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ORIGINAL ARTICLE

Design methodology for a simulator of a robotic surgical system

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Abstract
Traditional spinal surgery procedures are completed with limited direct visualization. This imposes limitations on the surgeon's ability to place screws into the spine. The Mazor Renaissance robotic system was developed to improve the accuracy of pedicle screw insertion. Current training for this device comes with significant constraints. This suggests that a simulation-based solution may be valuable to the current training. This paper describes efforts to apply the theories of human–system integration (HSI) and instructional system design to define the requirements for a design of a simulator for specific robotic surgery system. From this, an instructional plan was conducted, to which an HSI-driven design document for a simulation system was developed. This paper describes the efforts to create a design method for a simulator of a specific robotic surgery system and provides a blended design process, which can be used during the early life cycle of any surgical simulation design.

Keywords Robotic surgery simulator · Simulator design · Spine robot · Human system integration · Instructional design

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. With the introduction and broad adoption of laparoscopic surgery tools, MIS has expanded to include computer/robotic-assisted minimally invasive surgery [1].

Some specialties quickly adopted the use of computer-assisted minimally invasive surgery (e.g., gynecology and urology), while other specialties have recently shown interest. Among these emerging specialties are orthopedics and neurosurgery, in which difficult procedures focused on or around the spine are faced [2]. Many studies have examined the accuracy of traditional pedicle screw insertions and fusion [3–7], a common spinal procedure, and found that the rate of misplaced screws during these procedures was unacceptably high [6]. These rates have spurred the increased use of robotically assisted pedicle screw insertion [5, 6], and the increase of guidance systems in general [e.g., Mazor Renaissance Guidance System (Mazor Robotics Inc., Orlando, FL) for spine procedures and Mako Rio (Stryker Inc., Kalamazoo, MI) for hip and knee procedures].

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Mazor Renaissance Guidance System features and functions

The Mazor Renaissance Guidance System (MRGS) is used to optimize the pre-planning and accuracy of MIS and open spinal surgeries (Fig. 1). MRGS can be used for degenerative repair, pedicle screw fixation, and vertebral augmentation procedures. The system is comprised of three components:

- 3D pre-planning software;
- robot workstation;
- guidance unit.

The pre-planning software is used to create a pre-operative "blueprint" tailored to each patient (Fig. 2). The patient's pre-operative CT scans are uploaded into the software, which is installed on the surgeon's personal computer. The surgeon identifies and defines the clearest vertebral body from the pre-operative CT, labels the body, and then, the software constructs a 3D model of the patient-specific anatomy. The software allows the surgeon to visualize the placement of the screws from various planes and watch each screw which enters the spinal body in slices. This

Fig. 1 Mazor Renaissance Guidance System staged in an operating room

visualization allows the surgeon to see the exact angle and depth of each screw.

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 pre-operative plan completed before the surgeon steps into the OR. The pre-operative blueprint to the intra-operative anatomy is synced to register each vertebra and provide maximum accuracy for procedure (Fig. 3). The workstation software also controls the guidance unit (Fig. 4), manipulating it to the correct location for drilling.

The guidance unit is a cylindrical device that is placed on a mount that is secured to the patient (Fig. 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 pre-operative plan.

Current training for MRGS

The MRGS consists of several pieces of hardware and a complex pre-planning software. Currently, to train all components of the system, a trained representative conducts a bioskills' lab for new adopters and potential users, in which they train and practice with the device on a cadaver. While this provides a very realistic training environment, it is resource and time-consuming. 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.

Other robotic/computer-assisted surgical devices (e.g., the da Vinci robot, Intuitive Surgical Inc., Sunnyvale, CA) have successfully employed and benefited from utilizing simulation for training robotic skills and tasks [8–13]. While these technologies are used in many other specialties, a few spinal surgery simulators exist today.

To alleviate this training gap, we developed and executed an instructional plan (i.e., Dick and Carey Systems Approach Model to Designing Instruction, Dick et al. [15]), from which a design document for a simulation system was developed.

