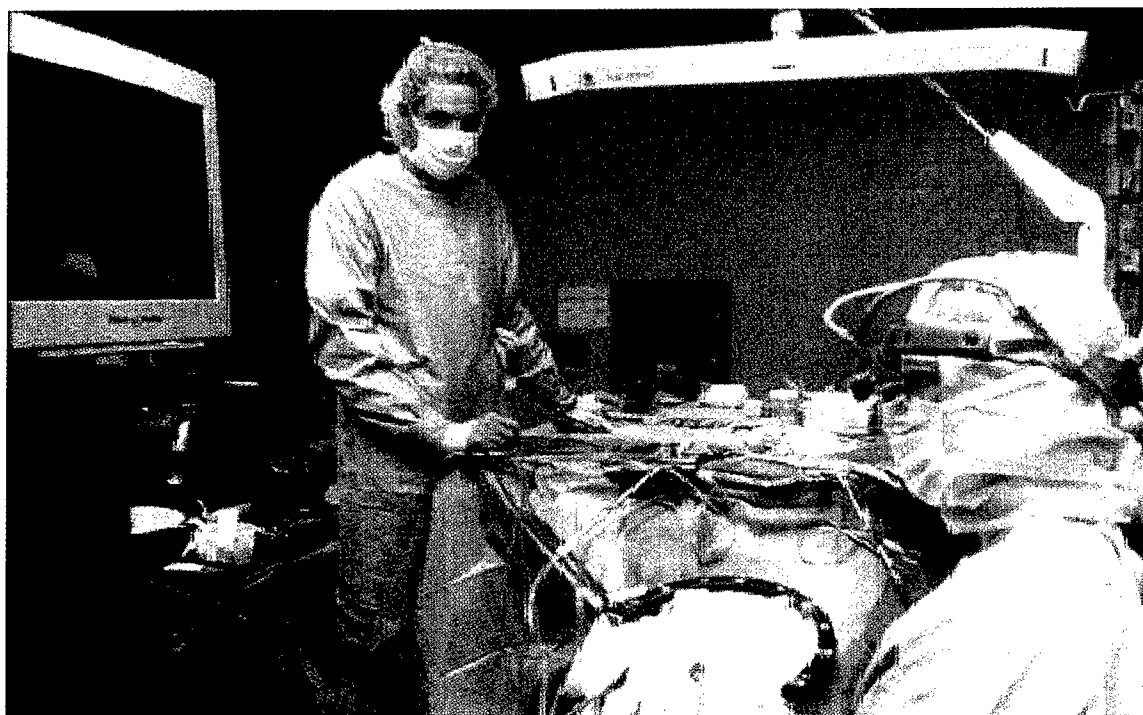


Figure 8-1: Image-Guided Surgery System In Operating Room
(Courtesy of Richard Bucholz, MD, St. Louis University)

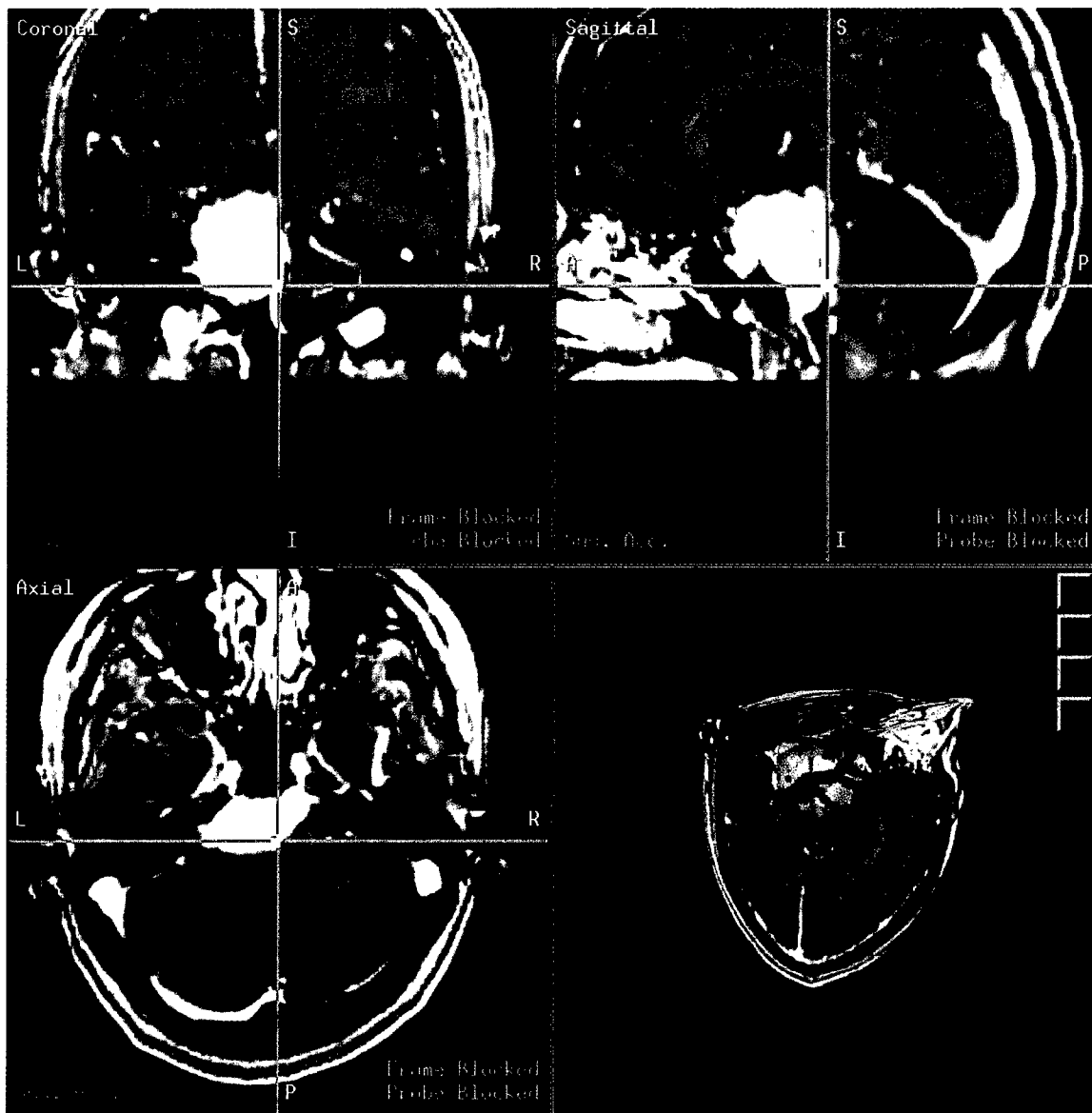


Figure 8-2: Image-Guided Surgery System User Interface
(Courtesy of Richard Bucholz, MD, St. Louis University)

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 selection 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.

