Use of a Surgeon as a Validation Instrument in a High-Fidelity Simulation Environment

Ben Andrack, Trevor Byrnes, Luis E. Bernal Vera, Gerold Bausch, Werner Korb
Innovative Surgical Training Technologies (ISTT)
HTWK Leipzig – University of Applied Sciences Leipzig
Leipzig, Germany

Introduction: A team has been working on a high-fidelity surgical training model for a lumbar disc herniation made of synthetic materials. Since other types of surgical training (as VR Simulators and cadavers) lack optical and haptic realism, the goal was to develop a training model that transfers knowledge about the feeling when operated on and enables training with a realistic workflow. Furthermore, after a training operation, feedback should be provided to the trainee about the applied stress to risk structures during an operation.

Methods: The model was designed iteratively with intense validation from surgeons. First, human tissues were developed separately, validated, redesigned and repeated. Then the model was developed in the same process. An intra operating bleeding system and a sensor system were developed and integrated.

Results: The surgeons were enthusiastic about the realism of the developed training model. It does not matter which instruments and techniques are preferred, surgeons have realistic haptic response and the surgical workflow follows a real operation when training on the model. This is a huge benefit when compared to VR simulators and cadavers.

Discussion: In future steps, stress data to the risk structures will be analyzed, in order to a better understanding of what the critical moments during this operation are and what the stress thresholds of the nerve roots are.

INTRODUCTION

The sense of touch is elementary for surgeons and the development of surgical skills involves memory of tactile experience (Lim, et al., 2009). For most of their training, surgeons train on cadavers however, cadavers tend to have different characteristics when compared to a living patient (Reznick & MacRae, 2006). This is the reason why a team set out to build a training model for spinal surgery, based on synthetic materials, which would be able to mimic the optical and haptic characteristics of a real patient.

The goal was not only to train a surgeon in a procedural workflow, as in other types of training (i.e. VR simulators, cadaver, etc.), but to (1) transfer knowledge about the feeling and the haptic forces applied to the human tissues and risk structures. Therefore it was mandatory to do an intense validation for the correct haptic properties of the human tissues developed in the training model.

A further goal of the project was to (2) simulate a realistic workflow in a training situation as it is in a real operation. What is meant is that the surgeon not only performs all the procedural steps of the approach but is also trained in typical instrument handling and psychological stress factors.

In this project, operating room (OR) observations and expert interviews illustrated a need for bleedings to be included for a realistic simulation (Korb, et al., 2011). This line-of-sight obstruction places the surgeon under time pressure and forces them to switch between surgical instruments as they would in a real operation.

In another example: VR simulations are not preferred for approaches where many different instruments are used, since most of the input devices of VR Simulators simulate only one or two instruments. This is probably one reason why training on a human cadaver is still considered the gold standard for many operation techniques. The downside to this kind of training is that it has no bleeding, and as a result it lacks the realistic workflow for certain situations (Fry & Kneebone, 2011).

Developing this high-fidelity training model was planned as a feasibility study for future training systems. Hence, a surgical operation that is often performed and one that had a limited number of anatomical structures was chosen: decompression of a lumbar disc herniation via an interlaminar approach.

The challenge during this operation is to remove the disc prolapse without inflicting additional damage to the dura mater spinalis and the inner laying nerve roots. In order to reach the prolapse, the surgeon has to shift the dura. Therefore a certain amount of mechanical stress and a potential risk of damage is always present during this approach. Experienced surgeons cause significantly less inadvertent durotomies than novices (Krämer, et al., 2005).

For this reason another goal was to (3) provide feedback to the trainee about the applied stress to the dura and inner lying nerve roots during a training operation.
METHODS

Step 1: At the beginning of the project, the team members conducted hospitations in the operating room, building the basis for “cognitive task analyses” to gain access to the implicit expert knowledge of the surgeons. In connection with expert interviews of surgeons (n=17) with different levels of education, the individual procedural steps of the approach and the specific challenges were analyzed.

In parallel, the team of engineers and material experts interviewed anatomy experts and surgeons, observed the approach in the operating room and on cadavers in order to experience the different anatomic structures and the properties of the tissues.

