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Research Article

Development of a Haptic Simulator for Pedicle Screw Insertion: A Pilot Study

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Abstract

Introduction: Pedicle screw insertion is a common treatment for fixing spinal deformities in idiopathic scoliosis. Surgeons using the free hand technique are guided primarily by haptic feedback. This is a sensitive process which carries risk of serious mechanical, neurological and vascular complications. Surgeons currently train using cadavers or live patients. In this study, a novel haptic training simulator is presented which imitates the sensations experienced by a surgeon in pedicle screw insertions. This haptic model is developed for normal bone scenarios. A study is conducted to examine the simulator's ability to distinguish surgeons with different skill levels.

Design: A robotic simulator is designed and built to simulate the two degrees of freedom involved in probe channeling. A haptic model is created and surgeons of varying experience levels are able to change various parameters in order to tune the simulator for the most realism. The surgeons also evaluate the simulator for its feasibility and usefulness.

Setting: Data collection was performed at the University of Toronto.

Participants: For the study, 11 surgeons consisting of 8 orthopedic surgeons and 3 neurosurgeons are recruited. Among them, two are senior, 4 are fellow and 5 are residents.

Results: A set of haptic model parameter values for normal bone are calculated. Some model parameters are found to be more sensitive and are tuned significantly differently among participants with different skill levels. Senior surgeons had narrower range of tuned values for four model parameters (out of seven). Initial findings indicate the feasibility of the simulator for surgical education.

Conclusion: This study demonstrates the feasibility of the novel training simulator to replicate haptic sensation in interaction with bone. Future research will be conducted with additional participants. Also, we will add visualization and modify haptics with higher bandwidth actuators.

Keywords: *Haptic Simulator; Pedicle Screw Insertion; Surgery*

Introduction

Idiopathic scoliosis is defined as a lateral curvature of the spine greater than 10 degrees with unknown cause. The reasons for treatment include improving physical appearance, reducing back pain, promoting physical comfort, and preventing excessive spine curvature. In pedicle screw instrumentation, screws are placed through the pedicle and inside the vertebral body and are then connected by a short rod which straightens the spine [1]. This type of surgery is often conducted using the free-hand anatomic technique and relies on visual and haptic feedback. Steps in pedicle screw insertion consist of identifying the entry point, removing the cortical cortex of the pedicle, creating the channel, palpation and placing the screws.

In the critical phase of channel creation, the probe is pushed through the pedicle and towards the vertebral body [2]. The required depth is different for different regions of the spine. The advancement of the probe should be smooth and consistent. A sudden change in resistance means that the probe is touching the pedicle wall or the wall of the vertebrae body. In such situations, a sudden downward motion (breach) can occur if the surgeon continues to apply force to the probe [3]. Imaging techniques provide some insight into the morphology of the bone, however, direct visualization within the operating room environment is difficult, and therefore haptics provides relevant sensory information to assist in this surgical task.

Creating a pathway through the pedicle by the free-hand technique is composed of two main degrees of freedom: rotation and linear (translational). Rotating the probe removes the soft cancellous bone and applying force creates linear translational movement along the pedicle axis. Optimal screw insertion relies on the experience of the surgeon and his ability to differentiate the tactile sensations associated with the different textures in the bone when performing channel creation [4]. This is because the surgeon has limited visibility of the internal organs or spinal cord. Complications can occur due to an incorrect entry point, an incorrect trajectory, or a failure to recognize wall breaches. The complications cause neurological issues, visceral organ damage and/or problems with mechanical motion [1,5,6].

