Pedicle Screw Insertion Surgical Simulator

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Abstract. Scoliosis is a sideway spinal deformity. If the curvature is measured to be more than 50°, surgery is required to straighten the spine. Pedicle screw insertion is a procedure that requires the placement of screws from the pedicle into the vertebral body. A rod is used to connect all the pedicle screws. The spine is straightened during the connection process. One of the most common techniques used for pedicle screw insertion is called the free hand technique, where the surgeon creates a screw channel by manually probing into the spine. The surgeon relies strongly on haptics feedback. However, small changes in force or direction can cause the probe to breach out of the spine. If the breach reaches the spine medial, the spinal cord could be damaged. Even experienced surgeons can not prevent breach.

In this paper, a pedicle screw insertion simulator is developed which combines visual and haptics sensation to recreate the channel creation process of the surgery. The device includes a linear actuator and a rotary motor. The simulator is tuned to four different surgical scenarios by 2 expert surgeons. Ten additional surgeons are asked to participate in the clinical study. Four research questions were examined: 1. Can experience help the surgeon improve correct breach recognition rate? 2. Can experience help the surgeon improve overall correct scenario recognition rate? 3. Is there any performance difference between surgeons with different experience levels? 4. Can the simulation trials become a learning tool for the simulation tasks? It was concluded that there is no statistically significant relationship between the wrong breach or total wrong recognition rate and surgical experience. Furthermore, there is statistical significance in the hard probing scenario between surgical experience and vertical force variance. Lastly, ANOVA analysis is used to examine breach force and velocity performance between three trials to evaluate learning with increase trials. The results are close to being statistical significant.

Keywords: Virtual reality · Scoliosis · Haptic · Surgical simulator Surgery · Pedicle screw insertion

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1 Introduction

More than 54% of adults will experience back pain during some part of their life [1,2]. Scoliosis is a sideway spinal deformity. The deformity causes the spine to form into a "S" or "C" shape. Scoliosis is determined if the curvature is bigger than 10° [3]. Scoliosis itself generally does not cause any pain. However, the lateral curvature can cause balance issues which can lead to problems such as back pain. If the curvature between any two point of the spine is measured to be more than 50°, the patients can feel significant discomfort. In such cases, surgery is required to straighten the spine [4].

1.1 Pedicle Screw Insertion

Pedicle screw insertion is a common procedure for scoliosis surgery [6]. The technique requires the placement of pedicle screws from the pedicle into the vertebral body (see Fig. 1). After all screws are placed into the spine, a rod is used to connect the screws together (see Fig. 2). Like all spine related surgery, this technique has many risks such as spine fluid leakage, nerve damage, and spine fracture.

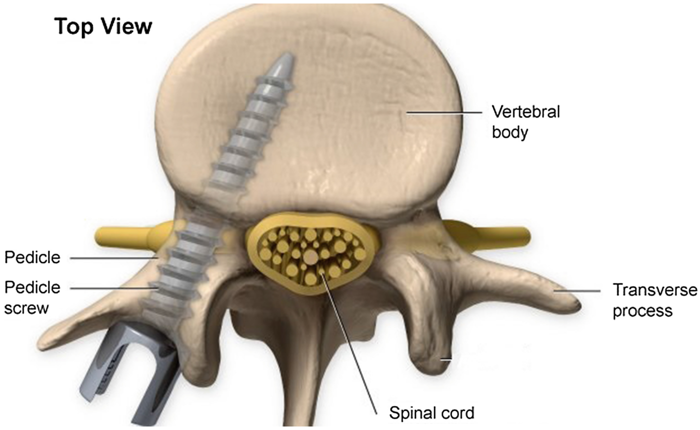

Fig. 1. Pedicle screw inside the pedicle [5]

One of the most common technique used for pedicle screw insertion is called the free hand technique [6,8]. During the free hand surgery, the surgeon has to probe manually into the spine without any visual feedback. It requires tactile haptics feedback, particularly because the bone structure is often deformed due to scoliosis [9]. In order to place the screw into the vertebra, a channel has to be created in the spine first. This procedure is called the channel creation procedure.

