ABSTRACT
We introduce a taxonomy for mixed simulation focusing on mixed simulators with physical exteriors augmented with virtual underlays for practicing medical procedures such as central venous access (CVA). We used CT and MRI imaging and 3D printing to develop anatomically authentic mixed simulators, i.e., exact physical and/or virtual replicas of their human models. Embedded 6 DOF magnetic sensors monitor tracked instruments during simulated procedures, facilitating after action review or self-debriefing. We implemented automated scoring algorithms that include tracking and grading of near misses. After 28 anesthesia residents trained with the CVA simulator, incidence of pneumothorax and arterial puncture in the simulated environment dropped from 11% to 7% and 13% to 7%, respectively.

Keywords: Mixed simulation, taxonomy, virtual underlays, medical procedural simulators

1 INTRODUCTION
During a “blind” (unguided) procedure, clinicians do not use medical imaging guidance, relying instead on anatomical landmarks such as the sternal notch, heuristics, knowledge of anatomy and past experience to guide an instrument (such as a needle) to its target. Complications such as hemorrhage and pneumothorax (lung collapse) from unintended puncture of arteries or lungs respectively can be as high as 19% during central venous catheterization [1]. Novices have not yet acquired experience and thus, particularly in teaching hospitals, complications from “blind” and guided procedures are of special concern. Because the training needs of our teaching hospital (specifically, training in iatrogenic pneumothorax prevention) were unmet by existing simulators, we developed a novel CVA simulator and subsequently used a similar design methodology to implement simulators for four other medical procedures.

2 TAXONOMY / PREVIOUS WORK
Simulation is a means to an end. In this paper, we focus on skills acquisition as the end goal of simulation. Skills can be classified into three main types (affective, cognitive and psychomotor) that form the skills triangle (Figure 1). Affective skills are about interacting with other humans such as interpersonal skills, leadership and teamwork. Cognitive skills involve thinking and the application of knowledge, e.g., situation awareness, decision making, strategy, risk assessment and risk mitigation. Psychomotor skills center on doing like manual dexterity, hand-eye coordination and spatial ability. The simulation technologies used for training and to acquire all three types of skills in healthcare fall into 3 main classes (biologic, virtual and physical) that constitute the simulation triangle.

Figure 1: The skills triangle; the simulation triangle (in healthcare).

Adapting Milgram & Kishino’s taxonomy [2] to simulation, we expand the base of the simulation triangle to define different types of mixed simulators (Figure 2). A mixed simulator includes both virtual and physical components. When a mixed simulator is primarily virtual, it is called an augmented virtual simulator; conversely, an augmented physical simulator is mainly physical. In this paper, we focus on augmented physical simulators, specifically those with virtual underlays, instead of overlays.

Figure 2: Taxonomy for the physical-virtual simulation spectrum

A physical simulator is devoid of virtual elements such as a mannequin patient simulator [3] suitable for learning psychomotor skills such as CPR (cardiopulmonary resuscitation). A virtual simulator such as a computer based trainer (CBT) has no physical, tangible elements. Interactions are mediated via pointing devices such as a mouse or joystick like in the web-enabled Virtual Anesthesia Machine (VAM) simulation [4]. Virtual simulators are well suited to convey cognitive skills and knowledge; e.g., they provide the ability to virtually peel off layers of a human body or a piece of equipment to provide insight into hidden internal anatomy, mechanisms and processes [4].
An example of an augmented virtual simulator is an augmented anesthesia machine [5], where an actual anesthesia machine acts as a physical tangible user interface to the virtual VAM simulation. When a tracked tablet implementing a see-through “magic lens” is pointed at a specific location on the physical anesthesia machine, corresponding abstract 2D graphics of the virtual simulation are overlaid upon that location, when viewed via the magic lens. Superposition of 3D virtual elements (mother’s hip bone, baby’s head) onto physical components (a pelvic mannequin) has also been performed using opaque, video see through head mounted displays in a birthing simulator [6].

