Human Systems and Instructional System Design for a Simulator of a Robotic Surgical System

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ABSTRACT

Traditional spinal surgery procedures are carried out with limited direct visualization and augmented with generous use of fluoroscopic imaging. This imposes limitations on the surgeon's ability to place screws into the spine and exposes the staff to large amounts of cumulative radiation. The Mazor Renaissance robotic system was developed to both improve the accuracy of insertion of the pedicle screw and to reduce the amount of energy exposure to staff and patients. The robot offers a significant advancement in the technology used in spinal surgery, which calls for very specialized training and education programs for surgeons seeking to adopt it. The current standard of training and employment of this device comes with significant constraints on both the trainees and trainers.

Currently, the training must be conducted at specialized training centers that can provide clinical equipment which includes Operating Room (OR) tables and lights, fluoroscopic imaging equipment, cadaveric tissue, surgical instrumentation, certified radiation technicians, tissue storage, and video recording capabilities. These requirements create a learning experience, which can only be supplied to a surgeon a single time and do not support surgeon-initiated refresher training. This suggests that a simulation-based solution may be a valuable supplement to the current training and education model.

This paper describes efforts to apply the theories of human-systems integration (HSI), instructional system design, and simulator engineering to define the requirements for a simulator of a specific robotic surgery system. Specifically, the aim of this project was to outline the instructional opportunities through several instructional analyses that can be filled with a spinal simulator while considering human performance concerns and constraints during the research and design phases of the system. From this, an instructional plan was conducted, to which a HSI driven design document for a simulation system was developed.

ABOUT THE AUTHORS

Danielle Julian, M.S., is a Research Scientist at Florida Hospital's Nicholson Center. Her current research focuses on robotic surgery simulation and effective surgeon training. Her current projects include rapid prototyping of surgical education devices and the evaluation of robotic simulation systems. Her background includes research in Human Factors and learning and training to enhance the higher-order cognitive skills of military personnel. She is currently a Ph.D. student in Modeling and Simulation at the University of Central Florida where she previously earned an M.S. in Modeling and Simulation, Graduate Simulation Certificate in Instructional Design, and a B.S. in Psychology.

Roger Smith, Ph.D., is an expert in the development of simulation devices and training programs. He has spent 25 years creating leading-edge simulators for the Department of Defense and Intelligence agencies, as well as accredited methods for training with these devices. He is currently the Chief Technology Officer for the Florida Hospital Nicholson Center where he is responsible for establishing technology strategy and leading research experiments. He has served as the CTO for the U.S. Army PEO for Simulation, Training and Instrumentation (PEO-STRI); VP and CTO for training systems at Titan Corp; and Vice President of Technology at BTG Inc. He holds a Ph.D. in Computer Science, a Doctorate in Management, and an M.S. in Statistics. He has published 3 professional textbooks on simulation, 12 book chapters, and over 100 journal and conference papers. His most recent book is *A CTO Thinks About Innovation*. He has served on the editorial boards of the *Transactions on Modeling and Computer Simulation* and the *Research Technology Management* journals.

Alyssa D.S. Tanaka, Ph.D., is a Principal Investigator at SoarTech Inc. and previously a Research Scientist at Florida Hospital Nicholson Center. Her research work focuses on the design of simulators for medical applications, robotic surgery simulation and effective surgeon training. Her projects have included rapid prototyping of surgical education devices, the validation of a robotic surgical curriculum and evaluation of robotic simulation systems. She has earned a Ph.D. and M.S. in Modeling and Simulation from the University of Central Florida, as well as a Graduate Simulation Certificate in Instructional Design, and a B.S. in Psychology and Cognitive Sciences from the University of Central Florida. She holds a diploma in robotic surgery from the Department of Surgery, University of Nancy, France.

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INTRODUCTION

Laparoscopic surgery, also known as Minimally Invasive Surgery (MIS), is a surgical technique that allows physicians to complete procedures through small incisions instead of large openings. MIS reduces surgical trauma, lessens the chance of infection, decreases blood loss, and reduces patient recovery time (Fuchs, 2002). With the introduction and increase of laparoscopic surgery tools, MIS has expanded to include computer (or robotic) assisted minimally invasive surgery.

