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DEVELOPING A WIRE NAVIGATION SIMULATOR FOR PEDICLE SCREW PLACEMENT IN MINIMALLY INVASIVE TRANSFORAMINAL LUMBAR INTERBODY FUSION

Jared Hill
Industrial and Systems Engineering
The University of Iowa
Iowa City, IA

Steven Long
Orthopedics and Rehabilitation
The University of Iowa
Iowa City, IA

Evan Williams
Biomedical Engineering
The University of Iowa
Iowa City, IA

Geb Thomas
Industrial and Systems Engineering
The University of Iowa
Iowa City, IA

Joan Bechtold
Orthopaedic Surgery
The University of Minnesota
Minneapolis, MN

Donald D. Anderson
Orthopedics and Rehabilitation
The University of Iowa
Iowa City, IA

ABSTRACT

Simulation training provides an opportunity for surgeons to learn key skills in a safe environment. This is especially important for surgical procedures where mistakes have high consequences, such as working near the spinal cord. Wire navigation is a common orthopedic skill that spans many procedures. This paper presents the design steps taken to modify an existing simulator intended to train surgeons on hip wire navigation so that it can be used to train surgeons on placing a K-wire during a minimally invasive transforaminal lumbar fusion, or MIS-TLIF. The new design was able to accommodate several unique features of the MIS-TLIF task and successfully simulate placing the guide wire in the pedicle body. Results show that the simulator design functions normally even in the face of hammering needed to place the guide wire, a unique step in this procedure compared with other wire navigation procedures. Additional work remaining involves developing a training curriculum so that surgeons can benefit from this new tool.

NOMENCLATURE

ACGME	Accreditation Council for Graduate Medical Education
AP	Anterior-Posterior
DHS	Dynamic Hip Screw
K-wire	Kirschner Wire
MIS-TLIF	Minimally Invasive Transforaminal Lumbar Interbody Fusion
OR	Operating Room
PSD	Pedicle Screw Diameter
SLA	Stereolithography

1. INTRODUCTION

The current structure for training orthopedic residents has undergone a significant shift to accommodate work hour restrictions set forth by the Accreditation Council for Graduate Medical Education. [1] The implementation of an 80-hour work week set forth by ACGME has catalyzed the implementation of new methods for training orthopedic residents to best accommodate this time constraint. The use of surgical simulation has grown as residents and program directors alike express desire for deliberate practice of surgical skills outside of the operating room (OR) [2,3].

While surgical simulation is on the rise in orthopedics, a majority of simulators specialize in specific areas such as arthroscopy [4]. In contrast, wire navigation is a generalizable skill utilized in multiple orthopedic specialties that has been less addressed in the realm of surgical simulation training. Wire navigation consists of drilling a surgical wire into bone along a specified trajectory while using 2D intraoperative fluoroscopic images to provide context to the wire location and trajectory. This skill requires complex visuospatial skills and anatomical understanding to interpret 3D space from 2D projective images. Visuospatial skills are complemented by knowledge of haptic feedback in wire placement to feel for differences in bone density between softer cancellous bone and denser cortical bone to better judge wire location. Wire navigation is an essential skill in orthopedics that is recognized by the American Board of Orthopedic Surgery as a core competency skill [5]. This means it is an expectation that you are competent in this skill prior to certification for practicing orthopedics in the U.S.A.

A wire navigation simulator has been previously presented by this team with a focus on wire navigation in the treatment of an inter-trochanteric hip fracture [6]. Wire navigation for the initial simulator focused on the placement of a Kirshner wire (K-wire) into the proximal femur to set the trajectory for a cannulated implant that would be later inserted (Figure 1). While the hip fracture procedure exemplifies an important use of wire navigation, there are additional orthopedic procedures that require development of skill in wire navigation, each presenting different design challenges.

Figure 1: The current wire navigation simulator platform for hip wire placement. A laser etched K-wire is tracked as it is advanced into a surrogate femur bone, with an associated laptop presenting virtual fluoroscopic images for navigation.

Minimally invasive transforaminal lumbar interbody fusion (MIS-TLIF) is a procedure that involves placing surgical wires through the pedicle of a patient's vertebral body as part of a fixation construct to support spinal fusion. This procedure presents significant risk to the patient, as the pedicle lies directly lateral to the spinal cord. Errors in wire navigation can compromise the spinal cord, causing lifelong harm to the patient. The average pedicle diameter in an L4-L5 vertebral body fusion is 12.7mm, providing little room for surgical error and emphasizing the need for skills in wire navigation [7]. In vitro and in vivo studies have reported lumbar pedicle screw misplacement rates from 5 to 41%. [8]. Errors in MIS-TLIF have also been linked to post-operative deficits including lower extremity weakness and paralysis [9,10].

