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A multimedia Electronic Patient Record (ePR) system for Image-Assisted Minimally Invasive Spinal Surgery

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Abstract

Purpose—This paper presents the concept of bridging the gap between diagnostic images and image-assisted surgical treatment through the development of a one-stop multimedia electronic patient record (ePR) system that manages and distributes the real-time multimodality imaging and informatics data that assists the surgeon during all clinical phases of the operation from planning Intra-Op to post-care follow-up. We present the concept of this multimedia ePR for surgery by first focusing on Image-Assisted Minimally Invasive Spinal Surgery as a clinical application.

Methods—Three clinical Phases of Minimally Invasive Spinal Surgery workflow in Pre-Op, Intra-Op, and Post Op are discussed. The ePR architecture was developed based on the three-phased workflow, which includes the Pre-Op, Intra-Op, and Post-Op modules and four components comprising of the input integration unit, fault-tolerant gateway server, fault-tolerant ePR server, and the visualization and display. A prototype was built and deployed to a Minimally Invasive Spinal Surgery clinical site with user training and support for daily use.

Summary—A step-by step approach was introduced to develop a multi-media ePR system for Imaging-Assisted Minimally Invasive Spinal Surgery that includes images, clinical forms, waveforms, and textual data for planning the surgery, two real-time imaging techniques (digital fluoroscopic, DF) and endoscope video images (Endo), and more than half a dozen live vital signs of the patient during surgery. Clinical implementation experiences and challenges were also discussed.

Keywords

ePR; System Integration; Pre-; Intra-; and Post-Op Surgical Workflow; Minimally Invasive Spine Surgery

1. Introduction

1.1 Bridging the Gap between Diagnostic Images and Surgical Treatment

This paper presents the concept of bridging the gap between diagnostic images and image-assisted surgical treatment through the development of a one-stop multimedia electronic patient record (ePR) system that manages and distributes the real-time multimodality imaging and informatics data that assists the surgeon during all clinical phases of the operation from planning Intra-Op to post-care follow-up. We present the concept of this multimedia ePR for surgery by first focusing on Image-Assisted Minimally Invasive Spinal Surgery as a clinical application. For this particular surgical procedure, in addition to images, clinical forms, waveforms, and textual data for planning the surgery, two real-time imaging techniques (digital

fluoroscopic, DF) and endoscope video images (Endo), and more than half a dozen live vital signs of the patient during surgery are needed to assist and monitor the surgery. All these data have to be acquired, displayed and archived in real-time as well.

1.2 Minimally Invasive Spinal Surgery

Back and neck pain is the price human beings pay for poor posture, prolonged sitting, lifting, repeated bending, obesity, and injury from accidents. This ailment gives the United States with a massive economic headache. Approximately 85% of inhabitants of the Western world are afflicted with some degree of back or neck pain at some point in their lives [1]. About 25% of our population has been incapacitated for two weeks or more due to back pain and an estimated 8 to 10 million people have a permanent disability from it [2,3,4,5]. The economic impact is obvious. In most cases, simple treatments such as bed rest, exercise, physiotherapy, and pain medication bring relief. Many sufferers are not so fortunate. If one or more of their vertebral discs ruptures and presses on nerve roots, the pain radiating from the back or neck and down the limbs can be incapacitating and severe. Until recently, the only treatment was surgical removal of part of the ruptured disc, a major operation that required general anesthesia, the dissection of muscle, removal of bone, manipulation of nerve roots, and, at times, bone fusion. In an effort to overcome the disadvantages of traditional surgical techniques, the scientific medical community began exploring the use of endoscopy (arthroscopy) for Minimally Invasive Spinal Surgery surgical operation [6,7].

An endoscope provides clear visualization and magnification of deep structures in real-time. With the advancement of scientific technology and miniaturization, including fiber optics, video imaging technology, laser treatment and experience gained through minimally invasive spinal surgery, there is a less traumatic discectomy procedure for some patients with disc problems. In the recent years, development of image-assisted surgery has improved the precision and reduced surgical tissue trauma. Figure 1 depicts the cervical, thoracic and lumbar spines on MRI before (Pre-Op) and after (Post-Op) the endoscopic-guide spinal discectomy. The lesion(s) at each spinal region is clearly cured after the surgery.

1.3 Rationale for a multimedia ePR System for Image-Assisted Minimally Invasive Spinal Surgery

Minimally Invasive Spinal Surgery will be the method of choice for future spinal surgery to treat cases of herniated lumbar discs, post fusion junctional disc herniation, neural compression, osteophytes, spinal stenosis, vertebral compression fractures, spinal tumor, synovial cysts and other types of spinal traumas. Despite the overall advantageous and benefits of Minimally Invasive Spinal Surgery compared to conventional open spinal surgery, there are challenges remained in Minimally Invasive Spinal Surgery including 1) Integration of Pre-, Intra-, and Post-Op surgical data from scattered data acquisition systems; 2) Overcoming the difficulty of real-time data collection during the surgery; and 3) Improving the efficiency of surgical workflow. An integrated real-time multi-media ePR system is an ideal solution to overcome these challenges. If successful, it will take Minimally Invasive Spinal Surgery to a higher level of excellence by combining surgical expertise in minimally invasive spinal surgery with the frontier advancements in imaging informatics.