While some specialties quickly adopted the use of computer assisted minimally invasive surgery (e.g., gynecology and urology), others specialties have recently shown interest. Among these emerging specialties are orthopedics and neurosurgeons who often face difficult procedures focused with or around the spine (Hu, Scharschmidt, Ohnmeiss, & Lieberman, 2015). Due to the spine's proximity to the central nervous system and major blood vessels, performing spinal surgery is a delicate and precarious procedure. Many studies have examined the accuracy of traditional pedicle screw insertions and fusion (Davne & Myers, 1992; Blumenthal & Gill, 1993; Lonstein et al., 1999; Devito et al., 2014), a common spinal procedure, and found that the rate of misplaced screws during these procedures was unacceptably high (Devito et al., 2010). These rates have spurred the increased use of robotically assisted pedicle screw insertion (Lonstein et al., 1999; Devito et al., 2010), specifically the use of the Mazor Robotics Renaissance Guidance System.

What is the Mazor Renaissance Guidance System?

The Mazor Renaissance Guidance System (MRGS) is used to optimize the preplanning and accuracy of both minimally invasive and open spinal surgeries (Figure 1). MRGS can be used for degenerative repair, pedicle screw fixation, and vertebral augmentation procedures. The system is comprised of three primary components:

- 3D pre-planning software,
- robot workstation, and
- guidance unit.

Figure 1. Mazor Renaissance Guidance System

The pre-planning software is used to create a pre-operative "blueprint" tailored to each patient (Figure 2). The patient's pre-operative CT scans are uploaded into the software, which is installed on the surgeon's personal computer. The software uses the pre-operative CT to construct a 3D model of the patient-specific anatomy, which the surgeon uses to place virtual screws. The software allows the surgeon to visualize the placement of the screws from various planes and watch each screw enter the spinal body in slices. This detailed visualization allows the surgeon to see the exact angle and depth of each screw.

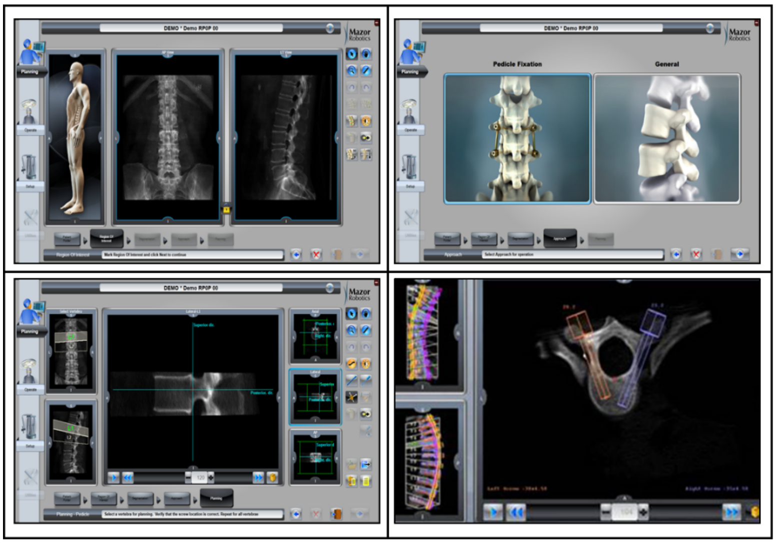


Figure 2. 3D Pre-planning Software

When the surgeon completes the pre-operative plan on their personal computer, it can be uploaded to the MRGS workstation. This workstation is the "brain" of the intra-operative process. In the OR, before starting the procedure, the surgeon will use the workstation to upload intra-operative fluoroscopy images. These captured images are uploaded and synced with the 3D preoperative plan completed before the surgeon steps into the OR. The pre-operative blueprint to the intraoperative anatomy is synced to register each vertebra and provide maximum accuracy for procedure (Figure 3). The workstation software also controls the guidance unit (Figure 4.), manipulating it to the correct location for drilling.

Figure 3. Robot Workstation

The guidance unit is a small cylindrical device that is placed on a mount that is secured to the patient (Figure 4). The guidance system receives the information from the workstation and moves to a specified orientation. In this orientation, the surgeon will drill in the exact angle specified in the preoperative plan.

Figure 4. Guidance Unit.

What are the benefits of using this system?