Although the accuracy of surgeons is not solely due to the surgeon's experience or lack of experience, studies showed that experienced surgeons have a significantly lower chance of having a medial breach than novices [7]. With the steep learning curve in this procedure, this haptic simulator can allow surgeons and residents to learn and practice the differentiation between proper and improper haptic signals in a low-risk environment. Since this surgery relies predominantly on haptic feedback, the differentiation between proper and improper haptic signals should be adequately taught to the residents. Among the current approaches in the education of surgeons, haptic simulators provide the trainee with the safest and most repeatable environment. Traditional surgical training includes supervised practice on live patients or cadavers. The former risks the comfort and safety of the patient, and also extends the time and cost of the operation in order to allow for corrections to be made. The latter is expensive and also imposes unrealistic physiological responses due to the embalming chemicals and lack of blood pressure in cadavers. Moreover, it is very difficult to assess the practitioners' proficiency through these techniques. Virtual reality simulators provide the trainee with unlimited practice with no time constraints and, by integrating sensors to the simulator, makes it feasible to assess skills [8]. Current simulators usually employ visual and/or touch modalities to replicate the real environment.

A problem with many of the available haptic platforms is that they fail to create realistic effects due to device limitations. For instance, the haptic feedback related to a spine biopsy simulator remained limited to interactions with soft tissues since the haptic device being used was unable to provide high realistic force peaks [9,10]. Most available works focus on the visual aspects of the surgical education [11-13]. As well, most virtual reality simulators for bone tissue procedures involve power drill simulations and not the free hand technique [14,15]. This work adds a linear degree of freedom to the rotary stage of previous work [16] and can simulate the haptic effects associated with the coupled two degrees of freedom involved in the pedicle screw insertion: rotation and linear progression. Haptic model parameters for a spine surgery with normal bone density are clinically tuned within this user study.

Although the proposed haptic techniques in this study are capable of simulating various anatomical scenarios, for the initial prototype virtual clinical testing is only performed for healthy vertebrae with normal size and normal bone density as opposed to an older, osteoporotic bone or a high-density bone in a young patient. The purpose of this pilot study is to examine the feasibility of simulating the haptic effects that accompany the channeling of a pedicle.

Material and Methods

Surgical observation and feedback from surgeons were used to create the haptic sensations. The rotary simulation model consists of two main haptic effects: vibration effects and viscous friction effects. Vibration is modeled as a series of bumps or detents in rotation and a time- varying proportional controller is used for the simulation. Viscous friction effects are generated by a derivative controller and the effects are felt as a resistive torque which increases relative to the speed of rotation. Detent interval, detent width, detent magnitude and viscous friction coefficient are haptic model parameters that are tuned by the users. Details regarding the implementation are fully explained in [17]. Detent interval determines the frequency of vibration. Detent width determines the sharpness of the sensation. Detent magnitude determines the vibration magnitude and viscous friction coefficient determines the magnitude of viscous friction.

Linear haptic effects replicate the vibration and resistance sensation felt as the probe proceeds through the pedicle. An open loop control approach is employed to create the effects. Linear progression is simulated as a piece-wise motion in the presence of the surgeon's vertical force. The frequency, the duty cycle of pulses and the scaling gain are the haptic parameters in the linear stage. Frequency determines frequency of vibration in the linear progression. For a small value, there are fewer steps in a linear progression, resulting in less vibration in a linear movement. Duty cycle determines the smoothness of linear progression. By increasing this value, each motion step can go further with the same amount of force applied to it. If it is at its maximum value (smoothest), then one feels continuous motion without any Pause. The scaling gain determines the speed of motion. This parameter can specify the amount of pressure that should be applied to get movement. Maximum input voltage of the actuator is 12 volts. Given this limitation, when the multiplication of scaling gain and user force gets over the maximum input voltage, the effect remains the same.

Through surgical observations and discussion with expert surgeons, it was found that surgeons rotate and push the probe simultaneously. Rotating while pushing eases clearance of the lattice layer and make the pathway clear for the screws. Another benefit of rotating the probe is that the surgeon can control the speed of progression, as opposed to when the surgeon just pushes along the axis with a higher force. To simulate this, angular velocity of the probe rotation is used in a condition that determines how subtle the rotation should be to allow for linear progression. It is verified through a comparison block whether the angular velocity is larger than a predetermined velocity. This condition controls the function of the coupling switch that passes the linear stage control signal to the actuator. The velocity condition is captured by conducting pilot studies and by receiving surgeons' feedback.