A curve or straight pedicle probe is used to channel though the cancellous bone. The surgeon requires haptics feedback to identify the position of the probe.

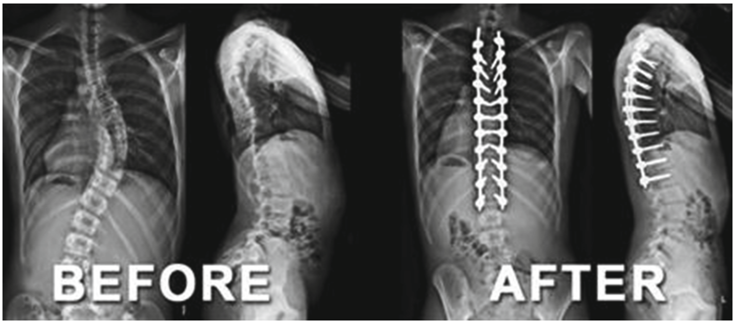

Fig. 2. Pedicle screw insertion before and after surgery [7]

Sudden changes in resistance could indicate breaking out of the pedicle bone and into the soft tissue. This event is called a breach [10]. If the breach is in the direction of the vertebral foramen, it is called medial breach. Due to the limited operating space, this is by far the most challenging part of the surgery. After removing the pedicle probe, the surgeon has to make sure only blood is flooding out of the spine. Any other fluid would indicate a breach.

There have been many studies on the accuracy of pedicle screw insertion. In one review conducted from 21 studies with 4570 pedicle screws in 1666 patients [6], the reported screw misplacement rate is around 11%. Revision surgery was performed on 12 patients for misplaced or loose screws. In another review, the reported accuracy rate from different studies for free hand pedicle screw insertion ranged from 69% to 94% [11].

Surgeon experience is an important factor that can affect the accuracy of free hand pedicle screw insertion. In a study conducted by Samdani et al. [12], 856 samples was collected and reviewed. The breach rate for surgeons with less than 2 years experience is 12.7%, 2–5 years experience is 12.9%, and 5 or more years of experience is 10.8%. There is no statistically significant difference between the three groups. However, for more serious medial breach, the breach rate for surgeons with less than 2 years experience is 7.4%, 2–5 years experience is 8.4%, and 5 or more years of experience is 3.5%. This is correlated by another study conducted by Lehman et al. [13], where it has shown that the surgeon's medial breach rate using the free hand technique decreases over an 8 year period. Due to the complexity of channel creation procedure, a simulator is developed as a training tool for the surgery. This is the main focus of this paper.

2 Previous Work

Luciano et al. [14] have developed a simulator that combines haptics with virtual reality. A CT scan is used to form the basic model for 3D spine. As for the haptics sensation, the group used an ImmersiveTouch haptic stylus to create force feedback. A lumber Sawbones spine model was used to evaluate the effectiveness of the simulator [15]. Although the haptics feedback force is minimal, the study did show the simulation can be helpful for training a non-expert in complex tasks [16].

In another study, Xing et al. [17] used the Phantom haptics device as the probe to simulate the pedicle insertion process. Spine modelling and collision detection are two important aspect of this paper. However, there was no clinical testing for this approach.

The main drawback of the existing haptics simulators is the lack of large force simulation. In order to simulate breach, a sudden change in force and velocity is required. All the existing simulators are unable to provide enough force in such an event.

3 Experimental Apparatus

The haptics surgical simulator developed by University of Waterloo in conjunction with SickKids Hospital is shown in Fig. 3. There is a rotary stage and a vertical stage. The rotary stage provides surgeon with a sense of pedicle density and the vertical stage can simulate the depth of the pedicle.