1.4 The Goals of the ePR

The two goals of this research development are:

1. To develop a totally integrated multi-media ePR system for image-assisted minimally invasive spinal surgery. All data collected for the patient from Pre-Op, Intra-Op and Post-Op will be acquired, displayed, and archived during each clinical phase of the

surgical workflow. Any data record of the patient in the ePR can be retrieved instantaneously anytime and anywhere.

2. To deploy the ePR at a clinical site for daily clinical use. Figure 2 depicts the ePR prototype system running at the Minimally Invasive Spinal Surgery Operating Room (OR) of a clinical site, with two large LCDs (liquid crystal display), one for the Pre-Op consultation integrated display, and the second for the Live Intra-Op integrated display.

2. Materials and Methods

2.1 General Minimally Invasive Spinal Surgery Workflow

The Minimally Invasive Spinal Surgery current high-level operation workflow includes pre-surgical consultation, pre-operation preparation, intra-operation image and vital signs acquisition and display, post-surgery documentation to patient recovery monitoring. The workflow can be broken down into three phases [8,9]: 1) Before surgery; 2) During surgery (including the preparation) 3) Post surgery. Each of the three clinical phases will be discussed below.

1. Before surgery (Pre-Op): This phase is the workflow involved prior to the actual surgical procedure. In the Pre-Op workflow, usually the patient presents with a problem and is evaluated by the physician to determine whether Minimally Invasive Spinal Surgery is needed and whether it would be helpful to the patient. If this case is true, then a procedure is scheduled. At this stage the surgeon or surgeons in combination with the physician assistant plan the surgical procedure using digital diagnostic images such as CR, CT and MRI. In addition to the information obtained from the medical studies, the patients also fill out a set of surveys that determine the level of pain that they feel.
2. During surgery (Intra-Op): During the surgical procedure, the surgeon(s) operate on the different disc(s) that need to be corrected. While operating, there is a significant amount of data being acquired that help monitor the body response of the patient to the procedure. This includes video and image data acquired with the endoscope. A single vertebrae procedure usually lasts 30 minutes on average.
3. After surgery (Post-Op): During this Phase the patient recovers from surgery. The patient is continuously monitored in the recovery area to assure all vitals signs are stable. In addition, a set of tests are also performed to assess the outcome of the surgical procedure which includes an additional set of forms that the patient fills out.

The recovery period after surgery lasts from 45 minutes to one hour. The patient is then discharged. Therapy can begin the next day and the patient can go back to work within 2 to 3 days.

2.2 Data Model of ePR System

The data model of the ePR for Minimally Invasive Spinal Surgery has been designed to extend the DICOM data model due to the similarities that exists for medical imaging data at CSI utilizing DICOM. From the DICOM data model the ePR for Minimally Invasive Spinal Surgery follows the relationship between the patient, the medical studies, series and images. The modified data model utilized for the current ePR contains additional entities that describe the data required for Minimally Invasive Spinal Surgery. These new elements that are added to the data model include the surgical procedure type, waveforms, the key image, survey forms for pain, and user information for access to the system. The data model is shown in Figure 3.

2.3 The ePR Dataflow

The initial Data flow utilized by the ePR system was based on the concept of the workflow presented in the General Minimally Invasive Spinal Surgery workflow and is shown in Figure 4 where each numeral represents a dataflow event.

There are three time phases, from the top down: the Pre-Op Image/Data module, the Intra-Op module, and the Post-Op module. Each of these modules contains four components: input module, input gateway, ePR server, and the visualization and display module.

2.3.1 Pre-Op Workflow—Following Figure 4,

1. Historical medical imaging studies in DICOM format are acquired from the PACS (Picture Archiving and Communications System).
2. The Gateway, which is a component of the ePR system, receives the DICOM images and processes them accordingly. The original image is kept in the ePR and a JPEG version is utilized for display purposes via the web interface of the ePR. All DICOM header information and metadata are extracted and recorded in the database.
3. Pre-Op authoring is performed by the surgeon(s) and the physician assistants. The surgical procedure information is entered into the ePR. At this Phase the patient's survey pain forms are also entered into the system. The surgeon selects some key images and authors annotations overlaid on the key images that will ultimately be utilized during surgery. The authorized images/data are displayed in the OR utilizing a 52-inch LCD display (see Figure 1).
4. Authorized images/data are archived in the ePR server.

2.3.2 Intra-Op Workflow

- 5, 6, and 7. The Integration Unit (IU) is connected to all clinical devices in the OR and continuously gathers live data signals from them during the entire surgical procedure, and display them in real-time on the second large 52-inch digital display (see Figure 1).
- 6 The Gateway Server receives the data from the IU and stores the data values and images in real-time at the database within the ePR system.

2.3.3 Post-Op Workflow

- 8 While the patient is in the recovery area, the system continues gathering some vital signs that are transferred to the Gateway Server.
- 9 The Gateway Server receives the data and stores the data into the database of the ePR system.
- 10 The surgeon uses the Post-Op authoring module to create a final report out of the data gathered during the pre-, intra-, and Post-Op Phases.
- 11 The final report will be kept in digital format at the ePR Server as the patients' permanent surgical record.

2.4 Minimally Invasive Spinal Surgery ePR System Architecture

Recalling Figure 4 which depicts the workflow and data flow model of the Minimally Invasive Spinal Surgery ePR system represented by a 3×4 dimension matrix model. The three rows are Pre-Op, Intra-Op, and Post-Op workflow process Phases; and the four columns are the input data integration unit (IU), input gateway, ePR server, and Image/Data display. From the

system architecture point of view, the ePR system should be designed for efficiency, effectiveness, and reliability of system operations. The fault-tolerant requirement of each component in the system is designed to support other existing components of the system for easy system back-up and cost containment. The ePR System architecture is shown in Figure 5 below and will be discussed in detail in the following paragraphs.