Due to the limited view of the surgical space, spinal surgeons rely on imaging techniques to provide views otherwise not accessible. In a typical spinal case, the surgeon will take several images after inserting each screw to ensure that the screw location and orientation are correct. Under these conditions, the patient is exposed to a lot of radiation during the case. Over the course of years of surgeries, the surgeon and operating room staff will be exposed to significant and possibly detrimental amounts of radiation. The MRGS allows surgeons to preplan screw placement. Once the preplanned placement is complete, the surgeon is able to watch a virtual play through of the placement. Before the surgeon steps into an OR the screw placement and replay has been virtual visualized. This method improves the accuracy of screw placement and builds confidence in the surgeons. In a traditional screw placement procedure, imaging is used prior to each insertion, during the placement process, and after the screw is placed. This system allows for significant reductions in the use of radiation for placement accuracy, which benefits the surgeon, staff, and patient.

The system also allows for a more precise screw placement than possible by the human hand alone. Research supports that this system allows for over 98 % accuracy of screw placement (Kuo et al., 2016)

Why do we need a simulator?

The MRGS consists of several pieces of hardware and a complex preplanning software. Currently to train all components of the system, a trained representative conducts a bioskills lab for new adopters and potential users for training and practice with the device on a cadaver. While this provides a very realistic training environment, it is resource and time consumptive. This limits the amount of time that can be dedicated to practicing with the system, as well as the types of users that get exposure to the training. While attending surgeons are likely to travel for the training, residents and fellows may not have the same opportunity. Regardless of the trainee, surgeons cannot dedicate multiple hours to travel to a training center and practice using a new system. These training sessions can be inconvenient and time consuming for a busy physician, leading to decrease repetition of training. While this lab is beneficial and gives the physicians the advantage of working closely with members of the Mazor team, physicians are not able to train or rehearse independently. Research suggests intervals of inactivity can lead to skill decay (Arthur, Bennett, Stanush, & McNelly, 1998).

Other robotic/computer assisted surgical devices (e.g., the da Vinci robot) have successfully employed and benefited from utilizing simulation for training robotic skills and tasks (Kiely et al., 2015; Hung, Jayaratna, Teruya, Desai, Gill, & Goh, 2013.). Multiple validation studies support da Vinci Surgical simulators (i.e., da Vinci Skills simulator, dV-trainer, and RoSS simulators) (Hung et al., 2011; Kenney, Wszolek, Gould, Libertino, & Moinzadeh, 2009; Seixas-Mikelus, Kesavadas, Srimathveeravalli, Chandrasekhar, Wilding, & Guru, 2010).
While these technologies are used in many other specialties, few spinal surgery simulators exist today. Of the Virtual Reality (VR) spinal simulators on the market, most focus on cranial or endovascular treatments (Alaraj et al., 2011; Mattei et al., 2013). This suggests that a simulation-based solution may be a valuable supplement to the current training and education model.

To alleviate this training gap, we conducted an instructional plan, from which a design document for a simulation system was developed. Any training that could be made available without the requisite use of the actual robot and a cadaver would significantly expand the training opportunities available for all users of the device. Access to this training should also contribute to improved surgeon performance and increased patient safety during procedures.

METHODOLOGY

To create a design for this system, a front-end analysis was conducted. This work involved a literature review, stakeholder knowledge elicitation from device trainers, training observations and several instructional analyses. A Human-Systems Integration (HSI) approach was used to drive the Front-End Analysis (FEA). During this process, a blend of HSI processes and instructional design analyses methods were used. While some of the processes within each method overlap, there are several techniques of each method that we felt were critical during the simulators design phase (Figure 5.).