8.3 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 three-dimensional 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 online 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 8-3.
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.

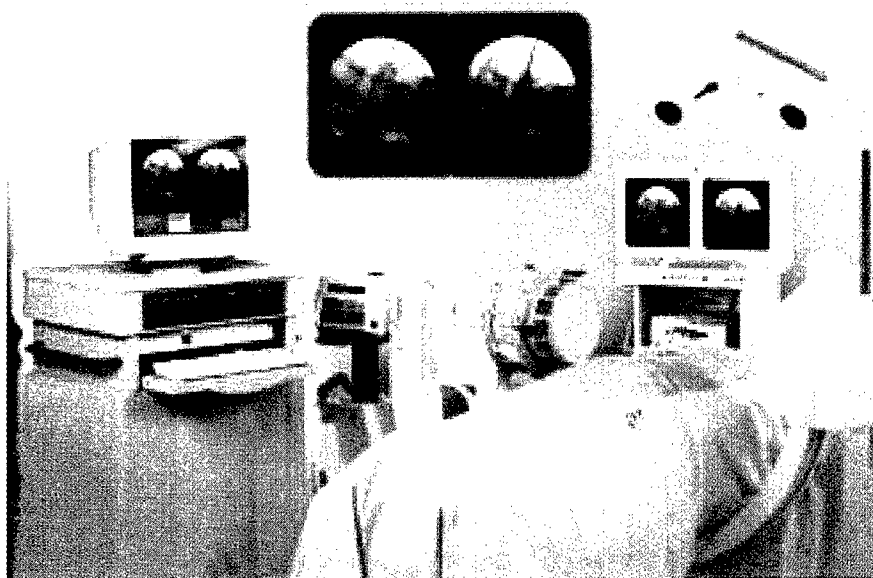


Figure 8-3: FluoroNav™ Fluoroscopy-Based Image-Guided Surgery System
(Courtesy of Medtronic—Surgical Navigation Technologies)

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 all are two-dimensional imaging modalities. These 2D images should be reformatted to be related to 3D data sets, such as computed tomography. 3D 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 8-4. These data can include:

1. Thermal data for radio frequency ablation and cryoablation.
2. Neurophysiological data such as evoked potentials.
3. Mechanical data measurements 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.
4. Pathological data identifying the tumor type and distribution that may impact the nature of the procedure being performed.

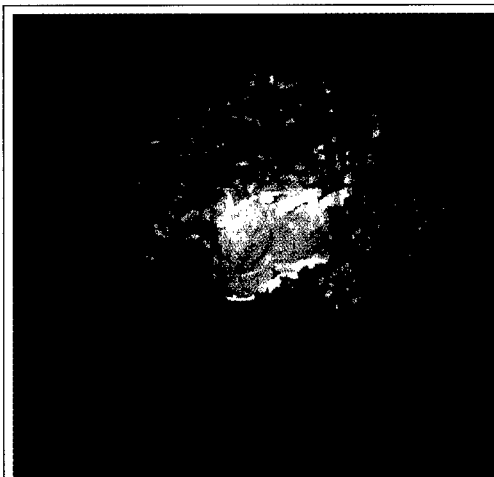


Figure 8-4: 3D Tumor Visualization
(Courtesy of Richard Bucholz, MD,
St. Louis University)

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.

8.4 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.

CHAPTER 9: SPECIAL SESSIONS

There were three special sessions 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." Summaries of each of these events are given in this chapter. The summaries are based on the workshop transcripts. The first summary was written by workshop participant Barbara Hum, MD, and the second and third summaries by the report editor, Audrey Kinsella, MA, MS.

9.1 THE OPERATING ROOM OF THE FUTURE

Editor's note: This report is based on the talk titled "The Operating Room of the Future" by Dr. Don Long, presented at the Workshop on April 18, 1999.

OVERVIEW

"There have been no major changes in operating room design in the last 100 years except to make the operating room larger."—Don Long, MD

The operating room (OR) of the future will adopt a modular design, where high-end imaging modalities such as magnetic resonance imaging (MRI) and computed tomography (CT) will be located in a central area and available for intraoperative imaging. The patients will be brought to these imaging modalities as needed during an operation on a sterile transport system. The goal of this modular OR is to enable surgeons to perform more effective surgeries with better patient outcomes. Although further technological developments are necessary, many of the components of the future OR are currently available. The next major step is a coordinated and comprehensive approach to the implementation of these components.

COMPONENTS OF A MODULAR OPERATING ROOM

Components of the modular operating room of the future include image guidance and intraoperative imaging, a patient transport system, robotics and voice activation, enhanced optics, and virtual reality displays along with three-dimensional visualization.

1. Image Guidance and Intraoperative Imaging

The operating surgeon should have the capacity for image guidance before, during, and after surgery. According to Long, the goal of image-guidance and intraoperative imaging is to verify that what has been done surgically is what the surgeon intended to do, and that it was done as safely and appropriately as possible. The surgeon must be able to verify the outcomes of the surgery before the patient leaves the operating room.

Long envisions the neuroradiology suite and the operating room merging together to become a single unit. Dedicated, high-end, fixed imaging modalities will be located in a central imaging area in a round-house concept and patients will be transported to these modalities as needed. Less expensive and mobile imaging modalities will also be available in the operating room.

The imaging modalities and capabilities that should be made available include:

1. Magnetic resonance imaging (MRI)
2. Computed tomography (CT), including mobile CT
3. Angiography with capabilities for endovascular techniques
4. Fluoroscopy
5. Functional MR imaging
6. Neuronavigational systems (image-guided systems)

2. Patient Transport System

A patient transport system will be designed to interconnect multiple OR rooms and imaging modalities via a track system and self-contained patient tables. The patient, the anesthesiologist, and necessary staff all will move to the scanner for imaging and then move back while maintaining a sterile environment. Coordination will be necessary such that the imaging modalities in the central area are available as needed.

3. Robotics and Voice Activation

Long envisions robotic assistance for hand support and instrument control. The benefit of robotics is to increase precision, decrease tremor, and provide a stop point to minimize surgical error. Robotic systems could also be used to constrain motion along a trajectory. In the spine, pedicle screw placement is one clinical application where robotic constraint of motion along a trajectory could be beneficial. In addition, all instrumentation should have a voice-controlled instrument delivery system, including irrigation, hemostasis, etc.

4. Optics

According to Long, the operating microscope is a "dinosaur" and will become obsolete. He believes that better methods to enhance light and magnification need to be developed and implemented, including the use of electronic systems or single fiber magnification and illumination. He also noted that, for neurosurgery, endoscopy would probably not play a major role in the future.