2.5 Four Major Components in the Minimally Invasive Spinal Surgery ePR System

The four major components in the Minimally Invasive Spinal Surgery ePR System are: 1) Integration Unit (IU); 2) Fault-tolerant Gateway server; 3) Fault-tolerant ePR Server, and 4) Visualization and Display. Both the Input Gateway and the ePR Server include data storage and archive, system database, system security, system fault-tolerance, continuous availability and failover. The GUI and display module resides within the ePR Server. All data input systems like medical imaging, surgical video, vital signs waveform recorders, and textual data recorder generate Pre-Op, Intra-Op, and Post-Op data, and they are all categorized as input data. The imaging and data systems that generate information are existing peripheral surgical supported equipment already within the OR but they do not belong to the Minimally Invasive Spinal Surgery ePR system. However, the ePR system must integrate these devices in order to receive the input data that is acquired before, during, and after surgery that support the surgical procedure.

2.5.1 Integration Unit (IU)—This component is responsible for acquiring all data from different peripheral devices that are presented in the OR during surgery (Intra-Op) that continuously measure all live vital signs, waveform signals, and surgical related images of the patient undergoing a procedure. The data acquired by the IU from all input devices are synchronized through a master clock and displayed live onto a customized interface using a 52" LCD (Liquid Crystal Display) screen (called Intra-Op Live Display) in the OR. The data gathered during surgery include the following:

- Digital C-ARM fluorographic images
- Digital endoscopic video images
- Waveform signals: EMG (Electromyography), BIS (Bispectral Index), and Vitals (Blood Pressure, Heart Rate, Respiratory Rate, PulseOX, Body Temperature and Partial Pressure of Carbon Dioxide).

The images, videos and data points mentioned above are transferred automatically and continuously from the various input sources of the different data devices in the OR during operation that are attached to the data input IU. The data is immediately saved into IU memory. The IU software displays the waveforms, images, and streamed videos properly every second (which is a default value) on the large Intra-Op LCD, and also makes a copy from the memory to the IU local hard drive with 1.5 TB (Terabytes) of storage space every five seconds (which is also a default value). These two default values can be adjusted interactively depending on clinical demands.

Normal procedures for a single vertebra surgery take about 30 minutes on average. This Intra-Op data is sent continuously to the Gateway where the images are processed if needed and then placed in a data folder shared with the ePR server where they will be permanently archived. The data values are also extracted and saved to the ePR system database. In addition to the one second input display refresh-rate described in the last section, the IU features a rule-based alert-mechanism that checks each input waveform for data that is out of the normal range. The IU has a set of rules based on clinical accepted medical practice that determines when a given signal is considered within the normal range for a patient. If at any given time during the surgical procedure, a signal falls outside the safe range, the IU will trigger an alert message on the Intra-

Op Live display. This assists the surgeon and key personnel in the OR to take necessary actions during the surgical procedure. It is noted that the default values might not be considered normal for all patients; thus, during the Pre-Op patient consultation time, these default values can be revised and properly adjusted as necessary.

2.5.2 The Fault-tolerant Gateway server—The functions of the Input gateway are receiving, staging, managing, and transferring input data during the three clinical workflow phases of the surgery: Pre-Op, Intra-Op, and Post-Op.

Pre-Op Phase: The gateway receives DICOM images and diagnostic reports from PACS. Once images are received by the gateway, a Pre-Op script is automatically launched by the gateway to properly extract all the information from the headers of the DICOM files. This data is then saved into the database. This whole process is automated at the gateway and does not require any user intervention.

Intra-Op Phase: During Intra-Op, the gateway receives live data from the IU using an API (Application Program Interface). The transfer protocol used is the HTTPS (HyperText Transfer Protocol Secure) Standard. Before any data is sent to the Gateway, the IU needs to properly authenticate itself in order to avoid conflict with other possible input devices. Once the data is received by the Gatewayserver, the API will place the data in a specific location in the ePR where a script will be executed to process the data accordingly.

Post-Op Phase: During Post-Op, the patient is under observation in the recovery area by a nurse and the surgeon. The vital signs and other monitoring equipment are used to evaluate the patient PostOp condition. During the 45 minutes to one hour observation, live data of the patient is continuously received and displayed at the bedside monitor by the Post-Op module.

2.5.3 The Fault-Tolerant ePR Server—The ePR Server is the heart of the Minimally Invasive Spinal Surgery ePR System and is the front-end of the system where the users will login to perform all the necessary tasks during the surgical workflow. The ePR Server allows access to the Pre-Op authoring module, the Pre-Op display in the OR and the Post-Op authoring module (see Figure 5). Administrative tasks such as giving the users access to the system, registration of patient information, scheduling, among others are also included.

The ePR by definition allows the participants to obtain any necessary information about the patient from a single interface, i.e., the information follows the patient. The ePR not only shows information about the medical examinations for the patients, but also any other related data such as clinical history and pain surveys acquired during the surgical procedure. The ePR is developed utilizing PHP (PHP: Hypertext Preprocessor) as the backend programming language. The data values are stored using a MySQL database [10]. The web pages are structured with HTML (Hyper Text Markup Language), and they are styled using CSS (cascading style sheet). The interfaces are dynamically updated using JavaScript. The web server utilized is Apache 2.2 [11].