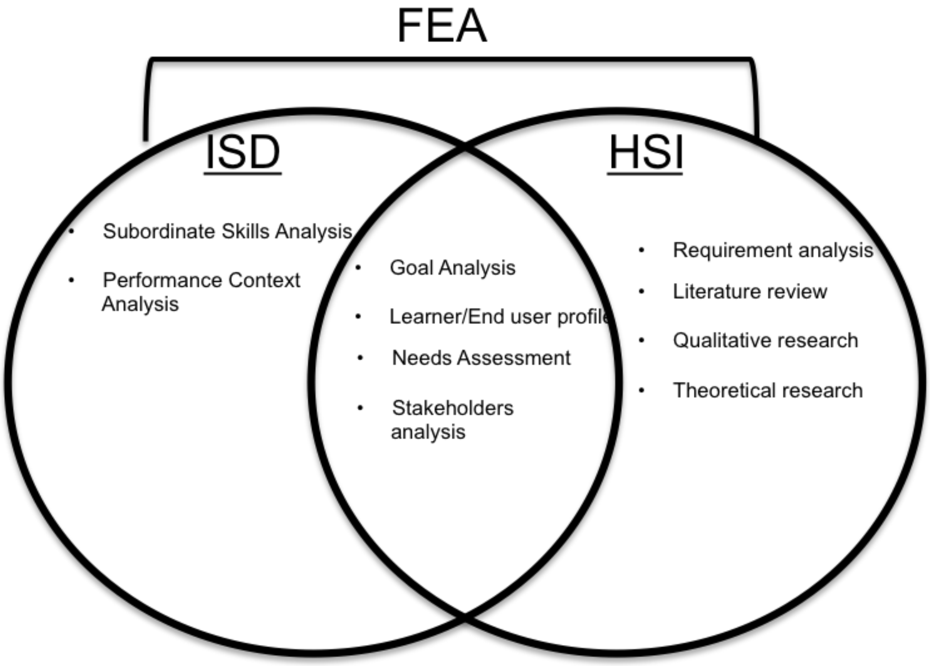


Figure 5. Blended Method used for MGRS Simulator Design.

While this paper describes the efforts to design a simulator of a specific robotic surgery system, this blended process can be used during the early life cycle of any surgical simulation designs and training programs. When designing a complex surgical simulator, one process may not consider all requirements and aspects needed to ensure an all-encompassing, comprehensive system. For this design, several instructional analyses were conducted to outline instructional opportunities while considering human performance concerns and constraints during the research and design phases of the system. From this, an instructional plan was conducted, to which a HSI driven design document for a simulation system was developed. The purpose of this paper is to explain this process and how it pertains to the design of a spinal surgical simulator. The following section outlines each of the analyses and processes that were completed and used to drive the design.

FRONT-END ANALYSIS

Literature Review

A detailed literature review was completed to identify current spinal simulators being used for spinal surgical education and training. Key terms were identified and searched in several leading databases (PubMed, Ovid, and Google Scholar). The results were evaluated based on relativity (i.e., containing information regarding current surgical spinal, neurosurgical, orthopedic, or spinal simulators). Few spinal simulators were found in general and only two virtual reality simulators were found (Luciano et al., 2011; Eftekhar, Ghodsi, Ketabchi, & Rasaee, 2002). The two spinal simulators that offer surgical pedicle screw placement procedures are ImmersiveTouch Inc.'s ImmersiveTouch Spinal Simulator and Swemac's TraumaVision.

ImmersiveTouch is a virtual reality system with haptic feedback and a stereoscopic display. This system consists of 3D glasses with an electromagnetic head tracking system, a half-silvered mirror, and a haptic stylus. The head tracking system provides differing perspective in tandem with head movements while the mirror creates an augmented reality in which the user's hands can interact with patient images using the haptic stylus, which also provides tactile feedback to the user. Users also have the option of using one or many (A/P, transverse, lateral) views of the operation as they complete the simulation (Luciano et al.,2011).

Swemac's TraumaVision consists of a duel-screen computer and software that simulates various procedures for orthopedic surgery, including a spinal surgery-training module for pedicle screw and guide wire insertion. A haptic stylus called Phantom Omni connects to the computer, allowing the user to practice hand movements like those experienced when performing surgery while receiving haptic feedback similar to how it would feel to use the surgical tools on bone. A foot pedal is used to administer fluoroscopy for imaging of the spine. Phantom Omni and the foot pedal are also compatible with personal computers.

While both of the available spinal simulators provide training on common spinal procedures in a virtual space, Mazor's unique preplanning software introduces a new learning curve beyond traditional spinal procedural. The current simulators provide an excellent computerized platform for similar procedures but are significantly flawed by not providing a physical simulation piece to provide the real haptic feedback needed for orthopedic surgery (e.g., resistance of boney anatomy). For this design, several analyses were conducted to identify learning curves of the MRGS, key components of the available computer-assisted surgical simulators we leveraged, and current training gaps were addressed to provide an all-encompassing trainer for the MRGS.