Some mixed simulators that include haptics [7] have fixed entry points for tools [8,9]. For medical procedures such as CVA and ventriculostomy where correctly determining the entry point is a crucial learning objective and a strong predictor of success, the simulator must allow ingress into the body at any entry point within an appropriate region instead of providing only fixed entry points. For laparoscopic simulators, trainee intervention is not by direct manipulation but mediated via instrumented laparoscopic tools [10]. With fixed entry points, the range of motion may also be constrained by the properties of the fixed entry point.

2.1 Central Venous Access Mixed Simulator

During central venous access (CVA), a needle connected to a syringe is typically inserted into the internal jugular (IJ) or axillary (subclavian) vein. While ultrasound (US) guidance is recommended for IJ central venous access, subclavian vein access is almost universally performed without US guidance, as a “blind” procedure. Clinicians rely on anatomical landmarks such as the sternal notch and the clavicle and heuristics to establish the entry point and trajectory to target the subclavian vein and a 3D mental model of the anatomy to safely steer the needle tip into the subclavian vein. The interaction between the user and the tool is not mediated but direct; using their hands and tactile feedback, trainees directly hold and steer the syringe/needle combination. It is difficult to get sufficient experience during training to achieve subclavian vein catheterization expertise, especially in civilian medicine.

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2.1.1 Methods

We physically modeled the torso, neck and head of an actual human including anatomical landmarks such as the palpable sternal notch and the clavicle and selected ribs, as well as the feel of the skin and underlying tissue to user touch and resistance to puncture at specific regions where the needle is usually inserted. The remainder of the simulator (primarily the relevant soft tissues (veins, arteries and lungs) was virtually modeled and registered to the physical component (the torso) with sub-millimeter accuracy. The 3D models for the torso and neck and the vein, artery and lung came from CT and MRI scans. The individual components (veins, arteries, lungs) from the MRI scan were manually reconstructed into separate 3D virtual objects with veins color coded blue, arteries red and lungs pink; Figure 3, right picture. We converted the CT scan of the torso, neck and head to a 3D model that was then used to create a full scale, anatomically correct, physical model via a 3D printer (zPrinter 310, Z Corporation, Rock Hill, SC); see Figure 3, left picture.

Table 1. The scoring algorithm for the CVA simulator

<table>
<thead>
<tr>
<th>Minimum score is best.</th>
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<tbody>
<tr>
<td>Orange = component of safety score</td>
</tr>
<tr>
<td>Blue = component of efficiency score</td>
</tr>
<tr>
<td>combined score = safety + efficiency</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>Item</th>
<th>Penalty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time to Venous Access</td>
<td>(sec)</td>
</tr>
<tr>
<td>Time starts when moderator presses &quot;Begin&quot;</td>
<td></td>
</tr>
<tr>
<td>Vein was not Accessed</td>
<td>300</td>
</tr>
<tr>
<td>Add Penalty if the vein was never accessed.</td>
<td></td>
</tr>
<tr>
<td>Venous Access Pneumo Safety</td>
<td>50</td>
</tr>
<tr>
<td>Add scaled Penalty if needle is within 4 cm* of lung</td>
<td></td>
</tr>
<tr>
<td>Vein Backwall</td>
<td>30</td>
</tr>
<tr>
<td>Add Penalty if vein is ever backwalled.</td>
<td></td>
</tr>
<tr>
<td>Pneumothorax Occurs</td>
<td>100</td>
</tr>
<tr>
<td>Add Penalty for causing a pneumothorax.</td>
<td></td>
</tr>
<tr>
<td>Pneumo Safety Penalty</td>
<td>100</td>
</tr>
<tr>
<td>Add scaled Penalty if needle ever came within 1 cm* of lung</td>
<td></td>
</tr>
<tr>
<td>Artery Puncture Occurs</td>
<td>100</td>
</tr>
<tr>
<td>Add Penalty for causing an arterial puncture.</td>
<td></td>
</tr>
<tr>
<td>Arterial Safety Penalty</td>
<td>100</td>
</tr>
<tr>
<td>Add scaled Penalty if needle ever came within 2 cm* of artery</td>
<td></td>
</tr>
<tr>
<td>Skin Pokes</td>
<td>33</td>
</tr>
<tr>
<td>Add a separate Penalty for each additional skin poke.</td>
<td></td>
</tr>
<tr>
<td>Skin Poke Pneumo Safety**</td>
<td>50</td>
</tr>
<tr>
<td>Add scaled Penalty if needle within 4 cm* of lungs</td>
<td></td>
</tr>
<tr>
<td>Attempt Count</td>
<td>33</td>
</tr>
<tr>
<td>Add Penalty for each extra pass farther than 2 cm into skin.</td>
<td></td>
</tr>
</tbody>
</table>