Data Storage and Archive and System Database: Managing the data acquired by the ePR system is a critical task. Therefore, a dual-system back-up mechanism is implemented as follows. First, the ePR server has the server hardware, and the Gateway has the Gateway hardware. Two identical server software packages are implemented, one in the ePR server hardware as the primary and the other in the Gateway hardware as the back-up. By the same token, two Gateway software packages are implemented, the primary package is in the Gateway hardware, and the secondary package is in the ePR Server hardware as the back-up. Refer to the middle row of Figure 5, the Gateway and the ePR server each has its own hardware, where

each hardware piece is housing both the ePR server software and the Gateway software; one is the back-up of the other. Figure 6 shows the dual-system backup mechanism.

The input data first comes to the Gateway hardware, where the Gateway software categorizes them by images, live waveform information, and textual information. Images include DICOM images in their original DICOM format as well as in JPEG format for web display; as well as endoscopic videos, endoscopic single frame images, and digital C-arm fluoroscopic images. The metadata in the DICOM images and other data are stored in the database disks. All acquired data and metadata are immediately backed up by the ePR Server hardware.

System Security: The system security has been considered carefully during the design in order to comply with the HIPAA (Health Insurance Portability and Accountability Act) requirement. Only the users who have been granted permission are allowed access to the system. At the same time the privacy of the communications are kept to avoid any non-authorized receiver to obtain a given patient's private information. To guarantee the security of the data, web access to the ePR is established with HTTPS that encrypts all communication between the server and the clients (web browsers). In addition, the ePR system handles permissions that will allow users to perform different tasks on the system. Different user groups in the system have a different set of enabled permissions, however, permissions can be overwritten for individual users by the system manager if necessary providing a greater level of flexibility.

System Fault-Tolerance and Continuous Availability and Failover: The information that is kept in the ePR is unique and cannot be obtained from any other sources if lost. To overcome any possible loss of data, a fault-tolerant solution that replicates the data of the ePR to more than one place has been implemented. The primary Gateway serves as the backup for the primary ePR server, and vice versa.

In addition to having the data being stored with more than one copy, system redundancy with automatic failover mechanism has been designed to access the data in case of the failure of any component in the system to guarantee system continuous availability.

2.5.4 Visualization and Display—The last of the four components in the ePR System is the Graphic User Interface (GUI) and Display. In order to have the ePR system to be utilized as an effective tool that can improve the workflow of the Surgery Department, it is important to have a user-friendly GUI that presents all necessary contents for the surgery in an easy to use manner. For this reason, the ePR system is designed with this concept to achieve this goal.

Because the entire ePR system operates in three interrelated Phases during a surgical procedure, from planning (Pre-Op), to surgery (Intra-Op), to patient recovery (Post-Op); the interface design between these three Phases are critical. The Display interface design (see Figure 5) includes the main page, the Pre-Op display at the patient consultation room, the Pre-Op display at the OR, the Intra-Op display at the OR, the Post-Op at the patient recovery area, the Post-Op at the OR for surgical documentation, and the administrative pages.

2.5.4.1 Pre-Op Authoring Module: The Pre-Op Phase of a Minimally Invasive Spinal Surgery procedure is where all necessary information prior to the surgery procedure is collected and organized in a patient e-folder. The Pre-Op happens days prior to the surgery and involves querying, interviewing, collecting, and storing of pre-surgical medical images, patient demographic information as well as other pertinent data value that would assist the surgery during the procedure.

Traditionally, surgeons have been relying on their memory for localization of where the procedure should be performed. They review the MRI and X-Ray images the day before surgery

and studied the approach to be taken during the procedure. These images are also brought to the OR for reference. But they are displayed in hard copy in an unorganized fashion scattered throughout the OR. The next few paragraphs focus on the organization of the Pre-Op patient information which requires a preparation process. This process should not be done during the time of surgery and the information should be saved in advance with the display streamlined and organized for efficiency purposes.

Creating a Surgical Procedure in the Pre-Op Authoring Toolkit: The interface allows the users to create the surgical procedures by first selecting the key images as well as adding annotations to those key images as shown in Figure 7. On this screen the PACS image and surgical procedures had been combined into one display in the Pre-Op module. Image studies related to the surgical procedure are shown on the left hand side based on the surgical data model (see Figure 7). To view an image in a study, the users can either drag the study shown on the list from the left to the viewing pane on the right hand side or by double clicking the study from the list on the left. Figure 7 displays a sagittal MRI image with patient's ID above the image. The toolbar with icons at the top of the viewing pane allows the users to perform certain tasks accordingly to the current status of the editing module.

1. To view images in a study: The two icons on both the right and the left sides allow the user to preview images in the study series.
2. To perform image manipulation: The toolbar for the Pre-Op include some basic image manipulation tools such as window/level, pan, and zoom. With this functionality, the images can be displayed optimally at the exact location of the lesion.

During a Minimally Invasive Spinal Surgery operation, it is important to correlate the axial view with the corresponding sagittal view of an MRI study. The neuro-navigator tool in the Pre-Op module allows such correlation through the display as show in Figure 7.