5. Virtual Reality and Three-Dimensional Visualization

Virtual reality displays will be used for three-dimensional (3D) visualization of MR, CT, angiography, and functional MR images of the brain and spine. Virtual reality displays will be used in all aspects of patient care. This includes 3D visualization intraoperatively, as well as for diagnosis and surgical planning.

CLINICAL ISSUES: SUCCESS AND FAILURE IN SPINE SURGERY

"The big problem we have with the spine is that we don't know why the spine hurts. If you don't know why something is symptomatic, it is very hard to devise treatments that are effective."—Don Long, MD

The challenge of treating spinal pain is that the etiology of the pain is often unclear. One theory holds that spinal pain is due to general inflammatory products from the degenerative process, some acute and some chronic. If this is the case, Long suggests that percutaneous interventions, rather than surgical procedures, may better address this cause of pain that is essentially chemical in nature. Other theories of pain include movement disorders such as acute dislocations, and neural compressions. These causes of spinal pain are a major issue for surgeons and can be operated on with reasonable certainty of correcting the problem, especially neural compressions.

Using the example of "failed back syndrome," based on a series of 7000 patients who underwent lumbar disk surgery, Long indicates three reasons for failed surgery:

1. Failure of the patient to meet the current criteria for surgery; that is, the surgeon operates on a patient for whom the option of surgery is not likely to be chosen by the majority of expert spinal surgeons.
2. Failure to correct the pathological problem.
3. Direct surgery-related injury to the structure of the spine.

Intraoperative imaging can improve the surgeons' ability to navigate around the anatomy, to visualize the pathological problem, and to verify if the problem has been corrected. Thus, intraoperative imaging directly addresses the second major reason for failed back syndrome; that is, failing to correct the pathological problem. Intraoperative imaging is necessary to make certain that the pathology has been corrected in order to decrease the incidence of failed back syndrome. In addition, Long challenges bioengineers to develop new fixators that would be incorporated biologically or have a limited stay in the body, replacing the current use of metal fixators. He also emphasizes that the diagnosis of instability needs to be made earlier. Then, in the future, percutaneous procedures will be used more often to correct the problem by the injection of growth factors, chemicals, and other substances that will reconstruct the spine—for example, by improving bone growth. These procedures will require precise control of the injection.

SUMMARY

"I think one-button activation in the operating room (to engage all of the surgical apparatus) is not unreasonable, and I think that should really be our goal."—Don Long, MD

According to Long, there have been no major changes in the operating room design in the last 100 years. The idea of the future operating room/radiology suite is for the complete system to follow a modular design. Imaging capabilities should be available to

the various OR rooms, as needed, for preoperative planning, control of the approach intraoperatively, and for verification after the procedure is complete. Intraoperative imaging is crucial for visualizing and correcting pathological problems in order to improve spinal surgery outcomes. In the future, functional imaging of the brain will also be particularly important. Since it is impractical for all OR rooms to have all the imaging capabilities, the best design is to locate the imaging in a central area available to the different OR rooms by developing a comprehensive patient transport system. In addition, robotic control of instruments and voice activation will increase precision and efficiency. Long envisions all displays to incorporate three-dimensional renderings and indicates new forms of magnification and lighting which need to be developed to eliminate the surgical microscope that is now interposed between the surgeon and the patient. In his view, the entire coordination of the OR should move towards the concept of a one-button activation. He cites the example of the Stealth Bomber where one button is pushed to activate it and make it ready for flight, whereas the B-52 Bomber took 14 people to manage its operation. In conclusion, it is clear that the operating room of the future is not just a new room but the coordination of new and existing technologies and personnel who can effect the vision of a better standard of surgical care.

9.2 OUTCOMES MEASUREMENT FOR SPINE INTERVENTIONS

Editor's note: This report is based on the special session titled "Outcomes Measurement for Spine Interventions," in which Drs. Richard North and Daniel Clauw participated at the Workshop, on April 19, 1999.

"What is required is not only to show that the operation was a technical success but also that it was a clinical success."—Daniel Clauw, MD

OVERVIEW

The measurement and assessment of patient health outcomes resulting from spinal interventions is a field of study that is in flux. Over time, a range of standardized measurements has gained favor, some having specific applications for spinal procedures, particularly measurement of low back pain. Until recently, demonstrating technical accomplishments, such as stabilization or tumor resection, were acceptable primary outcomes measures for spinal interventions.

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 possibly 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.

CLINICAL OUTCOMES MEASUREMENTS

The clinical tools for measuring and assessing the quality of spinal interventions are not well developed. Clinical outcomes measurement and assessment tools that are used for these applications generally fall into two types of study: generic; and disease- or body-region-specific.

Generic outcomes measurements can, as the term suggests, be used for persons in a number of different disease categories and clinical states, such as difficulties with the spine. Generic measurements (of which the McGill questionnaire is one example) tend to be better validated and more reliable than other measures. From the data collected, clear-cut measurements of the change in a patient's status and the cost of the procedure can be extrapolated. This capability can help administrators make choices among procedures by comparing their own data on costs of particular procedures and the outcomes data on demonstrated results of these procedures.

This outcomes/management scenario is not the final word needed for effective (or cost effective) decision making, however. In fact, disease- or body-specific outcomes measurements that are acquired for the same procedure may render the assessment data acquired from the generic measurements incomplete and wanting.

Disease- or body-region-specific, patient-oriented outcomes measurements are very much focused on parameters for a specific intervention. Pain relief for an intervention for rheumatoid arthritis or for lower back pain, for instance, can be measured using a disease- or body-region-specific tool such as the Roland Morris or Oswestry. The improvement resulting from the intervention can be assessed and tabulated, and appears to offer an adequate representation of outcomes.

However, generic and body- or disease-specific measurements can render as incomplete a picture of patient outcomes as a generic counterpart. Note a typical example:

A disease-specific outcomes measurement tool, like Roland Morris, one of the best for validated outcomes measures in the lumbar area, is used for a 70-year-old patient with osteoarthritis of the knees and low back pain as well as problems with coronary artery disease.

Which area of pain is being addressed in this particular intervention and is the outcomes measurement being focused only on this intervention and not other factors that may bring pain to the patient? In this example, the intervention for low back pain may be measured as successful. However, functional status that is measured by generic outcomes measuring tools like the SF-36 may not indicate any improvement at all. Other problems causing the patient pain were not measured by the disease-specific outcomes tool and the patient still reports pain.

Completing the Picture. To address this less-than-complete assessment of the patient's health outcomes, a trend today in outcomes research is to use both, or some combination of generic and disease- or body-specific measurement tools. Particular tools such as the SF-36, a generic outcomes measurement tool for functional status, are currently proving useful for measuring musculoskeletal interventions. Measurements using tools like the SF-36 can also be scaled and scored in a number of different ways, such as via subscales for pain, enabling them to be used for obtaining quality-of-life measurements as well.