Methods

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. An HSI approach was used to drive the front-end analysis. During this process, a blend of HSI processes [14] and instructional design analyses [15] were used. These approaches were selected, because some of the processes within each method overlap; however, there are several techniques for each method that we felt and were critical for the design phase (Fig. 5).

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 design. Several instructional design analyses were conducted to outline instructional requirements while considering human performance concerns and constraints during the research and design phases of the system. From this, an instructional plan was executed, from which an HSI-driven design documents for a simulation system which was developed. This article does

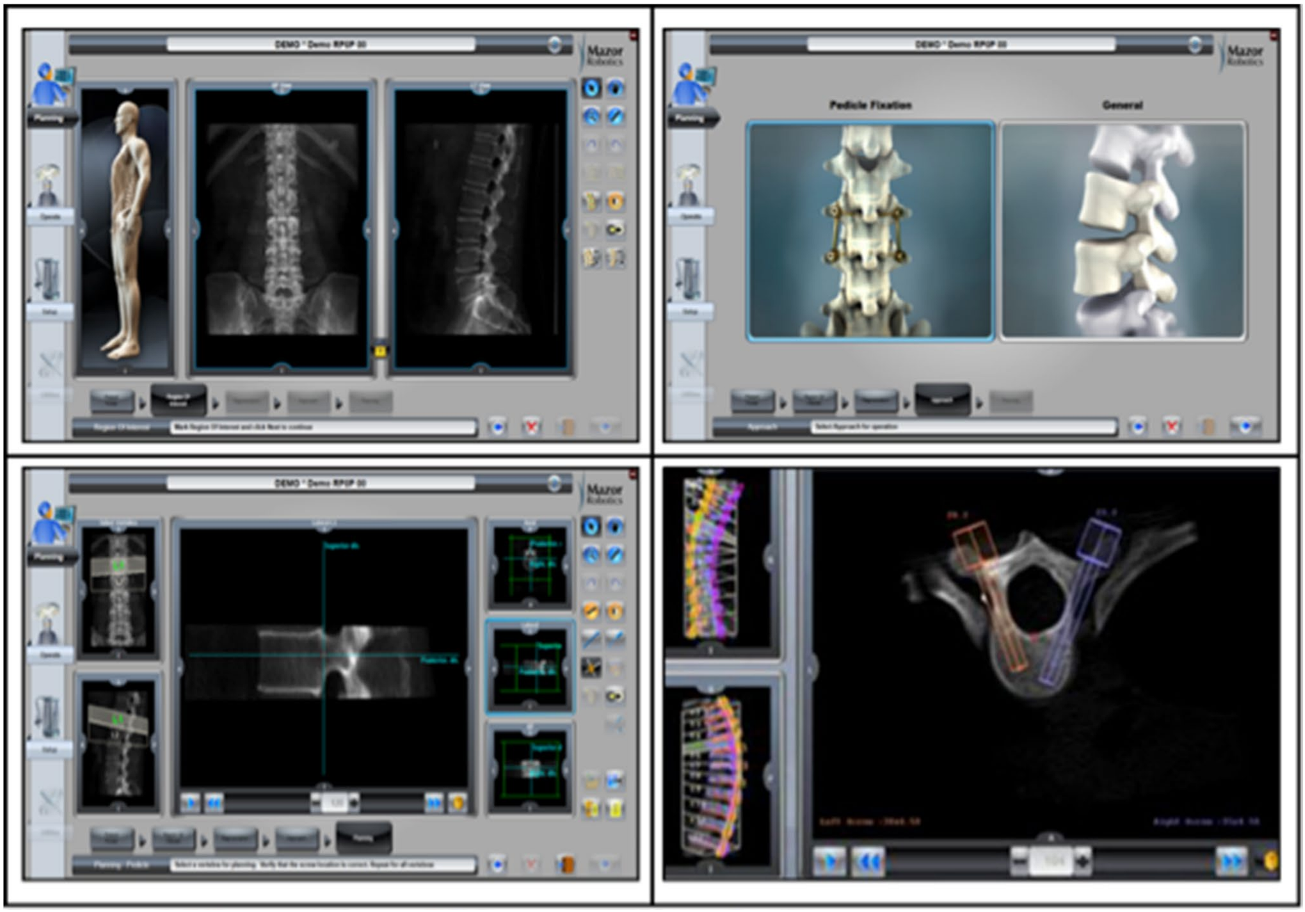

Fig. 2 3D pre-planning software

Fig. 3 Robot workstation

not contain any studies with human participants or animals performed by any of the authors. Therefore, for this type of study, formal consent is not required.