* Straight line trajectory from needle tip looking into patient; measures what happens if needle advance continues. Steeper trajectories into the patient incur more penalties. Penalties are inversely scaled with decreasing distance. ** if multiple skin pokes, score the one closest to a pneumothorax.

The simulated skin (lighter brown patch at top of right shoulder in Figure 3, left picture) is actually punctured by an instrumented needle from a commercial central venous access kit (TeleFlex Medical, Research Triangle Park, NC). A 6 degree of freedom (DOF) miniature magnetic sensor fitted inside the needle bore near the tip of the needle is tracked in real time by a 3D tracking system (Ascension Technology Corp., Burlington, VT) relative to the virtual 3D soft tissues surrounding the virtual subclavian vein, as it is manually guided by the user to the virtual target. The
needle is connected to a syringe (from the same commercial kit). A generic Windows 7 laptop interfaces with the tracking system, controls the simulation and can display a 3D visualization of the 3D virtual elements during a simulation session or debriefing.

We implemented a scoring algorithm to automatically, objectively and consistently (no inter-rater variability) score performance at the end of a training session (Table 1). The scoring algorithm was designed by experts in central venous access and is based on quantitative metrics that can be used to assess not only the performance of trainees but also the construct validity of the simulator as well.

2.1.2 Virtual Camera Tangible User Interface

Moving the virtual camera view in a 3D environment can be helpful during after action review, e.g., to appreciate how close or far away a needle is from a structure. We found during use of our simulators that instructors were generally unfamiliar with the keyboard shortcuts needed to pan, tilt and zoom the camera view.

To create an intuitive and user-friendly way to control the camera view without a keyboard, we added a 6 DOF magnetic sensor to a physical toy camera that acts as a tangible user interface (TUI) to the virtual camera position and orientation. When moving the virtual camera TUI in space with one’s own hand, the camera perspective is observed to change in real time during both a simulated procedure or during replay of a previous procedure. Panning is done by translation of the TUI. Tilting is achieved by changing the TUI’s orientation. Zooming is accomplished by moving the TUI closer to the torso. Whenever the user presses an instrumented shutter button on the virtual camera TUI, the camera view follows in real time the TUI. The user releases the shutter button to lock the camera perspective and discontinue the camera view tracking the virtual camera TUI.

2.1.3 Results

Vascular surgeons not involved with development evaluated the simulator anatomy and judged it authentic. The simulator was evaluated in a preliminary study with 28 anesthesia residents who each used the simulator 3 consecutive times. From Run 1 to Run 2, performance score as determined by the algorithm in Table 1 (0 to 100 scale; lower score is better) for all participants was improved, on average, by 28% and a 71.9 seconds reduction in average time to achieve subclavian venous access was obtained.

We performed repeated measure ANOVA on the outcomes from the three waves of data collection with follow-up pairwise dependent sample t-tests. There were reductions in average time (F=14.28, p<.0001), the number of attempts (F=10.77, p=.0001), number of skin punctures (F=6.59, p = .004) and score as determined by the scoring algorithm (F=14.59, p < .0001). For all outcomes, there were significant differences between Run 1 and Run 2 and between Run 1 and Run 3 (p < .05), but not between Run 2 and Run 3. The increased success rate from 82.1 (Run 1) to 92.9% (Run 3) was not significant (p = .08).