Other generic tools, such as the McGill questionnaire, are particularly well accepted for studying pain relief outcomes. To obtain accurate measurements, however, it is critical that the patient who is answering questions respond to the area of pain which the intervention is targeting. The patient, not only the clinician, has to assist in generating the measurement data.

A SUGGESTED TOOL KIT FOR OUTCOMES RESEARCHERS

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

TECHNICAL OUTCOMES MEASUREMENTS

The movement today away from strictly technical outcomes measures has made outcomes analysis a good deal more complex. In earlier days of outcomes analysis, successes in spinal procedures were judged on the basis of achievements: stabilization, for instance, or tumor resection. The question of focus was: Did the device work? For the most part, device-related outcomes, such as fixation, strength, and biocompatibility were the only outcomes measures used in spinal interventions.

Much more attention in the last decade is devoted to patient-oriented outcomes. As one of the speakers explains:

There's been a recognition that in general people don't come to an orthopedic surgeon saying, 'I want a spinal rod' or 'I want an implantable device.' They come in with a problem such as pain and they want the surgeon or the health care provider to fix that problem.

"Fixing" the problem has both technical and patient-oriented, subjective implications. The latter is being viewed as increasingly important today. A focus on quality-of-life outcomes measures has moved toward the forefront of concern at institutions such as the FDA, NIH, and various medical professional organizations, rather than the more technical, device-oriented focus of the past.

Accomplishing "successful" interventions is another complicated measurement. In the past, using standard outcomes measures like the McGill questionnaire and showing a statistically significant improvement, one could say a treatment was a success. New requirements for demonstrating success are:

- coordinating a contemporaneous control group or comparison group, and looking at differences in response rates in the study group that received the intervention and in the control or comparison group.
- determining a *minimally clinically important difference* (MCID) in the targeted parameter. For example, using the SF-36, a 6 or 7 point change is generally viewed as significant.
- accommodating the occurrence of "frequent failures"—in studies, or people who drop out of studies. Study sample sizes need to be larger than in the past to provide valid numbers to be used in results.

CONCLUSION

Outcomes measuring tools and items of importance are, according to participants in this discussion, a "changing target." Consensus has frequently shifted about what patient response/intervention parameters should rightly be measured and which are the best tools to do so. It is a challenge 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.

9.3 THERAPY TEAMS OF THE FUTURE

Therapy Teams of the Future: How Does One Make a Team of Experts?

Editor's note: This report is based on the special session titled "Therapy Teams of the Future: How Does One Make a Team of Experts?," moderated by Heinz Lemke, PhD, on April 19, 1999. Participants included Martha Gray, PhD (Harvard/MIT division of health sciences and technology), James Anderson, PhD (Johns Hopkins Medical Institutions), Richard Bucholz, MD (St. Louis University, St. Louis, MO), Ron Kikinis, MD (Brigham and Women's Hospital), and Thomas Whitesides, MD (Emory University, Atlanta, GA).

OVERVIEW

The creation of "therapy teams of the future" has a key component that is identifiable yet difficult to implement. It is: effecting peer relationships and multidisciplinary collaboration between engineers, scientists, and physicians.

A working and effective multidisciplinary entity is not simply a grouping of individuals with diverse backgrounds, it is suggested at this seminar by representatives who are involved in five bioengineering related programs in the U.S. Instead, it is one which works interactively and contributes as a team to solving particular engineering, scientific, and clinical problems.

Designing multidisciplinary training programs that "work" is, plainly, a considerable challenge. Approaches to multidisciplinary training that are identified at this session take into consideration the opportunity for shaping individuals' particular, expert qualities and accomplishments into, more broadly, team strengths. The impetus for developing multidisciplinary programs and training collaborative teams of engineers and clinicians is clear: the creation of these teams will be a critical step toward meeting the challenges of the exponential growth of new and sometimes complex technologies that are now being experienced in health sciences and technology development.

CLINICAL TRAINING NEEDS

Multidisciplinary programs which are now underway provide both clinical and technical training regardless of the learners' previous emphases in study. For decades, the typical course/program development strategy known to all of us has been linear, according to one of the session's speakers, and, it is suggested, one-dimensional. However, the exponential growth in health sciences and technology requires us to seek out a new "way of doing business"—namely, multidisciplinary education, if programs are to prepare students to meet the challenges posed by this growth.

The common thread among the multidisciplinary programs described at this session is an emphasis on shared problem solving. In one program, engineers and researchers spend time in clinics to examine "real problems." The teams, working with clinicians, uncover information about the need, cause, and possible corrective measures or tools that can be applied to these problems.

Other means for broadening students' exposure to clinical problems are made possible, in another program example, by assigning engineering students to dual advisors (one in engineering, the other in a clinical discipline), and heavily involving clinicians in product design. This preparation is thought to enhance the ability of students to work with and contribute to a multidisciplinary team.

Understanding the diverse backgrounds which participants bring to the training arena is critical for shaping clinical and technical training modules in multidisciplinary programs, the presenters note. This diversity is termed by one speaker as "equal footing," meaning that each learner's different foundation and different way of thinking must be appreciated in program planning efforts. In this speaker's program, courses are designed to present different perspectives on and understanding of clinical and engineering problems, one example being the study of physiology of inner ear and the technical and clinical approaches to interventions. All students attend classes which touch on these multiple viewpoints and emphases and so achieve a common grounding. At the problem solving stages, when in this program, students are required to work together, the value of a multidisciplinary approach is appreciated.

A new tack in learning is being followed, it is clear. Not independent training but interactive modes of learning and working are critical in multidisciplinary programs.

TECHNICAL TRAINING NEEDS

A drive to advance training in clinical needs at these programs and to help create multidisciplinary education that trains engineers in understanding medical and clinical problems is underway. Simultaneously, medical students and clinicians need to be taught something of engineering problems and applications of computers and technologies that are expected in the 21st century. [See *Editor's note* on page 94.]

What is reasonable for a clinician to expect of computers and other tools? In multidisciplinary programs now underway, clinicians and medical students who are training to be clinicians are, so to speak, taught technology transfer: they learn to use new technologies and participate actively in their development. This strategy enables, as one presenter notes, the transfer of basic research ideas from the idea and development stage to the patient bedside stage.

UNDERSTANDING THE PARAMETERS

It is a misunderstanding of the concept of multidisciplinary team training to associate it with "cross training." Engineers are not being trained to become spine surgeons, for instance. Portions of multidisciplinary training may take place through intensive coursework—as in a 6-week "boot camp" one presenter described, in which clinicians are taught the principles of engineering, and in another engineers the principles of medicine.

In another mode, the team training is facilitated by engineering students' participating in activity in the spinal surgical suite. At this institution, engineers operate the MR and CT systems and work with both clinicians and the instruments.

Both of these experiences represent ways in which educators can work toward resolving the problem of engineers' and clinicians' speaking "different languages." The common ground in this case is working with the tools and procedures of spinal interventions.