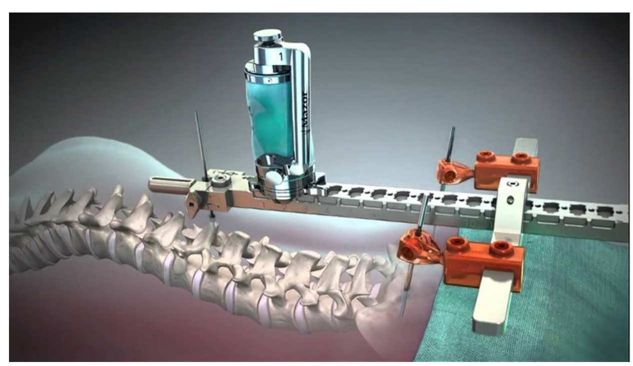

Fig. 4 Mount fixated to patient with secured guidance unit attached

Front-end analysis

Literature review

A literature review was completed to identify current spinal simulators. Key terms were identified and searched in PubMed, Ovid, and Google Scholar. The results were

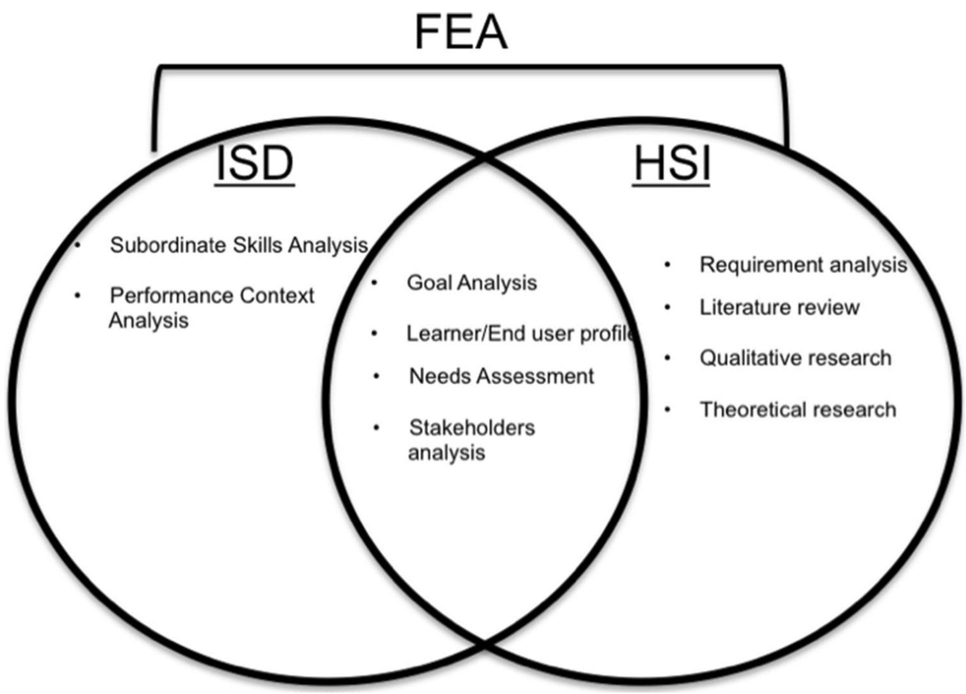

Fig. 5 Blended method used for MGRS simulator design

evaluated based on relevance (i.e., surgical spinal, neurosurgical, or orthopedic simulators). A few spinal simulators were found of any type and only two virtual reality simulators were found [16, 17]. The two spinal simulators that offer surgical pedicle screw placement procedures are ImmersiveTouch Spinal Simulator (ImmersiveTouch Inc., Chicago, IL) and TraumaVision (Swemac, Linköping, Sweden).