Prior pedicle screw simulators have shown promise for improving the placement of pedicle screws [11,12]. However, the virtual reality simulators developed lack haptic feedback and other simulators use highly specialized and costly equipment often only used in the OR. To address resident training in this high-risk procedure, our team adapted the current wire navigation platform to simulate wire navigation in pedicle screw placement. This simulator provides a low cost, radiation free representation of the OR while providing true haptic feedback of the MIS-TLIF. We here present the design process used to develop the new module and the resulting platform.

2. MATERIALS AND METHODS

2.1 Current Simulation Platform

The current hip wire navigation simulator consists of a heavy base that houses a pair of stereo cameras, a vertical mast for bone placement, and the surrogate of the anatomy of interest that is fixed on top of the mast. The two cameras located in the simulator have overlapping fields of view that create a 3D working envelope within which wire location is determined and tracked throughout the simulation. The location and fixation of the bone surrogate is an essential component to the simulator, as malalignment can result in image reconstruction errors or loss of the surgical wire from the working envelope. Adaptations to the simulator must place the surgical working envelope within that of the simulator cameras to ensure the surgical wire is continuously tracked throughout the procedure.

2.2 TLIF Pedicle Screw Fixation

MIS-TLIF is a procedure requiring pedicle screw insertion to treat common spinal instabilities such as spondylolisthesis and degenerative disc disease [13,14]. The patient is positioned on their stomach while anterior-posterior (AP) and lateral fluoroscopic images are used to guide the needle insertion. Commonly, a 1-2 cm incision is made and a cannulated Jamshidi needle is placed into the intersection of the facet and transverse process. Before advancing the needle into the pedicle, AP and lateral images are taken to confirm correct trajectory through the center of the pedicle. This is the wire navigation portion of the procedure to be replicated with the simulator. The Jamshidi is advanced into the pedicle utilizing intermittent AP and lateral images captured to assure correct trajectory (Figure 2). Once the Jamshidi has entered the vertebral body, a standard K-wire is advanced through its cannulas. Once the wire is placed, the Jamshidi guide is removed and a pedicle screw is advanced over the guide wire.

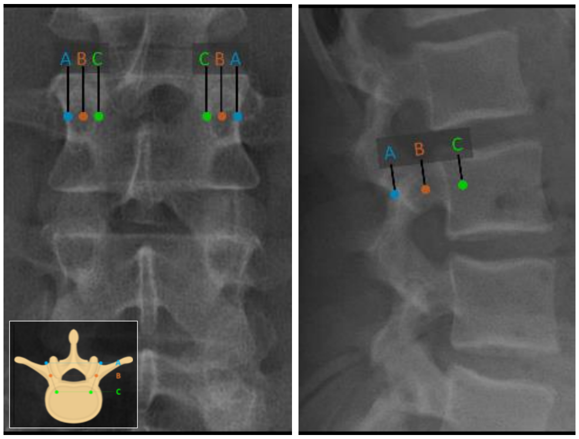

Figure 2: Illustration of landmarks for Jamshidi guide insertion using axial (left) illustration, and AP (middle), and lateral (right) fluoroscopic images. The Jamshidi needle is docked at the surface of the pedicle (position A) and then advanced to the pedicle center (position B). Upon further advancement of the Jamshidi tip (position C) the K-wire is placed through the guide cannula, and the guide is removed. The final pedicle screw trajectory is set by the K-wire location/trajectory.

2.3 Simulator Adaptation to TLIF Simulation

The hip wire navigation simulator was originally designed to represent a surgical approach where the surgeon is supralateral to the working area of the patient (Figure 1). The working area during spinal fusion consists of the surgeon standing beside the patient and working downward. In order to accommodate this positioning without modifying internal camera structure, a design choice was made to lay the simulator platform down on its side and position the patient anatomy as is typically done in the OR. Multiple designs were considered that would be able to accommodate this new positioning of the simulator body (Figure 3).

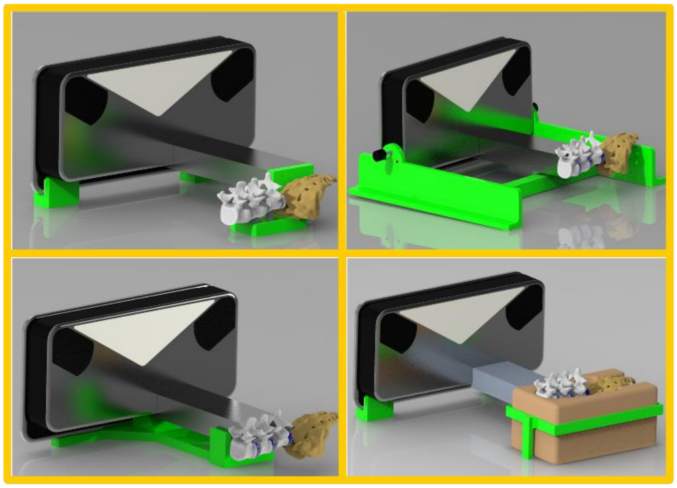

Figure 3: Four different modeled prototypes for accommodating the simulator repositioning are shown here. The top left image shows the final design chosen.