Key to this development taking place is customizing the training to learners' varied abilities. The multidisciplinary planning questions that need to be asked are: What is it that engineers and clinicians need to know to do their jobs effectively? How is the information they need best presented?

A modular curricula is important to effect a suitable approach to the range of abilities and needs of the learners, one participant emphasized. A focus on spinal interventions is provided in one example of a modular curriculum. Surgical simulators can be used to adapt to a novice level for explaining modeling the mechanics of the spine, for example; an altogether different simulator could be used by a surgeon to identify possible surgical interventions and resulting mechanical effects. Additionally, the same kind of simulator could be used in a different context to teach an engineer how to solve problems which involve biomechanical processes. This aspect of training requires development of instructional materials at different levels of sophistication, so that, depending on the level and background of the learner, needed information will be accessible.

PROGRAM DEVELOPMENT PRIORITIES

Key to multidisciplinary program development is broadening students' hands-on exposure to multidisciplinary problems—in engineering, science, and clinical care. This approach is becoming more expected and appreciated as one that is needed. One thrust of the National Science Foundation's funding requirement of Engineering Research Centers (ERCs) has in fact encouraged this tack. Implicit in its requirement is a move toward multidisciplinary education and work to get useable results. For example, one of the ERC requirements is for researchers to demonstrate successful transfer of technology from the academic environment and into industry and to the end user. An ERC program is judged successful if the technology is used by the clinicians (the targeted end user) and ultimately improves patient care.

Developing successful multidisciplinary programs in engineering and medicine requires a good deal of planning and long-term commitment. The most important goal, 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.

Editor's Note. The National Science Foundation (NSF) recently made award 9876363 to initiate "The Vanderbilt-Northwestern-Texas-Harvard/MIT (VaNTH) Engineering Research Center (ERC) for Bioengineering Educational Technologies." The lead institution is Vanderbilt University, Nashville, Tennessee; with Northwestern University, Evanston, Illinois; The University of Texas, Austin, Texas; and the joint Division of Health Sciences and Technology at Harvard Medical School, Boston, Massachusetts and the Massachusetts Institute of Technology, Cambridge, Massachusetts participating as core partner institutions. This ERC focuses teams of academic researchers and industrial personnel on the most effective pedagogy and educational technology needed to advance education in the complex, interdisciplinary field of bioengineering. Examples include research into asynchronous learning networks (ALNs), visualization, simulation, and Web-based learning as the major educational technology tools in bioengineering education, and development of modular, computer-based software. This ERC's vision for next-generation educational technology in bioengineering education integrates knowledge in bioengineering and other engineering fields, cognitive science, computer science/engineering, education, psychology, and the life and physical sciences.

CHAPTER 10: APPENDICES

Appendix A. Workshop Program

Appendix B. Workshop Participants

Appendix C. Questionnaire Responses Summary Paper Reprint

Appendix D. Bibliography Suggested by Workshop Participants

Appendix E. Report Bibliography

10.1 APPENDIX A. WORKSHOP PROGRAM

Program
Technical Requirements for Image-Guided Spine Procedures
April 17-20, 1999
Turf Valley Country Club (Ellicott City, MD)

Day 0 (Saturday)

Afternoon: Participants check-in (check-in time is 4 pm)
1800-2000 Opening ceremony: Reception and buffet
2000-2100 Organizing committee and Working Group leaders meeting

Day 1 (Sunday)

0730-0830 Breakfast buffet
0830-1200 Overview & vision
0830-0840 Opening remarks: Kevin Cleary, PhD
 Welcome, Workshop format and objectives
0840-0940 Overview and historical perspective (moderator: Matthew Freedman, MD)
0840-0930 Clinical state-of-the-art: Dietrich Grönemeyer, MD
0930-0940 Q & A
0940-1010 Morning coffee break
1010-1150 Vision and long view (moderator: Seong K. Mun, PhD)
1010-1030 Spine surgery in the 21st century: Don Long, MD
1030-1040 Q & A
1040-1100 Coupling information to action: Russell Taylor, PhD
1100-1110 Q & A
1110-1140 Panel discussion
1140-1155 Advanced technology direction for U.S. Army Medical R& D:
 Conrad Clyburn; Greg Mogel, MD
1155-1200 Conference business: introduction of Working Groups (Kevin Cleary, PhD)

1200-1330 Lunch by Working Group : current status

Working Group meeting 1: Define the current status in image-guided procedures of the spine for your Working Group (review questionnaire results and pre-Workshop report, get comments from Working Group members)

1330-1415 Free time
1415-1530 Diseases / procedures (moderator: S. James Zinreich, MD)
 (10-minute presentations, 5-minute Q & A)
1415-1430 Interventions: John Mathis, MD
1430-1445 Trauma: John Kostuik, MD
1445-1500 Tumors: Elizabeth Bullitt, MD
1500-1515 Deformity: David Polly, MD

1515-1530 Degenerative Disease: Richard North, MD
1530-1600 Afternoon coffee break

1600-1700 Working Group presentations by technical leaders (5-minute presentations, 5-minute Q & A)

1600-1610 Group 1: Operative planning and surgical simulators
Technical leader: Frank Tendick, PhD

1610-1620 Group 2: Intraprocedural imaging and endoscopy
Technical leader: Jeff Duerk, PhD

1620-1630 Group 3: Registration and segmentation
Technical leader: Ben Kimia, PhD

1630-1640 Group 4: Anatomical and physiological modeling
Technical leader: James Anderson, PhD

1640-1650 Group 5: Surgical instrumentation, tooling, and robotics
Technical leader: Michael Peshkin, PhD

1650-1700 Group 6: System architecture, integration, and user interfaces
Technical leader: Robert Galloway, PhD

1700-1800: Free time

1800-1930 Dinner by Working Group

Working Group meeting 2: Clinical Requirements

Using clinical areas identified in questionnaire, discuss how image guidance might be applied. Prepare summary statement for Monday morning presentation.