While both the available spinal simulators provide training on common spinal procedures in a virtual space, Mazor's pre-planning software introduces a new learning curve (e.g., virtual screw placement and appropriate image registration within software) beyond the traditional spinal procedural. The current simulators provide a computerized platform for similar procedures, but the haptic interfaces do not provide sufficient feedback fidelity for orthopedic surgery (e.g., resistance of boney anatomy). For this design, several analyses were conducted to identify learning curves of the MRGS and key components of the available computer-assisted surgical simulators that we leveraged, and the current training gaps were addressed to provide trainer for the MRGS.

Instructional design strategies

Needs' analysis

With limited articles found, the literature review suggests a gap in the current spinal surgical simulation training. As the technologies of surgery advance, new needs for training programs, devices, and simulators emerge. To further investigate the need for simulation training for spinal surgery and specifically the Mazor system, the research team attended Mazor training sessions with Mazor device trainers and representatives to outline the current training for this system, label the target population, and define the current training gaps (e.g., lack of repetition, access to training, and training cost).

Goal analysis

A 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. From this analysis, several learning objectives were defined to accomplish this overarching goal. The design of the simulator focused on reaching each of the objectives entirely to ultimately reach the end goal.

Subordinate skill analysis

To discover all the skills needed to reach the learning goal, a subordinate skills analysis was completed. 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 Mazor technology. These instructional design strategies helped to guide the design stage of the system to satisfy needs, goals, and objectives, and we integrated from HSI to develop functional and non-functional requirements and analyze stakeholders and end-user's to meet an optimal design.

Human–system integration processes

HSI processes were used to provide a multifaceted method focused on the entirety of the design, instead of focusing on the individual components while integrating critical human aspects [18]. Data from the goal analysis, literature review, stakeholders, and subject matter experts (SMEs) (i.e., Mazor trainers and developers, and spinal surgeons) were used to develop requirements. These requirements were set in place to ensure that the design of the system reached the overarching goal defined by the goal analysis, identified obtainable functions which needed to train the appropriate skills (i.e., system is capable of providing a virtual training exercise to familiarize and train all aspects of MRGS), 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 identifies who the stakeholders of this potential system would be, across the entire life cycle, and how they will use the system. Basically, this gave us a snapshot on who is most likely to use the Mazor simulator. We found that most users will be neurosurgeons or orthopedic surgeons, between 30 and 60 years of age, male dominant, with medical degrees and mixed model learning preferences. This drove the design to incorporate a portable aspect and an easy-to-use user interface (UI), to exclude medical terminology training and to have both physical and virtual modes of training.

Results

After conducting several instructional system design (ISD) analyses, evaluating the existing simulators, and defining the end-users, we identified an approach to creating a simulator for the MRGS. 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

We know from the end-user 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 (or tablet-style) and portable, so the learner can practice on their own time (i.e., not during working hours). However, the goal analysis suggests that 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).

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 Mazor system (e.g., drill, platforms, cannulas, etc) should be developed both physically and virtually and to communicate with both the physical torso model and virtual aspects presented through the CBT. For example, the drill will be an external haptic device (Fig. 6) 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 (e.g., drill) with the physical model (e.g., vertebrae on physical spine model) to the virtual CBT. Learners should be able to interact with the computer-based application with or without the physical model. The computer application can run on both a desktop PC and a laptop. Later, the application could be integrated onto a tablet to allow for a more compact training device. Designing the simulation to be both portable by including a psychomotor piece meets the end-users' request and has the ability to train the psychomotor skills defined within the overarching goal. While ImmersiveTouch and Swemac TraumaVision are large pieces of custom technology that use haptic devices, neither system provides a physical replica to practice psychomotor tasks.

Software

Information from the user analysis suggests that 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 MRGS system is the pre-operative planning software. The training system can leverage this software component to ensure effective transfer of training.