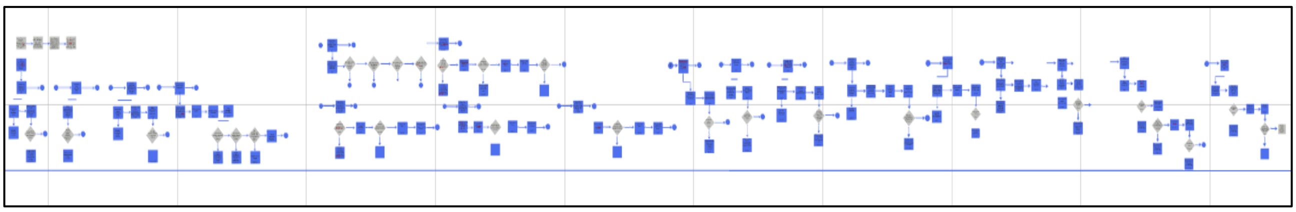
Instructional Design Strategies

Needs Analysis

With limited articles found, the literature review suggests a gap in current spinal surgical simulation training. As the technologies of surgery advance, new needs for training programs, devices, and simulators emerge. Just as the new surgical devices extend the capabilities of prior devices, the new simulators may extend the capabilities of existing simulators. To further investigate the need for simulation training for spinal surgery and specifically the Mazor system, the research team met with Mazor device trainers and representatives. Through several unstructured interviews the team outlined the current standard of training for this system, labeled the target population, and defined the current training gaps (e.g., lack of repetition, access to training, training cost).

Goal Analysis

Due to the complexity and multiple components of the Mazor System (e.g., preplanning software, intraoperative procedure, robot placement), an in-depth goal analysis was completed to gather a better understanding of all steps within each component needed to complete a full procedure. While the overarching goal is clear (Goal: After training with the simulator, surgeons will be able to use the Mazor software and guidance system for the pre-operative planning and intra-operative placement of pedicle screws), the sequence of operations and decision to achieve this goal is rather complex (Figure 6., to show the scale of the goal analysis). From this analysis several learning objectives were defined to accomplish this overarching goal. The design of the simulator focused on reaching each of these objectives entirely in order to ultimately reach the end goal. To ensure the simulator trains the correct skills for each learning objective, a subordinate skills analysis was conducted.



Figue 6. Snapshot of Complete Goal Analysis.

Subordinate skills analysis

The skills needed to use the actual Mazor system require both psychomotor and cognitive skills. In order to discover all the skills needed to reach the learning goal, a subordinate skills analysis was completed. For a complex task, such as surgery, several skills must be acquired before using this system. This analysis was used to define entry-level skills needed before utilizing the simulation system and to define skills needed to reach each learning objective. For example, the learners must be familiar with surgical procedures, instrumentation, and equipment relating to spinal surgery but the simulator should train the procedural knowledge and skills needed to use the actual Mazor technology.

While these instructional design strategies helped guide the design stage of the system to satisfy needs, goals, and objectives we integrated theories from HSI to develop functional and non-functional requirements and analyze stakeholders and end-user's to meet an optimal design.

Human-Systems Integration Processes

To develop requirements for the system, the research team used several processes. Data from the goal analysis and literature review, along with qualitative data from stakeholders and SMEs (i.e., Mazor trainers and developers, spinal surgeons) were used to develop functional and non-functional requirements. These requirements were set in place to ensure that the design of the system reached the overarching goal (i.e., train surgeons on all components of the Mazor Guidance System), identified obtainable functions needed to train the learner appropriate skills (i.e., system is capable of providing a virtual training exercise to familiarize and train all aspects of Mazor Guidance System), and defined ideal functions to increase learner satisfaction (i.e., anatomical tissue replicated in the simulated exercises will be provided in high fidelity).

In addition to eliciting information and expectations, the stakeholder analysis identify who the stakeholders for this potential system are, across the entire life cycle, and how the system will be used by them. Basically, this gave us a snapshot on who is most likely to use the Mazor simulator. This "profile" provided us with information on who the users will most likely be and what the users will most likely know and prefer. We found that most users will be neurosurgeons or orthopedic surgeons, between 30-60 years of age, male dominant, with medical degrees and mixed model learning preferences. This drove the design to incorporate a portable aspect, an easy-to-use User Interface (UI), exclude medical terminology training, and to design the system to have both a physical and virtual mode of training (or integrate both).

A context of use analysis was then conducted to collect information regarding where the developed training system will be used, to define possible safety issues, technical constraints, and to provide information on the end-users' organizational and social environment. From the information gathered from the SMEs and end-user profile, we designed the system to be portable to accommodate for the lack of dedicated training time the end-users are allotted. The system was also designed to accommodate users who are less technically inclined, that is, to run on desktop (or laptop) computer, something that majority end-users are familiar with and will not require much system maintenance. It is likely that the users will utilize the training system in either a dedicated simulation lab or at home. Therefore, the ability for the system to run without a proctor (e.g., system would include a virtual mentor and a digital scoreboard) was an important aspect to consider when designing the simulator.