Day 2 (Monday)

0730-0830 Breakfast buffet

0830-0930 Working Group presentations by clinical leaders (5-minute presentations, 5-minute Q&A)
(Moderator: William Wells, PhD)

0830-0840 Group 1: Operative planning and surgical simulators
Clinical leader: David Polly, MD

0840-0850 Group 2: Intraprocedural imaging and endoscopy
Clinical leader: Dietrich Grönemeyer, MD

0850-0900 Group 3: Registration and segmentation
Clinical leader: Elizabeth Bullitt, MD

0900-0910 Group 4: Anatomical and physiological modeling
Clinical leader: Ron Kikinis, MD

0910-0920 Group 5: Surgical instrumentation, tooling, and robotics
Clinical leaders: John Mathis, MD; John Kostuik, MD

0920-0930 Group 6: System architecture, integration, and user interfaces
Clinical leader: Richard Bucholz, MD

0930-1100 Technology applications (10-minute presentations)
(moderator: Larry Clarke, PhD)

0930-0940 Deformable modeling: Christos Davatzikos, PhD

Appendix A: Workshop Program

0940-0950 Display technology and user interface: Heinz Lemke, PhD
0950-1000 Accuracy issues in image-guided spine surgery: Neil Glossop, PhD
1000-1030 Morning coffee break
1030-1040 Intraoperative CT for spine tumor resection: Frank Feigenbaum, MD
1040-1050 Open MRI for spine procedures: Eric Woodard, MD
1050-1100 Questions and Answers

1100-1145 Special session on outcomes analysis (moderator: Gilbert Devey)

Speakers:

Daniel Clauw, MD

Richard North, MD

1145-1200 Group photo

1200-1330 Lunch by Working Group

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

1330-1415 Free time

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

Panel chair: Heinz Lemke, PhD

Each presenter should address:

- Breakthrough technologies
- Patient-surgeon interface
- Performance and training
- Engineer and physician collaboration
- Evaluation and economic impact
- Challenges for biomedical engineering educators

Speakers/panel members:

Martha Gray, PhD

James Anderson, PhD

Richard Bucholz, MD

Ron Kikinis, MD

Tom Whitesides, MD

1530-1545 Coffee break

1545-1715 Working Group meeting 4: Wrap-up and report preparation.

Summarize results of first three meetings, prepare viewgraphs for presentations Tuesday morning.

1715-1730 Working Group chairs meet with organizing committee (progress report)

1730-1830 Free time

1830-2030 Group dinner - brief presentations by sponsors

NSF: Sohi Rastegar, PhD

NIH/NCI: Larry Clarke, PhD

Picker International & Depuy Motech AcroMed: Lou Arata, PhD

Day 3 (Tuesday)

0730-0830 Breakfast buffet

0830-1100 Working Groups present reports (moderator: Gilbert Devey)

0830-0850 Group 1: Operative planning and surgical simulators

0850-0910 Group 2: Intraprocedural imaging and endoscopy

0910-0930 Group 3: Registration and segmentation

0930-0950 Group 4: Anatomical and physiological modeling

0950-1020 Coffee break

1020-1040 Group 5: Surgical instrumentation, tooling, and robotics

1040-1100 Group 6: System architecture, integration, and user interfaces

1100-1200 Summary speaker and discussion: Michael Vannier, MD

1200-1300 Group lunch

1300-1500 Working Group leaders outline reports

1500 Departure

10.2 APPENDIX B. WORKSHOP PARTICIPANTS

NAME	DEGREE	AFFILIATION
Anderson, James	PhD	Johns Hopkins Medical Institutions
Arata, Lou	PhD	Picker International & DePuy Motech AcroMed
Barrick, Fred	MD	Inova Fairfax Hospital
Bascle, Benedicte	PhD	Siemens Corporate Research
Blezek, Dan	PhD	Mayo Clinic
Brazaitis, Michael	MD	Walter Reed Army Medical Center
Bzostek, Andrew	MS	Johns Hopkins University
Bucholz, Richard	MD	St. Louis University
Bullitt, Elizabeth	MD	University of North Carolina
Burgess, James	MD	Inova Fairfax Hospital
Caplan, Norman	MS	Johns Hopkins University
Carignan, Craig	PhD	University of Maryland
Chao, Ed	PhD	Johns Hopkins University
Choi, Jae Jeong	MS	Georgetown University Medical Center
Clarke, Larry	PhD	National Institutes of Health
Clauw, Daniel	MD	Georgetown University Medical Center
Cleary, Kevin	PhD	Georgetown University Medical Center
Clyburn, Conrad	BS	U.S. Army
Davatzikos, Christos	PhD	Johns Hopkins University
Deli, Martin	BS	Witten/Herdecke University
Devey, Gilbert	BS	Georgetown University Medical Center
Duerk, Jeff	PhD	Case Western Reserve University
Freedman, Matthew	MD	Georgetown University Medical Center
Galloway, Robert	PhD	Vanderbilt University
Glossop, Neil	PhD	Traxtal Technologies
Goldberg, Randy	MS	Johns Hopkins University
Graham, Sarah	MS	Johns Hopkins University
Gray, Martha	PhD	Massachusetts Institute of Technology
Gregerson, Gene	MS	Visualization Technology, Inc.
Grönemeyer, Dietrich	MD	Witten/Herdecke University
Hata, Nobuhiko	PhD	Brigham and Women's Hospital
Herman, William	BS	Food and Drug Administration
Higgins, Gerald	PhD	Ciemed Technologies
Hum, Barbara	MD	Georgetown University Medical Center
Kikinis, Ron	MD	Brigham and Women's Hospital
Kim, Yongmin	PhD	University of Washington
Kimia, Ben	PhD	Brown University

Kostuik, John	MD	Johns Hopkins Medical Institutions
Langrana, Noshir	PhD	Rutgers University
Lathan, Corinna	PhD	Catholic University
Lemke, Heinz	PhD	Technical University of Berlin
Levy, Elliot	MD	Georgetown University Medical Center
Lindisch, David	RT	Georgetown University Medical Center
Liu, Alan	PhD	National Institutes of Health
Liu, Yanxi	PhD	Carnegie Mellon University
Loser, Michael	PhD	Siemens Medical Engineering
Loew, Murray	PhD	George Washington University
Long, Don	MD	Johns Hopkins Medical Institutions
Mathis, John	MD	Lewis-Gale Medical Center
Mogel, Greg	MD	U.S. Army
Mun, Seong K.	PhD	Georgetown University Medical Center
Murphy, Mike	PhD	Louisiana State University
Navab, Nassir	PhD	Siemens Corporate Research
North, Richard	MD	Johns Hopkins Medical Institutions
Peshkin, Michael	PhD	Northwestern University
Polly, David	MD	Walter Reed
Rajpal, Monish	MS	Johns Hopkins University
Rampersaud, Y. Raja	MD	University of Toronto
Reinig, Karl	PhD	University of Colorado
Sieber, Ann	RN	Johns Hopkins Medical Institutions
Shahidi, Ramin	PhD	Stanford University
Shin, Yeong Gil	PhD	Seoul National University
Staab, Ed	MD	National Institutes of Health
Taylor, Russell	PhD	Johns Hopkins University
Tendick, Frank	PhD	University of California San Francisco
Thakor, Nitish	PhD	Johns Hopkins University
Traynor, Laura	BS	University of Utah
Vannier, Michael	MD	University of Iowa
Wang, Joseph	PhD	Catholic University
Watson, Vance	MD	Georgetown University Medical Center
Wells, William	PhD	Harvard Medical School
Whitesides, Thomas	MD	Emory University
Woodard, Eric	MD	Brigham and Women's Hospital
Yoo, Terry	PhD	National Library of Medicine
Yun, David	PhD	University of Hawaii
Zeng, Jianchao	PhD	Georgetown University Medical Center
Zheng, Qinfen	PhD	University of Maryland
Zinreich, S. James	MD	Johns Hopkins Medical Institutions