To ensure that users will find the UI easy to use, we suggest that the simulator provides a mandatory entry-level

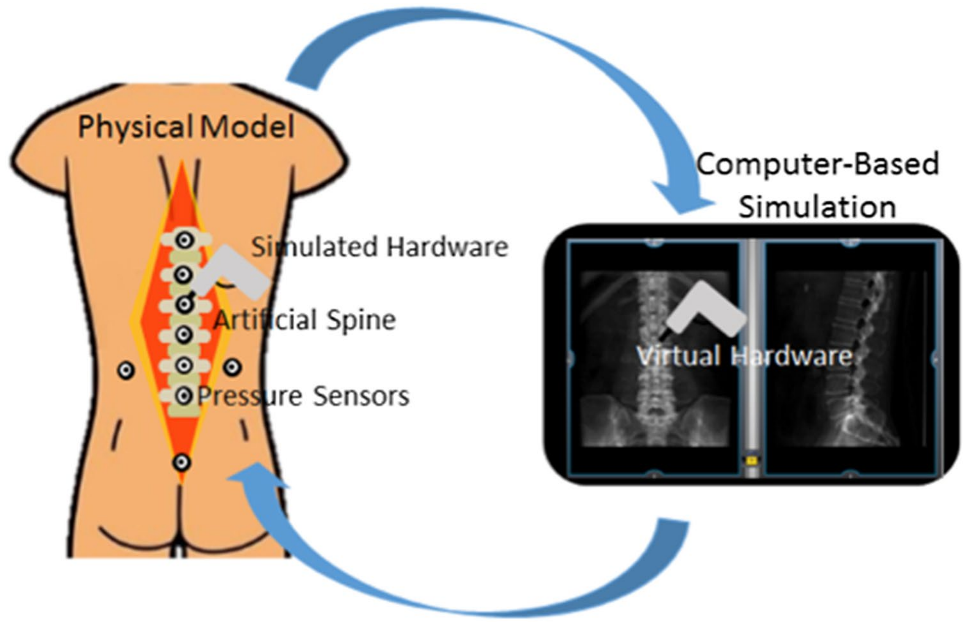

Fig. 6 Sketch of simulation model

training course or "buttonlogy" exercise. Here, the learners will be introduced to the different icons and buttons displayed throughout the system. As suggested by the context of use analysis, users will vary in experience level (i.e., novice or expert surgeons); therefore, this software must be modified to support all the portions of Mazor training needed for completing various spinal procedures. The software should contain multiple exercise categories like basic skills and procedure specific. A troubleshooting category should 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 increasing level of difficulty to provide an easy interface for learners to peruse. It should also provided secondary stakeholders (e.g., proctors) with a quick and easy view of exercises needed to build curricula.

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. 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. The scoreboard should provide learners with metrics specific to spinal surgery with the Mazor (e.g., screw placement and procedural knowledge on Mazor platform placement).

Graphics

An appropriate simulator for spinal surgery should provide 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. 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. Graphics must be designed based on actual spinal surgical images. While the ImmersiveTouch simulator does incorporate actual CT scans, the actual Mazor software goes one step further. This software uses patient CT scans to create a 3D image of the spinal pathology, the simulator software should also incorporate this component.

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 haptic devices as the instruments encounter tissue and boney anatomy. Two haptic devices will allow the surgeon to utilize multiple instruments during a simulated procedure. Both current surgical spinal simulators utilize an off-the-shelf device, the 3D System's Touch haptic device to provide the user with tactile feedback.

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 simulated drilling sensation and incorporate real-time collision detection 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 complete exercises either completely computer-based, with point-and-click mouse method or with the attached physical torso and the haptic devices.

Assessment

The user and context analysis provided information on the 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.

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).

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 were combined to complete an extensive front-end analysis. These processes helped to answer and define what the system is for, who the end-users are, and where the system will be used to create absolute and alternative requirements of the system. This blended process helped to fully understand the learning objectives and skills. These analyses helped to keep the design focused and provide what the end-users need to obtain the learning objectives with minimal "bells and whistles."

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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Compliance with ethical standards

Conflict of interest Danielle Julian declares she has no conflict of interest. Roger Smith declares he has no conflict of interest. Alyssa Tanaka declares she has no conflict of interest. Ariel Dubin declares she has no conflicts of interest.

Ethical approval This article does not contain any studies with human participants or animals performed by any of the authors.

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