The rotary stage of the haptics simulator is a 1DOF haptics simulator for probe channelling during pedicle screw insertion surgery [19]. The simulation

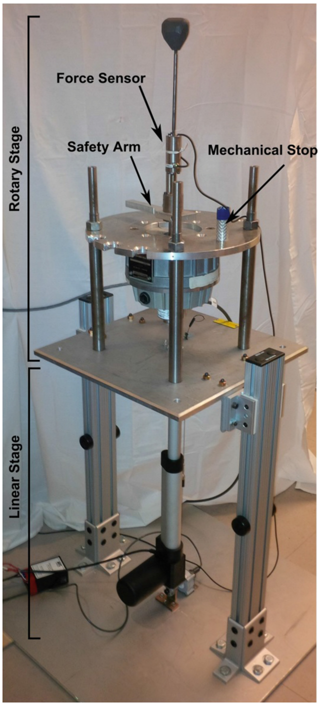

Fig. 3. Surgical simulator after phase two [18]

is performed by the surgeon from a probe at the top of the simulator. A force sensor is attached to the bottom of probe. It is used to measure the surgeon's applied force and torque on the probe. A servo DC motor is positioned at the bottom of the simulator. The motor is used to simulate the force and torque feedback of the probe's rotational movement inside the pedicle.

The linear stage is added underneath the rotary stage to provide the vertical movement [18]. The vertical probing process requires high speed motion with precision control. The actuator should be able to handle the large downward force created by the surgeon. The typical force created by a surgeon is around 150N [20]. Moreover, the surgeon is required to pick up subtle changes in force and dynamic. Quick response is important in such situations. A Bimba linear actuator with stepper motor and integrated driver was chosen, and the actuator is able to provide an initial thrust of 667N and top speed of 0.23 m/s. At 0.15 m/s, the actuator has an thrust of 180N [21].

The linear actuator is designed to run in real time closed loop control. The actuator is set to velocity mode, which the actuator is driven by a velocity command. The controller frequency is set to 1 kHz, which is also the human haptics resolution limit [22]. Since motor speed is directly related to the input current from the driver, the actuator controller can automatically increase operation current to account for the additional external force and friction applied on the actuator. Due to the fast response time of the driver, a sudden increase in external force should not affect actuator's performance.

4 Controller

The rotary stage involves a gain-scheduling PD controller strategy to create viscous friction and detent effects [19]. For the linear stage, the admittance controller uses external force to manipulate the movement of the surrounding environment or the virtual surface.

When the surgeon is probing inside the pedicle, one important detail is that the surgeon has to start rotating the pedicle before applying any vertical force. Therefore, a switch condition is added to the linear stage admittance controller. The admittance controller is only active after the rotary velocity is more than 10 degrees per second.

For the linear stage admittance controller, a virtual mass spring damper system is used to simulate pedicle insertion dynamics. The behaviour of the actuator is determined by a linear second order system.

$$M(\ddot{x} - \ddot{x}_0) + D(\dot{x} - \dot{x}_0) + K(x - x_0) = F_{ext} \tag{1}$$

where: M is the Virtual Inertia Coefficient, D is the Virtual Damping Coefficient, K is the Virtual Stiffness/Spring Coefficient, $x, \dot{x}, \ddot{x}$ are the Actuator Position, Velocity, and Acceleration, $x_0, \dot{x}_0, \ddot{x}_0$ are the Equilibrium Position, Velocity, and Acceleration, and F_{ext} is the External Force.