Clinical tests are performed to tune the rotary and linear haptic model parameters such that effects replicate the probe channeling through the pedicle. The focus in this test is on healthy bone with normal density. The test is designed with the focus only on haptic sensations and no graphical interface is presented to the user. The simulator is covered to reduce visual attraction

Participants

A total of 11 surgeons, composed of 8 orthopedic surgeons and 3 neurosurgeons, enrolled in the study. Among the orthopedic surgeons, 1 is a senior, 3 are fellows, and 4 are residents. Neurosurgeons consisted of 1 senior, 1 fellow and 1 resident. The senior surgeons each have 15 or more years of surgical experience. The fellows have 6 - 10 years of surgical experience and medical residents' experience varied between 4 - 9 years. Each participant is provided with consent letter. The protocol of this research was approved by the office of research ethics at the University of Toronto.

Apparatus: Haptic Simulator for Probe Channeling

The experimental platform includes hardware, software, and the interface between them. As seen in figure 1, the mechanical component of the rotary stage includes a fabricated probe handle which is coupled to the shaft of a non-geared DC motor [16]. The probe is machined so that it would feel and operate like the actual probe used by the surgeon. The probe is intended to have no mechanical play. An encoder is connected to the motor to enable measuring of the angular position.

To simulate the linear degree of freedom, an electrical geared motor is used that is capable of supplying very large forces (over 100N). The rotary stage of the device is connected to linear bearings which glide smoothly over the two aluminum posts.

The hardware is interfaced to the computer through the breakout board and data acquisition system (DAQ). The haptic model is implemented in the computer in the Matlab/Simulink programming environment with a discrete time solver at the sampling rate of 1000Hz. The output signals of the haptic simulation model are then sent through the analog channel to the amplifier and from there to the motors. The motors then create torque and force that is felt by the user as haptic sensations [17].

Experimental task

Before beginning data collection, a training session allows participants to learn about the haptic model and the effects. First, the main haptic effects such as the viscous damping effect, the pure vibration effect and the pure linear progression are presented to the participant. Following that, the parameters associated with each effect are introduced. Each model parameter is changed over a wide range of values, while other parameters remain fixed. This allows the surgeon to experience the haptic sensations related to each model parameter.

In the testing session, surgeons are asked to tune the parameters so that the simulation is equivalent in feel to that of a normal, healthy bone. The model parameters are initially set to the data collected from an expert surgeon with more than 25 years of experience prior to the test. While adjusting the first parameter, all other parameters are set to the expert's level. The researcher on the workstation side is able to use the graphical interface to tune the parameters based on the surgeon's verbal instructions. The target parameter is tuned twice; once initialized with a random value above the expert's level and once below the expert's level. The average of the two results is then calculated and set to the device. Following that, the same procedure is repeated for tuning the next parameter, with the only exception that the previously tuned parameter is kept at the tuned level while others are still at the expert's level. The order of parameter tuning was from the biggest effect to the smallest based on expert surgeon's assessment, i.e. for the rotary stage parameters: detent magnitude and viscous friction coefficient, detent interval, detent width; and for the linear stage parameters: duty cycle, frequency and scaling gain.

Once all parameters are adjusted and set to the device, surgeons are given another chance to feel their tuning and perform any final tuning that they may think is needed. Tuning all parameters at the same time could be confusing and misleading but tuning each parameter separately could also cause a response bias. This step of final tuning is aimed to reduce the participant's response error.

Figure 1: *Overview of the haptic simulator.*

Results

Introducing the reference set

An analysis is performed on the recorded values to find the reference set of values that is estimated through the surgeon's interpretation of the surgical scenario. 95% confidence intervals (CI) are used to estimate the intervals that the true mean values for the population are expected to lie with 95% confidence [18] (Table 1).