In addition to the input data described earlier, one type of Pre-Op data which is critical during surgery is the hand written whiteboard information located at the entrance of the OR which contains a very short summary of the patient such as name, gender, age, weight, height, any allergies, comorbidity and pain. Normally, the white board should contain all patients' information to be operated during the day. The Pre-Op authoring module described has been designed to integrate the whiteboard information onto the same Pre-Op screen for display in the OR during the surgery. The following survey measures are also included:

1. Visual Analog Scale (VAS): Is a psychometric response scale to describe the amount of pain a patient is feeling from a specific part of her/his body.
2. Oswestry Disability Index: A survey to identify how the pain in the back or legs is affecting the patient in his/her daily activities.

The design concept of the ePR system is user-friendly but effective at the same time. For these reasons, the criterion of the user interface is to minimize the number of mouse clicks needed to perform a certain task and to aggregate information adequately into a single interface whenever possible. The current Pre-Op authoring module is a self-contained interface where the users can download, edit, add, and delete the contents as needed. The Pre-Op has two major interfaces, one for editing and one for display in the OR.

Pre-Op Display: A Minimally Invasive Spinal Surgery procedure requires multimedia data during the Pre-Op Phase including patient history, images, and consultation results. These data should be organized and displayed in the Pre-Op display during surgery. An example is shown in Figure 8 which depicts the general patient information (first top row), whiteboard information outside of the OR (second top row), as well as the key images selected from the MRI study with their annotations during consultation (center). The term that is used for this

display is the Pre-Op Display since the Pre-Op authored data is actually displayed during the Intra-Op workflow Phase.

2.5.4.2 Intra-Op Live Display: Figure 9 shows a mock up example of the Intra-Op Live Display with waveforms and images. The horizontal axis is time. The stream from the vital signs device is displayed at the top row (left) and to the right there are five groups of waveform: three vital signs with blood pressure, pulse oxygen concentration and pCO₂, as well as BIS, IVF (Intravenous Fluid). Every dot in the waveform represents a data point over a one second interval. In the middle row, there are two images, the C-Arm fluoroscopic (right) and the endoscopic video images (middle), and one EMG waveform in the left. In the lower row, there is laser energy in joules. The video is updated on the Intra-Op Live Display with a frame rate of 30 per second (a default value).

Rule-Based Alert Mechanism: If a signal falls outside its safe range a three stage mechanism will alert personnel in the OR about that situation.

1. Warning mode: If the numeral falls outside the safe range it will change its color to red (as seen with the PulseOX and Blood Pressure in the figure)
2. Emergency mode: If the condition falls to a value greater or lower in 25% of the safe range then the Intra-Op Live Display will place an alert message on top of the screen.
3. Critical mode: If the data signal value is either greater or lower in 50% to the values in the safe range then the alert message will cover the whole screen.

2.5.4.3 Post-Op Module: The Post-Op Phase takes place after the completion of the surgical procedure, normally, the next several days after the surgery. There are three time substages: 1) Patient in the recovery area and then discharged, 2) the Surgeon documents the surgical results, and 3) follow up pain surveys after Post-Op for several months.

Post-Op Authoring Toolkit: When the surgeon performs Post-Op documentation, he/she can retrieve information from the Post-Op module pertinent to the surgery using the GUI. This process involves four major steps:

1. Finding the Patient from the ePR System. The correct patient can be located from the ePR via the worklist.
2. Selecting images. From this GUI, the surgeon can select endoscopic images that will be included in the final report by clicking the star at the top left corner of the viewing pane. As shown in Figure 10, that image has been selected for the final report.
3. Selecting Waveforms. The waveforms are displayed at the bottom of the GUI (Figure 10). They can be dynamically selected by clicking their corresponding boxes on the upper right side of the interface.
4. Data Synchronization. A slider at the bottom of the graph (green pointer in Figure 10) would allow for synchronized viewing of all the image and waveform data being displayed.

The data that was displayed and selected for documentation in Figure 10 includes a C-Arm fluoroscopic X-Ray image, heart rate, diastole and systole blood pressures, respiratory rate, BIS score value, oxygen pressure and partial pressure of carbon dioxide. The curve shown at the bottom of Figure 10 (Heart Rate) is a waveform obtained from another Intra-Op device. Figure 10 shown contains real-patient data with anonymized acquisition date and time and patient demographics.

Nurses and Front-desk personnel perform surveys several times after the surgery and enter the pain surveys data into the Post-Op module of the ePR system as a follow-up of the progress of the patient. The collective information can be used for future patient outcome analysis.

3. Results

3.1 Clinical Site for Developing and Implementing the Minimally Invasive Spinal Surgery ePR System

The design and implementation has been in collaboration with the California Spinal Institute (CSI), Thousand Oaks, CA. CSI is a full self-sufficient independent spinal surgery institute and performs between 5 – 10 minimally invasive spinal surgeries per week. It has its own diagnostic imaging facility including conventional X-rays, CT and MRI services and a commercial PACS. CSI also provides patients with the full in-house services for spinal surgery from Pre-Op consultation to Post-OP evaluation, check-up and therapy. The concept of developing the multi-media ePR system for image-assisted Minimally Invasive Spinal Surgery was conceived five years ago but technologies were not available until recently [9]. The go head development decision was made in early 2007.

Many parameters used in the design were based on daily clinical experiences at CSI during the past five years. The ePR system can be modified for Minimally Invasive Spinal Surgery operation at other similar healthcare facilities, and image-guided surgery OR's (Operation Room).