The design chosen for implementation (Figure 3 – top left) was one in which two U-shaped brackets would support the simulator body and the simulator mast insert would be replaced with a spinal dock that could hold the simulator level while providing a mounting point for the spinal model. This mounting point would allow for removal and replacement of spinal models after Jamshidi use. The two U-shaped support brackets, as well as the mast support, were created using stereolithography (SLA) 3D printing. These supports held the simulator level and placed the spinal model in an ideal location for the cameras to track the Jamshidi wire during the simulation.

The simulator's existing software was modified for the application of pedicle screw placement. CT data from the Visible Human Project were used to generate the fluoroscopic images (AP and lateral) needed in the MIS-TLIF procedure (Figure 4). A 3D lumbar spine model was segmented from the CT data. This model was 3D printed and filled with a urethane foam to simulate cancellous bone. The 3D printed spine model was mounted to the simulator mast. The same source CT data used in producing the 3D printed spine model was also used to create 3D virtual fluoroscopic images, ensuring optimal agreement between the images shown during simulation and the model being worked on by a surgeon. A silicone soft tissue sheath was also created to simulate the muscle and skin that would prevent direct visibility to the spine during the MIS-TLIF procedure (Figure 4).

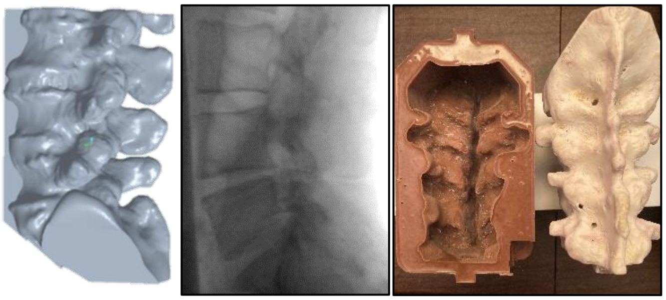

Figure 4: The digital spinal model is shown here (left) alongside the lateral digitally reconstructed image used for simulation of this procedure (middle). The 3D printed spine model and soft tissue are also shown (right).

A modified Jamshidi handle was created as a tool for the simulation procedure. In the standard OR procedure, the Jamshidi is a cannulated instrument that is used to help place the guide wire. Because the simulator works by tracking markings on the guide wire, our team decided it would be just as useful to place a handle on the actual guide wire and eliminate the need for the cannulated instrument. A standard handle was modeled in Creo and 3D printed. The handle was able to be press fit on to the etched guide wire that the simulator tracks during the simulation (Figure 5).

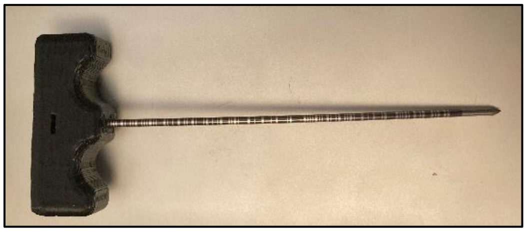

Figure 5: The modified Jamshidi instrument is shown here. The etched guide wire used with the simulator tracking system was able to be press fit into the 3D printed handle.

2.4 Simulator Accuracy Analysis

The small working diameter of the pedicle required an error analysis in order to ensure that the tolerance for Jamshidi placement detection was accurately represented on the simulator digitally reconstructed images. A standard K-wire (diameter=3.2mm) was used to represent a Jamshidi needle. The known image reconstruction tolerance on the simulator is 1mm in displacement and 1° of angulation [15]. The average lumbar pedicle diameter of 12.7mm and length of 24.3mm was used as a template for the working area of image reconstruction. From the known diameter and angular tolerance of reconstruction, a mathematical model of the working volume was created. This volume consisted of an acceptable area, where reconstruction was not at risk of displaying an incorrectly breached pedicle due to errors in tolerance of reconstruction (green), and an outer diameter of error, where at maximum error, the reconstructed image would return a breached wire image when in fact the wire had not breached the pedicle wall (red) (Figure 6).