Because of the high stiffness and damping of the pedicle, the relatively small mass of the pedicle is assumed to be zero. The actuator position is also assumed to be same as the desired actuator position. This is due to the fast response of the linear actuator, where the difference between desired position and actuator position is very small. The external force is said to be equal to the control force F assuming the inertial force are small. Assuming a virtual mass spring damper system have zero velocity at the surface of the system, the equilibrium velocity can be assumed to be equal to zero. Thus, the desired velocity feed into the actuator can be obtained from the following controller:

$$\dot{x}_d = (F - K(x_d - x_0))/D \tag{2}$$

Under normal pedicle screw insertion surgery, the probing process can be described as breaking though layers of a lattice. From the haptics perspective, the sensation can be described as a series of strong vibrations. This is due to the non-uniform density distribution of the pedicle bone. To simulate this effect, the vertical probing length is broken into many small layers, each layer represented by its controller in Eq. (2). An illustration of the probing process can be seen in Fig. 4(A). The spring and damping coefficient is unique to that layer. A switching controller is added to change the parameter for each layer (see Fig. 4(B)). Each layer is assigned with its own depth. The system will switch to a new layer once the probe reaches the end of the previous layer. A sudden change in resistance is felt by the operator.

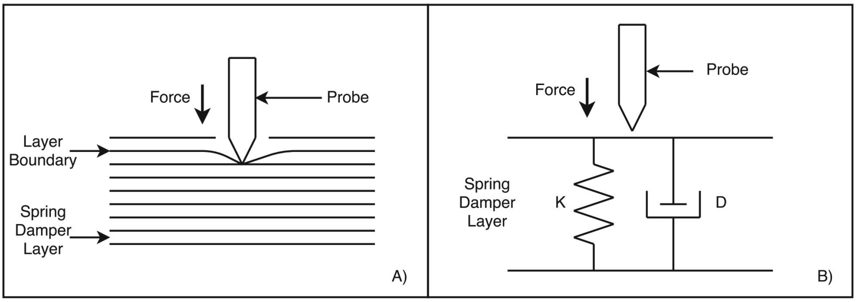

Fig. 4. Spring damper model of the pedicle bone. (A) Probe drilling into the pedicle layer. (B) Spring and damper inside each layer

Breach simulation is an extension to the normal pedicle probing procedure. In most cases, the breach haptics sensation is different compared to normal probing. The breach simulation procedure can be split into two parts. The first part is before the breach, where the probe is experiencing increased resistance. The second part is after the breach occurred, where the resistance is minimum. The controller uses two different sets of parameters to simulate the haptics sensation.

In most surgery conditions, there are obvious warnings before breach occurs. Surgeons have to recognize these warnings in order to avoid breach. The most important warning is the increasing probing resistance. This indicates the probe have reached the outer cortical of the pedicle (see Fig. 5). More often then not,

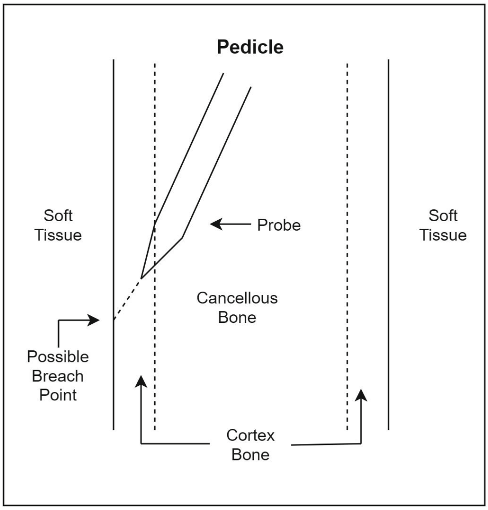

Fig. 5. Illustration of breach reaching cortex bone of the pedicle

the increase in resistance is due to narrow pedicle size. If the surgeon is determined to continue probing without stopping, then the surgeon has to increase the navigation force to overcome probing resistance or correcting the probe position. If the probe reaches past the pedicle wall, breach will begin. The breach resistance is decreased significantly. The breach point is identified as breach threshold in the simulation. This is the largest possible force exerted on the probe before breach. The breach velocity is determined by the breach force.

For the implementation, a reference location is used as a starting point for the increase in probing resistance. A parameter called resistance interval R_i is used to model the distance travelled by the probe between the reference location and the actual breach location. When the probe is travelling during this interval, the probing resistance is increased linearly. A scaling parameter, resistance factor R_f, is used as the slope of the change. The spring and damping coefficient from Eq. (2) will increase based on the resistance factor and probe location.