3.1.1 System Deployment—The prototype system was deployed in August, 2008 to the California Spine Institute (CSI) located in Thousand Oaks, California, which is the only clinical site in Southern California that performs Minimally Invasive Spinal Surgery. This site served as an initial approach to understand the general workflow of the surgical procedure. Because the goal of the system is to be able of being installed in other locations, the workflow and implementation was kept in its more general instance, avoiding any specific-related design for CSI. In the case that a particular part of the implementation was tailored for this site, the options were configured to be flexible. The customization of the modules used in the ePR will allow having the system implemented in different locations where other vendors are used.

This section summarizes the highlights.

Planning and design phase: The ePR system for Minimally Invasive Spinal Surgery was developed at the IPILab, USC. IPILab and CSI have had close collaboration for more than five years. There are three phases of the implementation. First, to test the functionality of the ePR system, a prototype for each of the ePR components was developed and integrated at the CSI research facility; in addition, mockup data was collected at CSI that included an Intra-Op signal simulator for the IU device. Second, once the system was tested fully in the laboratory environment, it was then deployed in the OR to obtain user feedback and clinical evaluation. The hardware and software components consist of the Gateway Server, the ePR server, and the IU. In addition, other software packages include the ePR web pages, the IU application, the database, and the web server.

The final stage of the clinical implementation was to deploy the ePR system in the OR. This stage has been challenging, since the OR is continuous in use for Minimally Invasive Spinal Surgery, both the clinical team and the engineering team have to work together to circumvent the clinical schedule minimizing the risk of any possible disruption of the clinical service through coordinating of various tasks among the teams member; this is especially true in the final stage of implementation, when the ePR has actually been used taking care of some regular duties usually reserved by the traditional surgical method.

Hardware installation: The ePR and Gateway servers were installed at CSI on a rack at their Server Room. Figure 11 shows the installation in progress and the final location of those servers.

In addition to the two servers above, the IU was also installed in one of the ORs at CSI. The IU needs to be connected to all required peripheral devices that are presented in the OR for monitoring the real-time patients' response during the clinical procedure. The IU, located in the OR, and its connection to input devices are shown in Figure 12.

Software installation: Once the servers were installed at the clinical facility, the next step was to configure all necessary software components of the ePR system. Those components include:

1. **ePR server:** The server requires the installation of the web server (Apache) and the database (MySQL).
2. **Gateway server:** Composed of a software DICOM listener that receives incoming DICOM studies sent from the PACS and a set of scripts to extract the metadata information and store it at the database.
3. **Integration Unit:** Software developed in C++ is utilized to make low level system calls to the different interfaces depending on performance requirements to display real-time data in the OR.

Training and Support for Clinical Users: The following users were among those trained for the use of the ePR system:

1. **Surgeons:** They received training on the Pre- and Post-Op authoring modules. In addition, they were taught to properly interpret the two large Pre-OP and Intra-Op LCD displays.
2. **Physician Assistants:** They were involved in both group and individual training sessions for Pre-Op authoring module.
3. **Nurses:** They were trained to properly enter information related to the patient's whiteboard data and survey forms.
4. **Front-desk assistants:** They received training for scheduling of surgical procedures, input of pain surveys for Pre-Op and Post-Op Phases as well as patient registration.
5. **Technicians:** The training given to them was on how to correctly understand the data presented at the LCD monitor displays at the OR.
6. **Administrative staff:** They were given training on how to add or remove a user from the ePR system and to manage the permissions for the different user types or a specific user as well.

The engineering team provided three months on-site baby-sitting of the ePR system as well as assisted the duty staff to prepare Pre-Op module. Figure 13 shows a typical training session. Clinical Implementation of the Post-Op module is currently ongoing.

3.1.2 Clinical Implementation Experiences

1. The implementation phases were planned based accordingly on the three workflow stages to provide a good understanding of the features included in the ePR System and at the same time to address any positive feedback from the users. Phase one implementation was included the Pre-Op authoring and display toolkit as well as general ePR features such as worklist navigation and DICOM Query/Retrieve. Phase two implementation included the Intra-Op display as well as the Pre-Op display on

large LCD monitors. Finally, phase three included the Post-Op authoring and display toolkit and is currently undergoing training sessions. Since the ePR System was installed in August 2008 at CSI, every surgical operation has utilized the Pre-Op Display module within the OR. This is a direct result of the clinical staff performing the Pre-Op authoring one day prior to surgery. In the same amount of time, the Intra-Op live display has been used to show a centralized view of all the data obtained from peripheral devices. Data captured from the IU module is currently stored in the ePR System automatically since May 2009.

2. Even though there was no formal evaluation from the users' training, all the people that were trained had been using the ePR with no major complaints. After a one year clinical operation with sufficient and meaningful data collected, a more formal user acceptance survey will be conducted targeted for a follow-up clinical experience paper.
3. The chief surgeon who is one of the architects of this system has monthly meeting with the ePR team to provide suggestions, input and user experience for system refinement and upgrades. He has been the champion of the project.

3.1.3 Next steps in Research and Development

Prototype version 2 for Integration Unit: The Integration Unit (IU) is a very critical component in the ePR system, but at the same time is very complex and needs to be refined to satisfy the ePR System requirements. The prototype version 2 of the IU has been designed to provide continuous availability, improve the performance for data collection, visualization and storage with expanded flexibility in order to support a larger set of devices and configurations.