Step 2: In the next step, the different anatomic tissues of the vertebrae, the intervertebral disc, the disc prolapse, the dura mater spinalis, the epidural fat and the ligaments were engineered and built as mock ups. Then these tissues where evaluated by surgeons for their optic and haptic accuracy. Therefore, tests with the typical instruments where carried out in order to evaluate the correct tissue properties in relation to the samples.

With this input of surgical experts, a first cycle of tissue redesign was performed by improving color and behavior using different synthetic and organic materials (polyurethane, epoxy, silicone, gelatin, latex, etc.) modified with additives of different types and textures (flocks, fabrics, etc. of cotton, synthetics, etc.). In another round of testing, the surgeons validated the properties of the tissues. Validation was done with a questionnaire (a combination of a four choice scale and free text answers). This redesign-validation cycle was repeated iteratively, until most properties of the copied human tissues where rated “realistic” or “almost realistic” and the surgeons did not see a need for a further redesign cycle.

Step 3: In the next step, a first complete training model was designed, using segmented computed tomography (CT) and magnetic resonance tomography (MRT) data from a real case. The built model was based on the tissues validated in Step 2. The model itself was validated by surgeons performing a complete discectomy. With the results from validation, it was redesigned. In total, this model has passed through two redesign cycles so far.

In relation to goal (2), in version 3, the model consists of an intra-operative bleeding system, which is capable of simulating two different kinds of bleeding: a permanent diffuse bleeding, which forces frequent suction in order to reduce the line-of-sight obstruction; and a second bleeding that starts automatically out of the bone when a laminectomy is performed. Thus, the surgeon has to react and to manage it appropriately.

In relation to goal (3), a sensor system has been designed into the model. It monitors the forces and possible damage applied to the dura and nerve roots during training. The system is capable of monitoring the following 3 parameters:

1. Cerebrospinal fluid (CSF) pressure: The CSF system including the synthetic dura is filled up with water to a pressure level of 15 mbar, simulating the nominal CSF-pressure of a person lying down. This constant pressure level is monitored via a pressure sensor in order to detect a certain pressure drop, indicating an inadvertent durotomy during training operation (see Figure 1).

   Figure 1: inadvertent durotomy

2. Nerve root compression: In the training model, the nerve root consists of a flexible silicone tube. An ultrasonic sound signal at a constant magnitude is sent from one end of the tube through to the other, where it is received and analyzed. Compression of this nerve root leads to a reduction in magnitude of the received signal. As a result, monitoring this magnitude provides information about the compression forces applied to the nerve root during operation.
3. Nerve root tension:
This is done by measuring the axial movement of the threatened nerve root (see Figure 3). In the training model, the appropriate nerve root is fixed on the cranial side, so it cannot move. On the caudal side, where the root leaves the dural sack and rounds the pedicle, it is fixed to a tension spring. This allows the surgeon to medialize the dura so he can reach the prolapse. The amount of axial movement reflects the tension force applied to the nerve root. This movement is measured through a position encoder.

Step 4: In the final stage of this project a workshop for novice surgeons (n=4) was carried out with version 3 of the model. First, in a master presentation, the approach was performed on the model by an experienced surgeon, who explained the procedural steps while performing. Then, in parallel, on two tables another two models were operated on by the novices. Afterwards, the positions between operators and assistants were switched and another two models where operated on. In the end, every novice had performed a complete operation on the training model and assisted with another one. Training ended with a debriefing, where the novices reflected on their experiences with the surgeon trainers. This validation information will be used in future development steps.

As shown, the development process of the training model was accompanied by an intense validation from surgical experts. Figure 4 summarizes the performed and possible future steps schematically.

RESULTS

The intense use of surgeons for a cyclical, iterative design-validation process has brought great success to the project. The surgeons were enthusiastic about the realism of the developed training model, during every performed operation. More than one surgeon stated that
the model was closer to a real patient than a cadaver. The haptic interaction, especially, was mostly rated “realistic” by the surgeons. In a small demarcated area the model convincingly mimics the human body in optical and haptic behavior (see figure 4). It does not matter which instruments and techniques are preferred, surgeons have realistic haptic feedback when they cut, drag, pull, tear, draw, stretch, drill, punch, or shave the copied human tissues. This is a huge benefit when compared to VR simulators and cadavers.