Complication rates for pneumothoraces and subclavian arterial punctures were reduced from 11% to 7% and 13% to 7%, respectively. On a five point scale (1=strongly disagree to 5=strongly agree), on average, participants agreed that the simulator was realistic (M=4.1) and strongly agreed that the simulator should be used as a training/educational tool (M=4.8).

In preliminary trials, the skin insert could be used for at least 100 punctures. In contrast to existing CVA part task trainers, the new simulator detects lung strikes, calculates and displays the margin of safety, i.e., the distance by which artery and lung puncture was avoided and offers recording and playback of the needle tip’s path and an automated scoring algorithm. The entire access procedure showing the 3D needle path relative to surrounding structures is captured and can be replayed for after action review (debriefing) or self-debriefing [11].

2.2 Other Applications

2.2.1 Regional anesthesia mixed simulator

During regional anesthesia (RA), a needle tip is guided, usually under ultrasound (US) guidance, to the vicinity of a nerve so that anesthetics can be deposited to anesthetize the region that is innervated by the targeted nerve. Interpretation of the ultrasound image can be difficult for novices especially if (a) they are not familiar with the concept or interpretation of a cross-section (which is what an ultrasound image is) and (b) the complex anatomy of the spine. Misplaced needle tips can result in inadequate regional anesthesia and unnecessary pain, discomfort and distress to the patient. We used the same design approach as in the CVA simulator for the RA simulator, adding a simulated physical US probe tracked with a 6 DOF magnetic sensor. Instead of using pre-recorded US images, the US images are generated in real time based on the position and orientation of the probe.

2.2.2 Ventriculostomy mixed simulator

During bedside or emergent ventriculostomy, a catheter is inserted into a brain ventricle, without imaging guidance, to drain fluid and relieve pressure building up in the brain. Neurosurgeons rely on anatomical landmarks and heuristics to establish the entry point at the skull and a 3D mental model of the brain to safely and efficiently steer the catheter tip to a lateral ventricle. We designed a mixed simulator to provide practice to novice neurosurgeons to facilitate placing the ventriculostomy catheter tip into the ventricle in one pass without striking other undesired inner brain components. Accessing the ventricle in one pass, rather than multiple passes, is desirable because it minimizes the trauma that the catheter (fitted with a rigid metal stylet to stiffen it during insertion) causes to brain tissues on its way to the ventricle.

2.2.3 Radio frequency lesion mixed simulator

Radio Frequency Lesion (RFL) is a guided procedure used to relieve trigeminal neuralgia, intense pain originating from the trigeminal nerve. A needle is inserted through the cheek muscle and then into the cranium via the foramen ovale under real time image guidance of the needle though fluoroscopy. Once the needle is in the trigeminal nerve region, and the location verified through stimulation, a radiofrequency lesion is used to destroy the part of the trigeminal ganglion which corresponds to the area of the pain, reducing or eliminating the pain. Neurosurgical residents are trained in the operating room by performing the procedure under the supervision of an attending surgeon. Especially during early training the resident physician uses significantly more operative time and fluoroscopic exposure in positioning the needle, increasing the risk from ionizing radiation exposure to both the patient and the staff. To allow resident physicians to gain expertise in patient positioning, optimizing radiographic views, needle trajectory and providing an appreciation of the appropriate tactile feedback, we developed a mixed RFL simulator.