10.3 APPENDIX C. QUESTIONNAIRE RESPONSES SUMMARY PAPER REPRINT

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Technical requirements for image-guided spine procedures workshop questionnaire summary

Gilbert Devey BS, Kevin Cleary PhD, Seong K. Mun PhD

Imaging Science and Information Systems (ISIS) Center
Department of Radiology
Georgetown University Medical Center
2115 Wisconsin Avenue, NW, Suite 603
Washington, DC 20007
Correspondence: cleary@isis.imac.georgetown.edu

Dramatic advances have been made in image-guided procedures in the brain over the past few years but relatively little attention has been given to other regions of the body such as the spine. A workshop titled "Technical Requirements for Image-Guided Spine Procedures" was conducted 17-20 April 1999 that reviewed the barriers to progress in this field and identified the technical and professional developments required to move ahead. The general objective of the workshop was to determine the technical requirements for image-guided procedures in the spinal column, spinal cord, and paraspinal region. Before the workshop, a questionnaire was sent to all the participants asking them to identify barriers to progress and areas for future research. The questionnaire results are presented in this paper.

QUESTIONNAIRE OVERVIEW

The questionnaire was sent to all the workshop participants some four months before the workshop. The questionnaire had three major sections: 1) system-level questions, 2) clinical questions, and 3) working group questions. The working group questions were divided by the six working groups: 1) operative planning and surgical simulators, 2) intraprocedure imaging and endoscopy, 3) registration and segmentation, 4) anatomic and physiological modeling, 5) surgical instrumentation, tooling, and robotics, and 6) systems architecture, integration, and user interfaces. As of this writing (March 1999), 28 questionnaires had been returned. The questions and a summary of the responses are presented here.

SYSTEM-LEVEL QUESTIONS AND RESPONSES

1. What are the major technical problems and research needs in image-guided procedures of the spine?
2. What are the major infrastructure and administrative issues that must be addressed to move ahead with image-guided spine procedures?
3. What piece of technology or technological advance do you wish you had today?
4. What will be possible over the next 5 years? Over the next 10 years?

As for the major technical problems and research needs, image registration was the most common response. Registration is a fundamental problem of image-guided surgery, and commercial image-guided

surgery systems require a step in which pre-procedure images are registered to the patient. For the spine, registration methods need to be developed that can account for the multi-body nature of the problem. Registration is also discussed in more detail in this paper in the registration and segmentation working group.

Several respondents mentioned the need for real-time imaging, particularly three-dimensional (3D) imaging such as CT or MRI. The issue of system integration and the need to develop a system tailored to the needs of spine surgery was also mentioned. The user interface for such a system needs to be developed so that information is presented to the doctor without interfering with the performance of other tasks.

Major infrastructure and administrative concerns include the coordination of clinical and technical personnel, the need to show the cost effectiveness of new technology, and a focus on solving clinical problems. Several respondents noted that engineers need to be more aware of clinical needs while other respondents said that physicians need to be more aware of what the technology can do and participate more in the design of technology solutions.

The desired technological advances were varied and included advances such as realistic and computationally efficient soft-tissue models, specific case simulation capability, real-time tissue segmentation and volume rendering, and improved image fusion tools.

Predicting the future is always a risky business, but several respondents believe that robotic systems for certain tasks will become more common over the next 5 years. Other respondents predicted progress in imaging modalities, including further development of CT-fluoroscopy and real-time MRI guidance. Over the next 10 years, the further development of the underlying technologies is anticipated, with one respondent suggesting that image-guided minimally invasive procedures would begin to dominate the operating room.

CLINICAL QUESTIONS AND RESPONSES

1. What 3 to 5 spine procedures do you most commonly perform?
2. In what 3 to 5 spine applications will image-guided procedures be widely used in the next decade? When will they be introduced (1-2 years, 3-5 years, 5-10 years)?
3. What are the major difficulties in introducing image-guided procedures? What would you like to be able to do in the spine that you cannot do right now?
4. What are the most time consuming aspects of spine procedures?
5. What are the 5 most common complications in spine procedures?

It should be noted that there were only seven respondents to the clinical questions. The most commonly cited spine procedures were discectomies and fusions, while several respondents also mentioned tumor resection. Other procedures included pedicle screw placement, C1-2 transarticular screw placement, lumbar cage placement, vertebroplasty, osteotomy for deformity, discography, and sympathectomies. Many of the procedures require the placement of hardware and others require directing an instrument to a precise spot percutaneously. Image guidance in one form or another is essential in both of these cases.

Applications where respondents believed image-guided procedures would be widely used in the next decade included existing applications such as pedicle screw placement and new applications such as deformity surgery. Other applications cited were tumor resection, spinal endoscopy, and the placement of interbody devices such as cages. One respondent noted that image-guided procedures are already widely used in the spine at some institutions.

Both technical and administrative issues were seen as the major difficulties in introducing image-guided procedures. On the technical side, image-guided systems need to be both accurate and easy to set-up. The registration process is still seen as difficult and cumbersome by many clinicians. On the administrative side, the turf battle between specialties needs to end, FDA approval is seen as a stumbling block, and reimbursement codes for image-guided procedures need to be expanded.

The responses to what physicians would like to do in the spine that they cannot do right now include guide pedicle screw placement, visualize margins of tumors, percutaneous spine fusions, multi-segment tracking, and laminoplasty.

The most time consuming aspects of spine procedures were noted as procedure dependent. Responses included taking off the bone in decompressive procedures, taking out the tumor in tumor resection, getting the exposure needed in complex cases, neurological decompression, scar removal, and nucleotomies in special imaging.

In response to the most common complications, the importance of proper patient selection was stressed. Complications included infection, neural damage, bleeding, failed fusion, and spondylodiscitis.

WORKING GROUPS QUESTIONS AND RESPONSES

As noted in the Overview, there were six working groups. Each working group had a clinical co-chair and a technical co-chair. In the questionnaire, the participants were asked to list their top three choices for a working group, and each participant was asked to respond to as many questions as they felt comfortable with. In this section, a brief description of each working group is given followed by the questionnaire responses to the first three questions given below. The responses to question 4 concerning spine procedures are given across all working groups in the last section, Spine Procedures. The questions were the same for each working group, except the name of the working group was changed. As an example, the questions for the operative planning and surgical simulators group were:

1. What are the major technical problems with operative planning and surgical simulators?
2. What other factors are limiting the use of operative planning and surgical simulators?
3. On a scale of 1 to 5 (5 being very widely used), how widely used do you think operative planning and surgical simulators will be used in the spine in the next 5-10 years?
4. Which spine procedures could benefit most from advances in operative planning and surgical simulators?