Additionally the integration of the intra-operative bleeding system (2) significantly enhances realism to the workflow. The basic diffuse bleeding decreases the visibility in-situ and the capability to identify the anatomical structures. Diffuse bleeding also binds one hand of the surgeon to the suction unit, which impedes the work and increases the complexity of instrument handling. By increasing the amount of bleeding into the model, an additional stress factor can be easily provoked in a training situation.

According to (3), a sensor system collecting data about CSF pressure, nerve root compression and nerve root tension has been developed, integrated and validated in the model. Validation had shown that the included sensors do not influence the haptic interaction negatively. In fact, they are not even recognized during operation.

A first set of data have been collected during validations and training operations of the validation workshop. The sensor system worked well and logged a couple of thousand measurements during these operations (n=7). Data have not yet been analyzed in detail.

**DISCUSSION**

Access to the operating room is imperative when designing models for surgeons; this has enabled the team to glean very valuable information about the working processes, procedures and workflow through close observation and documentation.

With relation to (1): The complete development process of the synthetic human tissues was based on the experience of surgeons. Not a single measurement in comparison to real human tissue was done during the project. Nevertheless, the positive results of the validations and the feedback we received have proven the success of this methodology. We believe that material design which is only evidence based on material properties as hardness, elasticity, Young's modulus, etc. would not perform better, since the relevant haptics of a material (i.e. rebouncing when cut with a blunt instrument) cannot be defined by a material constant. It seems to be more useful to get a comparable, qualitative answer from an experienced surgeon. Statements like “it feels like crab meat when cut”, include much more information in it than some material constants.

What proved to be more difficult than the haptics was the research on how to simulate it. Most material deficits arise from the homogeneity of the synthetic materials. But no human tissue is homogeneous! With this in mind, we often worked with fabrics or flocks as additives in order to break this homogeneity. It has been demonstrated that there is no general solution for developing human tissues. Every tissue needs to be designed individually.

In future steps, additional surgical experts will perform the operation on the training model in order to collect the force data applied to the nerve root. The idea behind this is to analyze the strategic differences of the approach of experienced and novice surgeons in the context of the applied forces to the nerve roots. Hopefully, this will lead to a better understanding of what the critical moments during this operation are and what the stress thresholds of the nerve roots are. The obtained data about the threshold forces would be used in later training sessions with novices to show them better strategic procedures of the approach and to give them quantifiable feedback about their operation.

Another application for these measurements would be a live feedback for the surgeon in a training situation, quite similar to an intra operative neurophysiological monitoring (IONM). If it would be possible to give live feedback during a training operation, the trainee could figure out for themselves, the best strategy of how to reach the prolapse by applying a minimum of force to the nerve roots. This would be a great improvement to cognitive training experiences.
ACKNOWLEDGMENTS

Innovative Surgical Training Technologies Leipzig (ISTT) is an applied research project part of the University of Applied Sciences Leipzig (HTWK Leipzig). Since 2010, the team has been using different human factors approaches to plan, design and iteratively develop this surgical training model.

A special thank you goes out to our cooperation partners: the Neurosurgery Department of the University Hospital Leipzig, Professor Dr. J. Meixensberger and his staff. This partnership enabled us to have access to the operating room, surgeons (and supporting surgical staff) to conduct hospitations, building the basis for our cognitive task analyses. Thank you for the invaluable support. We would like to thank Dr. Jens Adermann and Dr. Markus Dengl, of the University Hospital Leipzig, for their validation and surgical training expertise without which the project would not have had success.

The project would also be impossible without the expertise of Dr. Steinke and Dr. Hammer of the Department of Anatomy (Universität Leipzig). We would also like to thank Martin Weide for his contributions to this project, during which he also completed his Master’s degree. Last, but not least, without the dedication of the complete ISTT team of engineers and researchers, led by Professor Sturm, none of this would be possible. Thank you!

REFERENCES