2.2.4 Spinal implantation mixed simulator

Spinal instruments are implanted under open surgical, radiographic and image guided protocols. Like in the radio frequency lesion procedure, exposure of the patient and surgical staff to excessive ionizing radiation when a novice is taking a prolonged time to learn to implant spinal instruments is a concern. We developed a mixed simulator similar to the RFL simulator to allow training without exposure to radiation.
3 DISCUSSION

Newcomers to simulation often confuse simulation with technology, focusing on the simulation technology instead of the simulation goals such as skills acquisition. We introduce the concepts of the skills triangle and the simulation triangle to emphasize that in simulation too, “form follows function”. In general, there is a relatively good mapping of the skills triangle to the simulation triangle as they are both depicted in Figure 1. For example, since affective skills are about interacting with another human, biologic simulation in the form of human actors role playing patients with specific symptoms or diseases can help to hone skills such as asking intimate questions to strangers (patients). Unlike physical simulators, virtual simulators are unconstrained by the laws of physics and readily allow us to add to our cognitive skills and knowledge, e.g., by visualizing normally invisible structures, mechanisms and processes. Unlike virtual simulators that are constrained to mediated (instead of direct) interaction (such as via pointing devices), physical simulators are ideally suited to learn psychomotor skills, e.g., allowing real instruments to be directly used and manipulated without any limitations from a mediating interface.

While the terms “mixed reality simulator” or “augmented reality simulator” have been previously used [10], our motivation for proposing a novel taxonomy for simulation is based on the fact that a simulation is not reality (the real thing) but an attempt to simulate reality. Simulators are, by definition, not real and using reality when describing a simulator can be confusing. While simulators are not real, they certainly can be physical. We substitute physicality (instead of reality) as the opposite of virtuality to adapt Milgram & Kishino’s taxonomy to simulation. Further, as the title of their seminal paper suggests, Milgram & Kishino’s taxonomy is geared primarily at displays (output) while the proposed simulation taxonomy considers both output and input (in the form of user interventions, crucial elements in an interactive simulation).

Central venous access requires both cognitive and psychomotor skills with the actual procedure itself requiring minimal affective skills. From the cognitive side, the trainee needs to have a correct 3D mental model of the anatomy surrounding the target, an appreciation of the risks and a strategy to mitigate the risks by selecting an appropriate entry point and choosing a trajectory that minimizes collateral damage if the target is missed. Psychomotor skills such as manual dexterity and spatial ability are required to successfully place the needle tip in the vein. A mixed simulator provides the best attributes of both physical and virtual simulators in meeting the psychomotor and cognitive learning objectives respectively for a CVA simulator.

A mixed simulator to teach a procedure with potential for significant complications, i.e., subclavian vein catheterization, has been created and validated as a learning tool that allows novices to gain useful experience and confidence without risk to patients. The CVA simulator has been used to train anesthesia, emergency department and interventional cardiology residents, fellows, faculty clinicians and physicians in private practice in the US and overseas. Unlike the simulator developed by Magee et al [12] for ultrasound guided needle placement, our approach used for all five procedural simulators, employs anatomically correct physical components produced via 3D printers.

3.1 Innovation

Numerous elements are presented in this paper that exploit the latest developments in technology and are integrated in novel ways to implement augmented physical simulators with virtual underlays. A future version of the CVA simulator will include simulated ultrasound guidance, like the RA simulator.

- 3D printers to create anatomically correct physical components of mixed simulators from 3D objects reconstructed from medical imaging scans
- Miniature 6 DOF tracking sensors to track actual instruments (instead of using input devices such as haptic pens like the Sensable device) increases realism
- Record and replay capability that can facilitate collocated after action review
- Automated scoring algorithms that can facilitate self-debriefing and validation
- Tracked Tangible User Interface to intuitively control the virtual camera view and facilitate debriefing
- Physical interaction between real instruments and physical internal components (such as bones) to create inexpensive tactile feedback

4 CONCLUSION

In this paper, we introduced the skills triangle, the simulation triangle and a novel taxonomy for simulators combining virtual and physical components that may be used in the future to inform the design of mixed simulators. In addition, we developed a set of five augmented physical simulators with virtual underlays. One of those mixed simulators, the CVA, was shown to improve learning outcome.

REFERENCES