Difference between current version and the version 2 of the Integration Unit: The main difference between the two versions of the Integration Unit is the capability of handling fault tolerance and continuous availability: the first prototype of the IU did not provide any fault tolerance. The second prototype provides fault tolerance by adding a second set of key pieces from the IU. This is similar to what have been done to the PACS [12]. Among the pieces added are: more robust UPS (Uninterruptible Power Supply); NAS (Network Attached Storage) for storage; the main processing unit is provided by means of two identical clustered blade servers. In case of any failover the recovery is done automatically. In addition, the second prototype is assembled in a self-contained mobile cart that enhances the flexibility for implementation in different environments. At the same time the second prototype has increased the number of ports to include more peripheral devices present in the Operating Room.

The software that acquires, displays, and stores the data also requires an update to handle the new infrastructure for the second prototype. Upon completion of the second prototype, one copy will replace the existing first prototype within CSI and the second copy will be deployed at a second clinical site to be determined.

4. Discussion

4.1 Lessons Learned

Much of the experience gained and many lessons learned in developing the multi-media ePR for Image-Assisted Minimally Invasive Spinal Surgery are similar to that of early times when PACS was developed and deployed in radiology departments, and later to hospitals. However, there are some differences due to the fact that ePR users are mostly local and not hospital-wide. Among these, are listed in the following as well as any comments on the differences and similarities between them whenever appropriate.

1. **Lack of standards from peripheral data and imaging devices used in the OR.** This was the major obstacle during the implementation phase. There are many vendors who sell peripheral devices to ORs where no data format or communication standard compliance is required. Different vendors export their data in different ways, adding complexity to the mechanisms for data retrieval and limiting the interoperability to certain vendors and products. In imaging, most ORs still use Pre-Op hardcopy for reference during the surgery. For image-assisted surgery, the Intra-Op endoscopic and C-Arm radiographic images are for assisting the surgeon during the surgery, and there is no requirement for keeping hard or soft copies for surgical document. The multimedia ePR system for Minimally Invasive Spinal Surgery, on the other hand, keeps all live data during the surgery in the database, they will be selected by the surgeon to include in the patient report during Post-Op authoring. Therefore, it had been a major challenge for acquiring data from real-time peripheral devices as well as images from endoscope and C-Arm radiography in the OR during surgery. In PACS installation, similar problems were encountered in imaging modalities connectivity, but this issue was resolved by the mandated compliance to DICOM standard in almost all the purchases in imaging systems and PACS in the late 1990s. The development of the Integration Unit (IU) in the ePR system prototype is the first step allowing all devices to be integrated. We anticipate several years down the road, surgical OR may see the advantages of data integration in the ePR and enforce vendors to output data with certain standards.
2. **The clinical environment was different from the laboratory environment.** When the ePR prototype was moved from the laboratory environment to the clinical site, the engineering team encountered a culture shock. In the former, the laboratory environment was under control and debugging and modifications could be performed easily. Whereas in the latter, the reality of the real world sank in, and it was very difficult to make modifications for two reasons: 1) Once the ePR was installed, the clinical use of the system has always been with the highest priority, any modifications were secondary, 2) Users were reluctant to continuously adopting new changes. Unlike PACS installation which has long passed this R&D mode, nowadays a prototype system would be rarely installed in the clinical site without extensive test at the manufacturer site first.
3. **The Clinical institution was not always in control of its computer and ICT (Information and Communication Technology) equipment.** Installing new applications in clinical computers might sometimes require administrative privileges. In addition, configuring and adding new servers to CSI might need to be performed by a third party IT (Information Technology) team that could cause implementation issues. This issue would be encountered in many PACS installation as well.
4. **User Acceptance.** Whenever a new application in the ePR was implemented at CSI, users might be reluctant to fully embrace the new application. It is because it would temporarily disrupt their normal routine clinical workflow even if the system would ultimately improve their clinical workflow in the long run. The user acceptance is easier in PACS now since the healthcare community has gained more than 15 years of experience.
5. **Graphical User interface challenging for new users:** When a new application was developed, training becomes crucial since users were not familiar with the interface and functionality. This issue is 100% the same as PACS when the user is first time or switches to a new PACS, or a new GUI is installed.

4.2 Design Principles and Reproducibility

1. **The Design principle.** The design principles of the ePR system are modularity and reproducibility. The system has three major components, Pre-Op, Intra-Op, and Post-Op, they are operated as a complete system. In order for the Post-Op to function properly, both Pre-Op and Intra-Op have to be operable. In the same token, in order for the Intra-Op to be functional, Pre-Op has to be operable. However, Pre-Op can be used without the Intra-Op and Post-Op in operation. In this case, no data from the Pre-Op would be input to the Intra-Op and Post-Op modules.
2. **Reproducibility.** The infrastructure of the ePR system is applicable to most image-assisted minimally invasive surgical operation rooms. However, certain customization may be required. For example, different surgical input including images, waveforms and textual data may need new designs for various input device interfaces. The Integration unit (IU) infrastructure has been tested to handle up to a combined total of 12 waveforms data points, imaging inputs and video streaming sources. In addition, the Display format and GUI need to be redesigned to suit various surgical requirements.

5. Conclusion

A step-by step approach was introduced to develop a multi-media ePR system for Imaging-Assisted Minimally Invasive Spinal Surgery. First, the clinical need for the Minimally Invasive Spinal Surgery ePR was introduced. Then, the three clinical Phases of Minimally Invasive Spinal Surgery workflow in Pre-Op, Intra-Op, and Post-Op were discussed. The three-phased modules; and the four components: the input integration unit, fault-tolerant gateway server, fault-tolerant ePR server, and the visualization and display component. A prototype was built and deployed to a Minimally Invasive Spinal Surgery clinical site with user training and support for daily use. Finally, special experience gained and lessons learned from developing the system were discussed. This methodology can be extended to other image-assisted minimally invasive surgery.