The developed requirements, end-user profile, and the information provided by the context of use analysis were revisited several times throughout the design process. SMEs were asked to iteratively review the requirements and design considerations to ensure the design considerations continued to meet the end-users need.

RESULTS

After conducting several ISD analyses, evaluating existing simulators, and clearly defining the end-users, we identified a preferred approach to creating a simulator for the MRGS. While there are several "must have" components for a successful simulation, we considered all of the data collected from each analysis across all processes. Therefore, each system component was selected based on the data and information collected throughout our front-end analysis. The following section briefly highlights key elements needed to train the perceptual and cognitive components defined by the analyses.

Hardware

The end-user profile provided an overview of the audience that will likely use the system. We know from this analysis that the end-users will be practicing physicians that have limited time for training. In considering the time restraint, we suggest that the system be computer-based and portable. However, the goal analysis suggests both procedural and *psychomotor* tasks are required to safely employ the actual system. To practice these psychomotor skills (e.g., attaching the guidance robot to patient), a physical replica should be integrated with the computer-based trainer (CBT).

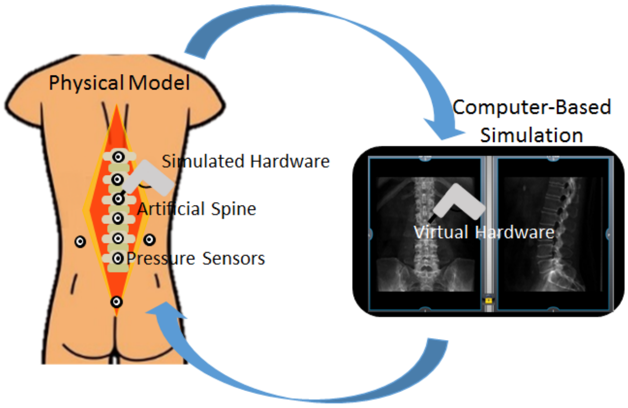


Figure 7. Initial Sketch of Simulation Model

The end-user profile also suggests that the learners prefer a mixed mode of instruction and training. Mixing computer-based procedural knowledge with actual hardware that interacts with the physical model provides the users with both didactic-like and physical simulation training. With the physical model, all other tools and hardware needed to operate the actual Mazor system (e.g., drill, platforms, cannulas, etc) should be developed both physically and virtually and communicate with both the physical (i.e., physical torso model) and virtual aspects (i.e., computer-based trainer) of the trainer. For example, the drill will be an external haptic device (Figure 7) that is calibrated with the virtual instruments within the simulation. Several pressure sensors should be integrated within the model to provide input from physical instrumentation interacting with the physical model to the virtual CBT. Learners should be able to interact with the computer-based application with or without the physical model. This feature allows the simulator to be easily accessible, affordable, and engaging for the target audience (Figure 7). Designing the simulation to be both portable and include a psychomotor piece meets the end-users request and has the ability to train the psychomotor skills defined within the overarching goal. To our knowledge no other spinal simulator is portable, nor offers a physical feature. Both ImmersiveTouch and Swemac TraumaVision are large pieces of custom technology, while they both use devices to provide haptic feedback; neither system provides a physical replica to practice psychomotor tasks.

Software

From the analyses we found several areas in which the software can address users needs, preferences, and drive design suggestions. Information from the user analysis suggests a large portion of the user population are non-digital natives (i.e., those born before the advent of digital technology) that most learners will likely be hesitant towards new technology, so this design suggests using a training interface that is transferable. A major component of the Mazor Guidance system is the preoperative planning software. The training system can leverage or mock this software component to ensure effective transfer of training. This will allow learners to master elements needed to successfully complete preoperative plans.