	95% Confidence Interval				
Parameter	**Lower**	**Upper**	**Median**	**Mean**	**Std.**
Rotary stage Detent interval	1.46	2.37	2	1.91	0.59
Detent width	0.36	0.61	0.5	0.48	0.16
Detent magnitude	0.46	0.77	0.6	0.61	0.21
Viscous friction	10.19	16.04	15	13.11	3.81
Linear Stage Duty cycle	0.60	0.74	0.65	0.67	0.09
Frequency	8.01	9.88	8.5	8.94	1.22
Scaling Gain	0.14	0.20	0.16	0.17	0.04

Table 1: *Summary statistics.*

We refer to these intervals as our benchmark reference set and they could be used in the future as values to set in the haptic simulator. Using Interquartile range (IQR), four outliers are found [18]. Among the rotary stage parameters, detent interval and detent width have one outlier. As well, among the linear stage parameters, frequency and duty cycle contained one outlier each. These outliers were all from the fellow and resident neurosurgeons. This may be due to this procedure being less commonly performed by neurosurgeons. As well, these participants conducted a surgical workshop on cadavers within three days of the clinical testing and that could potentially have affected their perception of operating on a healthy bone. To maintain consistency, all parameter values from these two neurosurgeons are removed from the data set before performing CI computation.

It is not feasible to find exact parameter values that generate the most realistic haptic sensations on a normal bone. First, there is often a range of bone that falls within the normal category. Also, different surgeons have different haptic perceptions since different cues are combined for each individual to form a perception. It can also be quite difficult trying to recall haptic sensations. However, we can expect that the true means for these parameters in the populations of surgeons would fall within these CIs based on the data from our sample.

It can however, be determined that there is sufficient evidence to conclude that at least 50% of surgeons can perform within 25% tolerance of the average of the two senior surgeons' tuned values for five model parameters. The completion rate (proportion within 25% tolerance of expert's values based on sample size of 9) is calculated [19]. The exact probabilities from binomial distribution are then found to show the chance that the observed proportion comes from a population of completion rates of greater than 50% [19]. Five model parameters along with their exact probability are detent interval (p = 62.30%), viscous friction coefficient (p = 82.81%), duty cycle (p = 98.93%), frequency (p = 94.53%) and scaling gain (p = 82.81%) (Table 2). For our pilot study, these high probability values for five parameter are good evidence that our introduced reference set is worth pursuing.

Assessing the difference among different groups of surgeons

We would like to determine whether significant differences exist among resident, fellow and expert surgeons. However, the sample size is too small for each category to be able to claim a powerful result.

Parameter	Average of seniors'	Completion	Exact
Rotary stage Detent interval	1.85	55.6 %	62.30%
Detent width	0.4	33.3%	17.19%
Detent magnitude	0.85	44.4%	37.70%
Viscous friction	15	66.7%	82.81%
Linear Stage Duty cycle	0.7	88.9%	98.93%
Frequency	8.25	77.8%	94.53%
Scaling Gain	0.16	66.7%	82.81%

Table 2: *Percentage of surgeons able to adjust the simulator parameters to within 25% of the average of the two expert surgeon's values (N = 9).*

Analysis of Variance (ANOVA) is employed to compare means of group for all parameters except for the detent width that violates homogeneity of variance [20] (Table 3). Outliers are excluded from data. Results show statistical significance for frequency in the linear stage ($p = 0.005$).

Detent interval, detent magnitude, viscous friction coefficient, duty cycle and scaling gain, all have p-values larger than the significance level (0.05) and so none of them were able to discriminate between the three groups. However, detent magnitude has a small p-value (0.13). With more participants, we may find enough evidence to reject the null hypothesis.

To examine the null hypothesis for detent width for which the difference in its variance is statistically significant, Welch's test is conducted [20]. Test result ($p = 0.32$) reveals that there is no significant difference among the means of the resident, fellows and senior surgeons.

Looking interval more closely at the data (Table 3), among 7 parameters, senior surgeons have a narrower range for four parameters including the detent in- terval, the viscous friction coefficient, the duty cycle and the frequency of vibration. Interestingly, they have an agreement for two of the parameters, the viscous friction coefficient in rotary stage and the duty cycle in linear stage. However, more senior surgeons should be recruited to further validate such results.