Abbreviations

API	Application Program Interface
BIS	Bispectral Index System
CO ₂	Carbon dioxide
CR	Computed Radiography
CSI	California Spine Institute
CSS	Cascading Style Sheet
CT	Computed Tomography
DICOM	Digital Imaging and Communications in Medicine
EMG	Electromyography
ePR	Electronic Patient Record
GIF	Graphics Interchange Format
GUI	Graphical User Interface
HIPAA	Health Insurance Portability and Accountability Act
HIS	Hospital Information System

HTML	Hyper Text Markup Language
HTTP	HyperText Transfer Protocol
HTTPS	HyperText Transfer Protocol Secured
ICT	Information and Communication Technology
IA-MISS	Image-Assisted Minimally Invasive Spinal Surgery
IPILab	Image Processing and Informatics Laboratory
IRB	Institutional Review Board
IT	Information Technology
IU	Integration Unit
IVF	Intravenous Fluid
JPEG	Joint Photographic Expert Group
LCD	Liquid Crystal Display
MB	Megabytes
mmHg	Millimeters of Mercury
MRI	Magnetic Resonance Imaging
OR	Operating Room
PACS	Picture Archiving and Communication System
PHP	PHP:Hypertext Preprocessor
PNG	Portable Network Graphics
RAM	Random Access Memory
RIS	Radiology Information System
RS232	Recommended Standard 232
SC	Secondary Capture
SDK	Software Development Kit
TB	Terabytes
USC	University of Southern California
VAS	Visual Analog Scale
VGA	Video Graphics Array

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Figure 1. Minimally invasive spinal surgery on cervical, thoracic, and lumbar spines. Upper row: Pre-operation arrows show the areas where the disc protrudes the spine. Lower row: Post endoscopic-assisted spinal surgery shows the lesions have been cured.

Figure 2.

Schematic of the dynamic multi-media ePR system for Image-Assisted Minimally Invasive Spinal Surgery. The ePR prototype system is running at the Minimally Invasive Spinal SurgeryOR of CSI, with two large LCDs (liquid crystal display), one for the Pre-Op consultation integrated display, and the second for the Live Intra-Op integrated display.

Figure 3.

The data model of the ePR system. It extends the schema of DICOM to accommodate surgical information including live waveform and several standard surgical forms. Additional entities have been augmented to the data model.

Figure 4. Dataflow of the ePR system for Minimally Invasive Spinal Surgery. There are three time Phases (vertical): Pre-Op, Intra-Op and Post-Op; and four operational modules (horizontal): input units, gateway, ePR Server and database, and visualization and display, which forms a 3×4 matrix. Each numeral represents one event in the dataflow explained in the text.

Figure 5.

The ePR system architecture showing three operation phases (first column): Pre-Op, Intra-Op and Post-Op; as well as four operation modules (partitioned and scattered systematically). Some partitioned modules are bundled up together for ease of data transfer and fault-tolerant back-up. The arrows show the data flow during the three phases of operation. The outside light gray color side-way “U” band is the Display module backbone with five rectangular box subunits. Inside the opening of the “U” in dark gray are the Integration Unit, Fault-tolerant Gateway, and Fault-tolerant ePR Server. Within the Gateway and the ePR Server, the Database and Filesystem software are interrelated and shared by both components.

Figure 6.

The Dual-system back-up Schema with two hardware pieces: ePR Server hardware and Gateway hardware. Each hardware piece has two components of software: ePR Server software, and Gateway software; and a tandem database with hard drive for data and metadata archive.

Figure 7.

(Left – Figure 7A) The Pre-Op authoring module page. The upper left hand text list depicts the surgical data model showing the studies and procedures. After the user clicks an item in the list, the proper image, in this case, a sagittal MRI is shown on the right. (Right – Figure 7B) The Neuro-navigator tool allows the correlation of the position of the lesion in the sagittal (left) and the axial view (right). The red lines are the two corresponding sagittal and axial sections.

Figure 8.

The Pre-Op display organized during patient consultation as seen on the Pre-OP display monitor in the OR during Intra-OP. Top Text Row: Patient General Information, Second Text Row: Whiteboard information, Bottom row: Images and annotation during Pre-Op consultation; left: CR image, middle: sagittal MRI with annotation and right: transverse MRI.

Figure 9.

A mock-up example of the Intra-Op Live Display as seen on the Intra-Op large monitor in OR. Top row from left to right: Video stream of vital signs and six waveforms coming from three vital signs, BIS and IVF; the horizontal axis is time. Middle row from left to right: Waveform of EMG, endoscopic image and Fluoroscopic image. Bottom row: Laser output values.

Figure 10.

The Post-Op authoring module displaying a patient case showing data acquired during the surgery. The x-axis represent the time, while the y-axis represent the numerical value of the data points. The green mark represents the time frame when this page was captured. This module can be utilized by the surgeon to create an image and waveform Post-Op results document in pdf format. The graph showed at the bottom is the sequence of Respiratory Rate values over the whole procedure time.

Figure 11.
The ePR Server installation at the Server room of CSI. J. Document, was installing the servers.

Figure 12.

Integration Unit (IU, left inside the red ring) installed in the OR connected to different input sources. (Middle: Input units cables are connected to the back of the IU; Right: Vital Signs device is being connected.).

Figure 13.
Group training in Pre-Op authoring at the consultation room