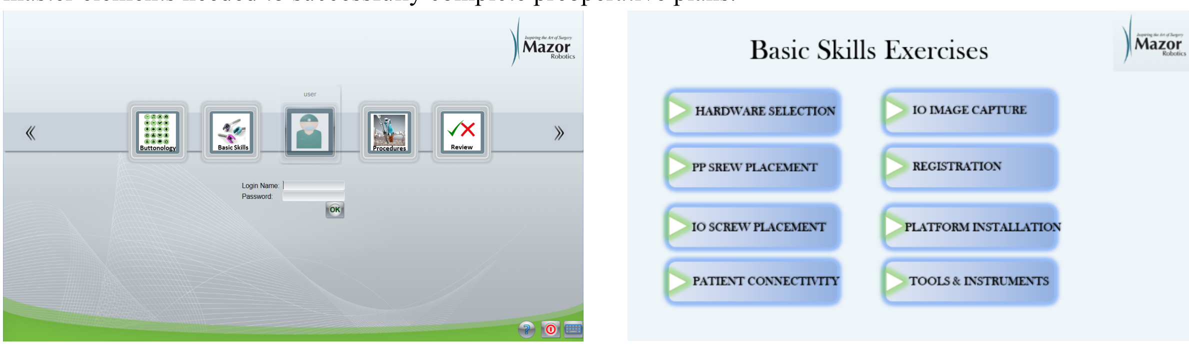


Figure 8. Example of UI

To ensure users will find the user interface (UI) easy to use, we suggest that the simulator provide a mandatory entry level training course or "buttonlogy" exercise (Figure 8). Here, the learners will be introduced (via a virtual mentor) to the different icons and buttons displayed throughout the system. The purpose of this exercise is to familiarize learners with the pre-planning software and the simulation system. As suggested by the context of use analysis, users will vary in experience level (i.e., novice or expert surgeons), therefor this software must be modified to support all portions of Mazor training needed for completing various spinal procedures from start to finish. To satisfy all training aspects of the actual system the software should contain multiple exercise categories like Basic Skills and Procedure Specific (or cases). A troubleshooting category should also be introduced to train troubleshooting methods for non-standard technological issues and malfunctions that may arise during procedures. Simulated exercises should be contained within an exercise engine. The engine should arrange the exercises by levels of difficulty (i.e., simple procedures to most difficult) to provide an easy interface for learners to peruse. It should also provided secondary stakeholders (e.g., proctors, simulation lab managers) with a "quick and easy" view of exercises needed to build specific curricula or training courses (Figure 8).

Another design consideration suggested from the analyses was to provide a virtual guide and automatic feedback. As the context of use and performance analysis suggested, learners will often use the system at home or on their free time. This suggests that no proctor will be available to guide and assist the learners throughout the simulation exercise. Guidance should be offered throughout the simulation, and at the end of each exercise an automatic scoreboard should be produced for learners to reflect on their performance. Incorporating these components should allow the system to be easily accessible and provide the users with data, ultimately eliminating the need for a proctor.

Graphics

An appropriate simulator for spinal surgery should assimilate suitable visual characteristics. The end-user profile suggests that learners feel most comfortable with actual anatomy (e.g., cadaveric tissue), so we suggest that the simulator provide both, realistic graphics and actual images of appropriate human anatomy. To meet this criterion and provide users with a variety of spinal pathologies to ensure a spectrum of training scenarios, the simulation should incorporate a variety of actual computerized tomography (CT) scans in a 3D view (Figure 9). These scans should be true representations of scans that the learners will encounter in the future. Graphics depicting human anatomy will be animated to appropriately demonstrate anatomical structures and tissue reaction. To do so, the graphics must be designed based on actual spinal surgical images. While, the ImmersiveTouch simulator does incorporates actual CT scan, the actual Mazor software goes one step further. This software uses patient CT scans to create a 3D image of the spinal pathology, the leveraged software should also incorporate this component into the simulator.

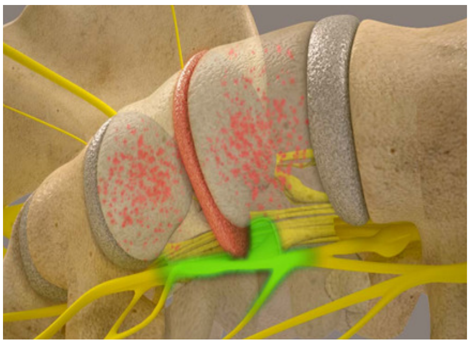




Figure 9. Examples of graphics

Tactile feedback

The Mazor system provides guidance to the surgeon but the surgeon must still perform the actual psychomotor processes required for each spinal procedure. To train the psychomotor skills defined by the goal analysis, the system was designed to incorporate a haptic device as the instruments encounter human tissue and boney anatomy. In order to implement haptic feedback into a simulated environment, an external haptic device must be incorporated to provide accurate tactile sensations. Both of the current surgical spinal simulators utilize an off-the-shelf device, the Omni Phantom to provide the user with tactile feedback (Figure 10.)

Figure 10. Omni Phantom Device.