Discussion

There are relatively few surgeons in Canada performing pedicle screw insertion. Therefore, participant recruitment was a major challenge for the clinical tuning of parameters. Moreover, not all surgeons perform the surgery regularly and most residents develop their surgical skill set on cadaver bones rather than the healthy bones of young patients, who comprise the highest volume of scoliosis surgical cases. Despite the small sample size, among the participants is a senior surgeon who performs a major proportion of all this type of surgery in Canada.

The participants' expertise were quite varied by multiple factors including their level of training, number of performed operations in operating room, number of performed operations on bony tissue, and the number of operations performed specifically for pedicle screw insertion. Some had more surgical experience with robotic tools. The neurosurgeons less often perform this procedure, performing them sometimes only once or twice a year.

The senior and fellow surgeon participants found the haptic training simulator to be a useful tool in teaching probe channeling in pedicle screw insertion. The current device is capable of simulating the various force and torque effects a surgeon feels in this surgery. The

Parameter name		Expertise level	N	Mean	Std. Deviation	Significance level (ANOVA)
Rotary Stage	Detent interval	Senior	2	1.85	0.56	0.98
	Fellow		3	1.89	0.82	
	Resident		4	1.96	0.61	
	Detent width	Senior	2	0.40	0.28	0.32†
	Fellow		3	0.40	0.12	
	Resident		4	0.59	0.09	
	Detent magnitude	Senior	2	0.85	0.14	0.13
	Fellow		3	0.61	0.24	
	Resident		4	0.50	0.10	
	Viscous friction coeff.	Senior	2	15	0.00	0.52
	Fellow		3	14.16	2.75	
	Resident		4	11.370	54.11	
Linear Stage	Duty cycle	Senior	2	0.70	0.00	0.83
	Fellow		3	0.68	0.08	
	Resident		4	0.65	0.12	
	Frequency	Senior	2	8.25	0.35	0.005
	Fellow		3	10.42	0.80	
	Resident		4	8.19	0.47	
	Scaling gain	Senior	2	0.15	0.06	0.617
	Fellow		3	0.19	0.05	
	Resident		4	0.16	0.02	

Table 3: *Summary statistic based on expertise level.*

†Welch's test result.

current simulator is a first of its kind in the field of spine surgery, with the ability of replicating the haptic sensations in free-hand probe channeling through the bone with high-fidelity haptic feedback.

Study results suggest that senior surgeons have a relatively smaller range of tuned parameter variation in comparison to the resident and fellow surgeons for most haptic model parameters, indicating that senior surgeons have developed more precise and consistent haptic perception. Noting that there are only two senior surgeons in the study, additional experienced surgeons are required for further validation in future research. However, these initial results indicate the possibility that these tighter tuned parameter variations could be used to screen trainees for how close their skill level approaches those of the expert surgeons.

Some haptic parameters are more sensitive than others in an operation. According to the ANOVA test results for frequency (linear stage parameter), the means are significantly different among the three group. Also, for detent magnitude, significance value is very close to the significance level (0.05). This indicates that one practical way to see if training helped is to observe the pattern in these two parameters. They can be employed as a metric to differentiate the trainees in terms of haptic skill performance.

Conclusion and Future Works

To our knowledge, this simulator is the first of its kind that is able to simulate high forces created in the free-hand technique probe channeling in pedicle screw placement. The focus of the current study was on simulating haptics sensation for normal healthy bone. Pedicle screw insertion is performed on a large variety of patients who present with various spinal dis- orders. Future work involves data collection for other anatomical scenarios such as osteoporotic bone. We will need to broaden the study sample size and use a higher bandwidth actuator.

Since this haptic simulator is planned to ultimately serve as a surgical training tool, future direction for this work includes determining appropriate training techniques and investigating ways for surgical skill assessment. The setup would employ the reference set of values tuned within the clinical testing for various anatomical scenarios. Through an interactive training system, the proficiency of the surgeons can be tracked. This simulator received positive feedback on its usefulness in surgical training. This work is an initial step toward the development of haptic simulator that can be used as a tool to train the force-based surgical skills of surgeons for different surgical scenarios.

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