The most common breach scenario is breaching into surrounding soft tissues. This haptics sensation is much softer than probing inside the pedicle. In order to adapt to this change, the vertical direction admittance controller's parameters are readjusted for the simulation. If a breach has occurred, then the resistance of simulator will drop dramatically, which results in sudden drop in the vertical resistance. The low breach resistance is accomplished by setting the stiffness coefficient to zero, and the damping coefficient to a much smaller number. The desired velocity feed into the actuator from Eq. (2) is now simplified to the following equation:

$$\dot{x}_d = F/D_b \tag{3}$$

where D_b is the breach damping coefficient.

During breach, the soft tissue and body fluid can reduce rotational resistance, in most cases, the rotational resistance is close to zero. A rotational switch is implemented to shut down the rotational motor after breach has occurred. Since the rotational motor is a servo motor, shutting down is motor does not lock the rotation. Therefore, the rotational resistance is close to zero.

In total, four scenarios were created for the clinical study. These scenarios are hard bone probing, soft bone probing, lateral breach, and in-out-in probing. The illustration of these scenarios is shown in Fig. 6. The first two scenarios (hard probing and soft probing) are variation of normal probing inside the pedicle. The simulation is achieved by scaling the vertical tuning parameters according to the bone density. Each scenario has its own specific spring damper system. The lateral breach scenario is breach to soft tissue as explained in the previous paragraph. The in-out-in probing is an extension to lateral breach. In this case, after the probe breaches into the soft tissue, due to the curvature of the pedicle, the probe can be navigated back inside the pedicle. The implementation of this part is repeat of the lateral breach but includes a restoration to the previous bone probing scenario [20].

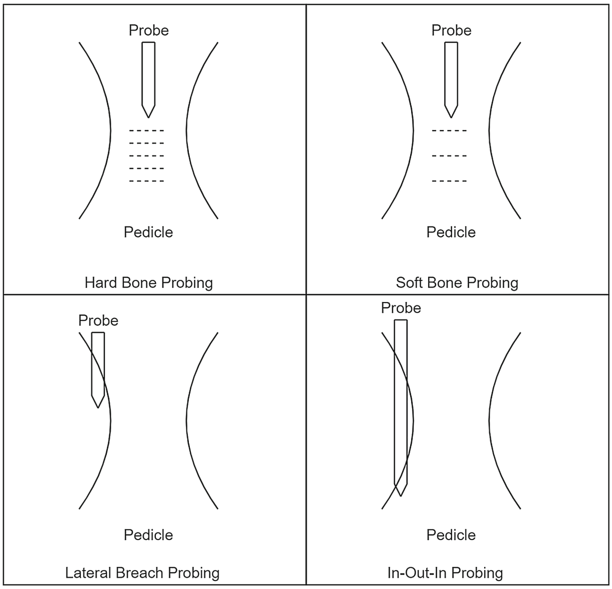

Fig. 6. Four simulation scenarios developed by the surgeons

In order to simulate real surgical procedure, 8 unique parameters have to be tuned in the linear stage. The parameter are shown in Table 1.

The simulator tuning session was conducted by Dr. Zeller and Dr. O'Shea from Toronto SickKids Hospital. Dr. Zeller is a world class spine surgeon with over 25 years of experience [23]. And Dr. O'Shea has more than 5 years of

Table 1. Linear stage tuning parameters

Normal probing parameters	Breach parameters
Spring Coefficient K	Resistance Interval R_i
Damper Coefficient D	Resistance Factor R_f
Equilibrium Point x_0	Breach Interval L_b
Equilibrium Interval Scale L	Breach Damping Coefficient D_b

experience [24]. Details of the tuning process can be found in [25]. This will be considered to be the benchmark or true parameter values. The other participants will be studied in comparison to these expert's tuned parameter values.