For haptic interaction to properly take place, a simulator must determine when two objects have touched one another in a virtual space (i.e., collision detection) and understand where the contact point has occurred. When items collide, the surface and deformation of the virtual space is visually and hapticly rendered to the user in real time (Alaraj et al., 2011). Like the other current surgical spinal simulators, a mobile, "off-the-shelf" device should be incorporated to mimic the drill used in spinal surgeries. The device will provide the user with a falsified drilling sensation and incorporate real time collision detection in order to sustain sensory feedback. For this simulator, the haptic device will only be used when learners use both the computer-based simulation and the physical model paired together. This feature allows surgeons to completed exercises either completely computer based, with point-and-click mouse method, anywhere and at anytime, or with the attached physical torso and off-the shelf haptic device for a more realistic feel. This feature was included to address the users need for a realistic physical device as well as the reality of time constraints and accessibility.

Assessment

The user and context analysis provided information on current standards of training and preferred evaluation methods. Surgical education has now shifted away from the traditional apprenticeship model (i.e., "See one, do one, teach one") towards an experiential based framework. This suggests that many surgical educational organizations will support the use of a training system that provides the surgeon with unlimited practice and with automatic assessment. Until recently the "gold standard" of training was to receive feedback and assessment through an expert surgeon. While we know that human assessment is imperative, it also can be difficult due to surgeon availability and demanding schedules.

To provide a valuable assessment within the training system, scoring benchmarks and thresholds should be established. These benchmarks should be set based on expert users (e.g., Mazor trainers or surgeons that frequently use the guidance system). The benchmarks will indicate acceptable and unsatisfactory scoring for each major learning objective and desired skills outlines by the goal and subordinate skills analyses. Following an ISD assessment strategy, each decision within the simulation would correspond with one of the learning objectives and be assigned a tool to assess said skills (e.g., virtual system, physical system, or both). Table 1 provides an example of the assessment strategy for this particular simulator design.

Table 1. Example portion of Assessment Strategy.

Skill	Objective	Domain	Item/Criteria	Media & Tool Selection
Properly upload/open patient's imaging	Demonstrate the procedure needed to import unique CT scans or open CT scan from exercise/patient data base.	Knowledge	Choose the option to upload patient specific CTs from their own collection or chooses a certain CT pertaining to pathology they wish to manipulate. Use planning tab and upload icon from the system. CT must follow Mazor's protocol (i.e., low-dose, 1mm contiguous axial slices). Choose to open pre-existing cases from the planning tab in the system.	Virtual
Select the Region of Interest (ROI)	Determine and select the correct vertebral bodies for given pathology.	Knowledge	Use the steps below to select ROI: 1. Draw a line on the correct vertebral bodies. 2. Include a body above and below ROI. 3. Mark path of vertebral foramen (in both AP and lateral view)	Virtual
Appropriately perform ROI segmentation.	Determine the vertebral units of the ROI.	Knowledge	Separate the vertebral column into vertebral units. Segmentation should not cut through end plates.	Virtual
Correctly label vertebrae	Accurately label vertebrae	Knowledge	Select and label one vertebra in the ROI to populate the remaining	Virtual

DISCUSSION

Several analyses were completed for the potential to create a simulator device for a computer assisted spinal surgical guidance system, the Mazor Renaissance. For this design, two popular design methods (ISD and HSI) were combined to complete an extensive front-end analysis. These processes helped to answer and define what the system is for, who are the end-users, and where the system will be used in order to create absolute and alternative requirements of the system. Basically, this blended process helped to fully understand the learning objectives and skills. These analyses also helped to keep the design focused and provide what the end-users need to obtain the learning objectives with minimal "bells and whistles." The data collected from the several analyses guided our design to answer the demands of the end-users (i.e, easy to use, portable, self-guided, etc). Uncovering such detailed information at the beginning of the systems life cycle can help mitigate issues that are often seen in surgical simulators (e.g., semi-realistic anatomical imagery, portability, haptic feedback, etc).

While both systematic methods create an "action plan" that covers the breadth of a systems early life cycle, utilizing analyses and processes from both focused the depth of this potential system. For future surgical simulators, developers should utilize instructional strategies to fully uncover the goals and objective, while utilizing HSI approaches to iteratively consider the end-users and stakeholders throughout the entire design to guide requirements and design considerations. While this paper described the efforts to design a simulator of a specific robotic surgery system, this blended process can be used during the early life cycle of any surgical simulation designs and training programs to ensure an all-encompassing, comprehensive system.

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