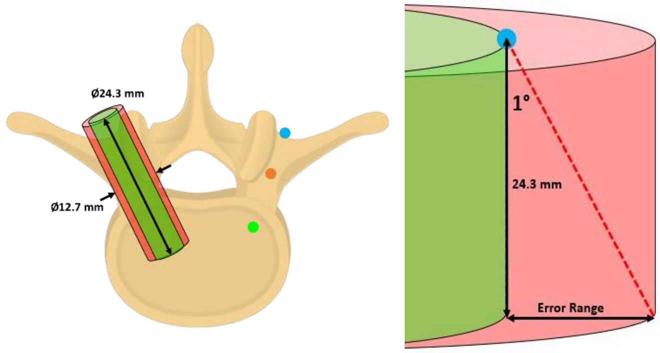

Figure 6: Working zone (green) and zone of possible error (red) for image reconstruction.

A triangle of known height (pedicle length) and angulation (simulator error) was created from these values. The unknown error range in pedicle diameter image projection was constructed as the width of the triangle. With the known height and angle, error range was calculated using equation 1 below. Acceptable error for image reconstruction was defined as a working range radius 10 times larger than the error radius.

$$Error\ Range = tan(1^\circ) * 24.3mm \tag{1}$$

2.4 MIS-TLIF Jamshidi Tracking Implementation

In addition to the error analysis, our team was able to implement the design and test the feel and perceived accuracy with the new simulator module. Given that this procedure requires surgeons to hammer on the Jamshidi handle with a mallet, one concern was the ability of the cameras to stay in focus during a simulated wire placement. To test this, we took images at the start and end of a simulation test to see what, if any, changes in focus could be observed. Changes in focus would likely also mean a reduction in simulator accuracy.

3. RESULTS AND DISCUSSION

The results of the theoretical accuracy calculations showed that when placing the guide wire at the full depth of the spinal body, there would be a potential error of 0.42mm outside the intended wire placement. Since the radius of the pedicle is roughly 6.4 mm, this is within the 10% error margin goal.

The simulator was assembled (Figure 7) with all the newly designed components and tested to see how well it could reconstruct the wire position relative to the spine model. In testing the simulator, it appears that the physical model agrees with the theoretical accuracy calculations. Figure 8 shows 2 different image reconstructions of the wire in 2 different locations on the spine model. In each of these images, the wire tip was placed so that it just touched the surface of the bone. From these images, it appears that the wire reconstructed location was also just on the surface of the spine model. Additionally, this test proved that the wire position could be reconstructed at multiple levels of the spinal model and on both the left and right sides of the patient, showing that the working envelope of the simulator was properly aligned with the working envelope of the surgical procedure.

Figure 7: The new spine model is shown mounted to the simulator. The Jamshidi handle has been placed into the silicone soft tissue, and images reconstructed on the laptop accurately show the wire on the spine model surface.

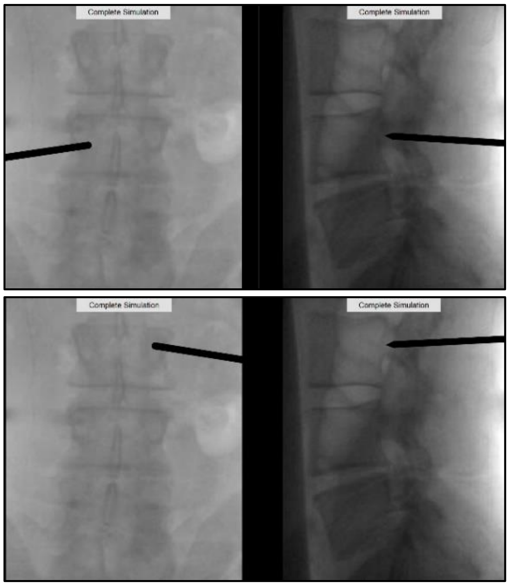

Figure 8: The top images show a pair of wire placements at the L4 level where the wire tip just touches the surface of the spine model. The bottom image pair shows the wire reconstructed at the L3 level.

In one test, the wire was also hammered into the spine model to test the durability of the simulator during the vibration from the hammering. Figure 9 shows two raw images from the simulator camera system, one taken at the beginning of the simulation and the other at the end of the hammering. After hammering the wire into the model with approximately 15 strong hammer strikes, it appears that the simulator was able to hold its focus. The image reconstruction during this time had zero errors and showed the wire slowly progressing into the pedicle body.

Figure 9: The left image shows the wire on the simulator before any hammering of the Jamshidi handle. The right image shows the wire after it had been hammered into the spinal body, still is sharp focus.

4. CONCLUSION

This study has presented a new simulation platform for placing a K-wire during a MIS-TLIF procedure. The simulator, originally designed for hip wire navigation procedures, was successfully modified to accommodate simulation of the spinal procedure. Preliminary testing has shown that the new model works as intended and has the accuracy needed to be believed and trusted by training surgeons. Next steps will be to develop a training curriculum for the procedure and begin working with resident surgeons who are new to this procedure.

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