5 Experimental Procedure

In order to evaluate the effectiveness of the simulator, a clinical study is conducted with 10 other surgeons. All of them are orthopedic surgeons from Toronto SickKids Hospital. The surgeons are composed of 2 senior surgeons, 4 fellows, and 4 residents. Participants were asked to complete a set of 12 trials on the surgical simulator. The trials can be broken down into four different scenarios with each scenario performed three times. The order of the trials was randomized.

For each trial, the participant's objective is to create a screw channel using the probe in a single motion. Ideally, the participant should reach the designated probe stop point without any motion pause. This includes breach scenarios.

For the study, the participants are blind to the number of scenarios and the trial order. However, the participant is informed that the test scenarios are free hand pedicle screw insertion simulation that includes potential breach simulation. After each trial is completed, the participant is asked whether they experienced a breach during the trial. If the answer is yes, then a additional question is asked to confirm the location of the breach. The simulation is completed when the participant completes all 12 trials.

6 Discussion

6.1 Research Question No. 1

Can experience help the surgeon improve correct breach recognition rate?

H_0: The surgeon's experience background has no effect on breach recognition rate.

The summary of the study results on number of incorrect breach identifications is shown in Table 2. The wrong breach identification number is retrieved from the incorrect breach recognition from lateral breach and in-out-in breach. In total, the surgeons performed 6 breach trials. The average correct breach

Table 2. Incorrect identification results from lateral breach and in-out-in breach.

Surgeon experience (years)	# of wrong breach identifications/ total breach trials
6	2/6
3	1/6
1	0/6
1	1/6
0.5	0/6
0.33	0/6
0.1	0/6
0	3/6
0	1/6
0	1/6

identification rate for the 10 surgeons is 85%. In order to analysis the results, a linear regression t-test is conducted on number of wrong breach identification results with respect to the surgeon's experience (Table 3).

Table 3. Regression analysis results for surgeon's experience vs number of wrong breach identification.

Predictor	Coefficient (β_m)	SE coefficient (SE(β_m))	T(t_m)	P(p_m)
Constant ($m = 1$)	0.7105	0.3796	1.8717	0.0981
Years of experience ($m = 2$)	0.1588	0.1744	0.9106	0.3890

By following the standard procedure of regression analysis, a *p*-value is obtained from the test. The results of the test is shown in Table 5. It was found that the *p*-value number of wrong breach identification test is 0.3890. In this test, the *p*-value is significantly larger than the typical significant level of 0.05. Therefore, the null hypothesis is not rejected. Based on the results, surgeon's experience has no effect on the number of wrong breach identifications.

6.2 Research Question No. 2

Can experience help the surgeon improve overall correct recognition rate?

H_0: The surgeon's experience background has no effect on overall wrong recognition rate.

The summary of the study results on number of incorrect identifications is shown in Table 2. The number of wrong identifications is retrieved from all four scenarios, this includes the wrong breach identifications. In total, the surgeons

Table 4. Total number of incorrect identification results

Surgeon experience (years)	Total # of wrong identifications/ total trials
6	3/12
3	3/12
1	2/12
1	1/12
0.5	3/12
0.33	0/12
0.1	0/12
0	5/12
0	2/12
0	4/12

performed 12 trials. The average correct identification rate for the 10 surgeons is 81.8%. Similar to research question 1, a linear regression t-test is conducted on number of wrong identification results with respect to the surgeon's experience. The results are shown in Table 5. It was found that the *p*-value for total number of wrong identification test is 0.6920, which is not statistically significant. Therefore, the null hypothesis is not rejected. It is interesting to note that the p-value is higher in wrong breach identification test than the wrong identification test (Table 4).

Table 5. Regression analysis results for surgeons experience vs total number of wrong identification.

Predictor	Coefficient (β_m)	SE coefficient ($SE(\beta_m)$)	T (t_m)	P(p_m)
Constant ($m = 1$)	2.1537	0.6494	3.3164	0.0106
Years of experience ($m = 2$)	0.1225	0.2983	0.4107	0.6920

6.3 Research Question No. 3

Is there any performance difference between surgeons with different experience levels?