OPERATIVE PLANNING AND SURGICAL SIMULATORS

Pre-operative planning 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. Surgical simulation may be used for training and education, and technical issues include the development of better haptic interfaces.

The major concern here is that the models used in these systems are not as sophisticated as they need to be for realistic results. There are still basic research issues that need to be addressed in tissue modeling, deformable modeling, biomechanical modeling, and image segmentation. Patient specific models need to be incorporated and available in a timely fashion for operative planning to become clinically useful.

A related concern is that better haptic interfaces for more realistic force and tactile feedback are required. This is partially a function of the model used for force feedback and partially a function of the hardware available. For operative planning, the user interface needs to be intuitive and easy to use so that a physician can operate the system with minimal training.

INTRAPROCEDURE IMAGING AND ENDOSCOPY

This working group includes all the imaging modalities that may be used during procedures including the intraprocedure use of CT, MRI, ultrasound, and fluoroscopy. As intraprocedure imaging becomes more common, the question of which modality is most appropriate for which procedures will continue to arise. The tradeoffs between cost, accuracy, and information provided were discussed. This group also considered the use of endoscopic images in spinal procedures, and the potential for fusing endoscopic images with the 3D imaging capability of CT or MRI.

With respect to technical problems, improvements in hardware developments to reduce size and cost while improving imaging resolution are required. Interventional MRI and the associated instruments are

generally seen as too expensive, while other modalities such as CT and fluoroscopy output ionizing radiation. Endoscopy problems include limited visibility, difficulty with knowing where one is in relation to the anatomy, and difficulty in dealing with complications. Two respondents questioned whether endoscopy would play a major role in spine procedures since it may be more applicable to procedures where there are large cavities such as in the abdomen. Finally, registration was also mentioned several times here, and seems to be a pervasive issue.

Most of the respondents felt that intraprocedure imaging and endoscopy would be widely used in the spine in the next 5-10 years. There were 17 responses to this question, and on a scale of 1 to 5 (with 5 being very widely used) the average response was 3.8. One respondent felt that intraprocedure imaging would be widely used, but endoscopy would not.

REGISTRATION AND SEGMENTATION

This includes 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 remains an elusive goal.

The major technical problems mentioned with registration include the need for manual intervention, limited robustness, the lack of methods for accurate real-time registration of a non-rigid object, and the limited accuracy of fiducial-free registration methods. For segmentation, most current methods are too slow and too manually intensive. The problem of motion of spine segments between imaging and surgery needs to be addressed. Finally, there is a lack of standards for determining performance requirements, assessing accuracy, and validation of algorithms.

The majority of the respondents felt that registration and segmentation would be widely used in the spine in the next 5-10 years. There were 15 responses to this question, and on a scale of 1 to 5 (with 5 being very widely used) the average response was 4.1. It might have been better to break this question out since most researchers would probably think registration will be widely used, but segmentation may not be widely used.

ANATOMICAL AND PHYSIOLOGICAL MODELING

This includes 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 remain as to the creation, use, and validation of models. Accurate and reliable models are key to advancing the state-of-the-art in surgical simulation and operative planning, among other areas.

Many respondents felt that current models are not realistic enough, and a fundamental problem in anatomical modeling is soft tissue modeling. In physiological modeling, the complexity of developing an accurate model incorporating phenomena such as hemodynamics was noted. Other issues include the development of patient specific models, computational efficiency, and validation.

There were mixed opinions regarding how much anatomical and physiological modeling would be used in the spine in the next 5-10 years. There were 12 responses to this question, and on a scale of 1 to 5 (with 5 being very widely used) the average response was 3.1. While some respondents felt it would be very widely used (two scores of 5), others felt it would not be used very much at all (two scores of 1), and others felt it would be used somewhat (three scores of 3).

SURGICAL INSTRUMENTATION, TOOLING, AND ROBOTICS

Surgical instrumentation includes cages and other devices for fusing the spine. Tooling includes the special purpose devices 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.

The major technical problems in this area including developing technology that is safe, reliable, and easy to use in the operating room. The equipment should also be compatible with imaging modalities such as MRI and CT. Other problems include accuracy, suitable man-machine interfaces, and real-time navigation. Other factors limiting the use of this technology include cost, liability, and FDA considerations. One respondent noted that it would be better to adapt conventional instruments to this technology rather than attempt to develop new techniques and procedures around this technology. Another respondent noted that economics is a major issue, and there is still a perception that the gain of the technology is minimal compared to the inconvenience and risk.

Most respondents felt that surgical instrumentation, tooling, and robotics would be fairly widely used in the spine in the next 5-10 years. There were 13 responses to this question, and on a scale of 1 to 5 (with 5 being very widely used) the average response was 3.6. As in previous questions, it might have been better to break out these technical areas. One respondent gave two scores: a score of 5 to surgical instrumentation and tooling but a score of 2 to robotics.

SYSTEMS ARCHITECTURE, INTEGRATION, AND USER INTERFACES

This group defined the 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 easily use? What is the appropriate user interface for such a system (3D mouse, heads up display, touch screen, voice operated, eye tracker)? This group also considered various technologies that are not covered by other groups including image-guided surgery systems.

The major technical problem here is creating a system that is powerful yet easy to use. Several respondents commented that current image-guided systems are still too difficult to use in the operating room, and that a technician is required to operate the system in many cases. The user interface is a key issue, and user interface design requires collaboration of experts from different fields. Conveying the information a surgeon needs in a format he/she can use is still a problem.

Other factors limiting the user of these technologies include the lack of complete component technologies, economic justification, and liability issues. The use of different file formats by different medical imaging device manufacturers was also noted as a problem, but this may be resolved by the DICOM medical imaging standard.

Most respondents felt that systems architecture, integration, and user interfaces would be fairly widely used in the spine in the next 5-10 years. There were 10 responses to this question, and on a scale of 1 to 5 (with 5 being very widely used) the average response was 3.8.

SPINE PROCEDURES

The responses to question 4 concerning spine procedures are given here across all working groups. The question (for working group 1) was: Which spine procedures could benefit most from advances in operative planning and surgical simulators?

The most frequent responses were percutaneous procedures including screw placement, fusion, biopsies, and bone cement injection. Scoliosis was also frequently listed, as was fusion in general. Other procedures mentioned include cement injection, decompression, deformity surgery, discectomy, disk herniations, endoscopy, free sequesters in the spinal canal, interbody devices, intervertebral disk procedures, multi-segmental procedures, trauma and reconstruction, tumor removal, and wiring.

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10.4 APPENDIX D. BIBLIOGRAPHY SUGGESTED BY WORKSHOP PARTICIPANTS

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