H_0: Surgeon's experience has no effect on the measured data such as operation time, breach time, velocity variance, mean force and force variance.

In order to evaluate the difference in the surgeon's performance with different experience level, the collected data was examined and processed to retrieve numerical values such as operation time, velocity variance, mean force, and force variance. In order to account for the variation between trials, the mean of each surgeon's three trials results was taken. Because there is no sudden motion change in the soft probing and hard probing scenario, the complete duration of the trial was examined. For the breach scenario, due to the short length of normal probing travel in breach scenarios, only the breach section of the trial was examined.

Due to the small sample size, possible outliers may have strong affects on the regression test. A modified Z-score test is conducted before each regression analysis [26]. A outlier is identified if the absolute value of the modified z-score is bigger than 3.5. The M-estimation robust regression using bisquare estimator is used for the analysis.

The result p-value of the robust regression analysis is shown in Table 6. In most of robust regression analysis conducted, no trend or significance was discovered from the data. However, the force variance does provide some interesting results. First, The p-value of robust regression analysis for hard probing force variance is 1.34e−4. Because the p-value is less than 0.05, the null hypothesis is rejected. For the soft probing, surgeon 10 is removed from the data set due to high z-score value of 8.72. The p-value of the robust regression analysis is 0.1049. Although this is the above the 0.05 statistically significant level, more data samples could potentially reject the null hypothesis. All other p-values are much bigger than 0.05, which is not statistically significant.

The results of such a small force variance p-value is probably because experienced surgeons are more comfortable with the surgery. They are able to change their applied force according to the simulation haptics feedback. The inexperience surgeons are more focused on completing the task, which means they are more mechanical with less force variance. It is also interesting to note that from research question 2, experienced surgeons did not perform better compared to inexperienced surgeons in overall recognition rate. This indicate that improving force variance performance can not help surgeons in better recognition rate. The large variance may prevent surgeon from recognizing the drop in resistance during breach event. It could be interesting to find if lowering expert's force variance can lead to better recognition rate.

Table 6. Robust regression analysis p-value.

	Soft probing	Hard probing	Lateral breach
Operation time	0.5784	0.9792	0.3269
Velocity variance	0.629	0.8164	0.2707
Force variance	0.1049	1.34e−4	0.3424
Mean force	0.9233	0.3969	0.3838

6.4 Research Question No. 4

Can the simulation trials become a learning tool for the simulation tasks?

H_0: Simulation trial cannot be a learning tool for the simulation tasks.

The main goal of the simulator is to help new surgeons prepare for breach event. One effective way is to examine if there are any progress in participant's results over the course of the study. In the analysis for breach event, the data was split into three groups based on each participant's trial sequence. One way ANOVA was used to evaluate between the three trials. The main goal is to find out if surgeons is able learn or adapt during the study and if there is any difference in performance between first, second, and third trial. The resulting p-value is shown in Table 7. One of the most importance information for breach is the breach velocity. The p-value from ANOVA for breach velocity is 0.0627, which is close to statistically significant. The p-value for breach mean force is at 0.0693. Because both p-value is above statistically significant of 0.05, the null hypothesis is not rejected. Although the above two numbers are not statistically significant, it is interesting to further analyse these data with a larger sample size as they are very close to significant. This potentially can prove there is performance difference from the first trial to the third trial and the simulator is a great learning tool for the tasks.

Table 7. One way ANOVA p-value

	Breach velocity	Velocity variance	Force variance	Mean force
p-value	0.0627	0.2064	0.1008	0.0693

7 Conclusion and Future Research

Pedicle screw insertion surgical simulator is a new kind of training simulator. It is able to simulate the hardest and most dangerous part of the pedicle screw insertion surgery, which is the pedicle channel creation process. A simulator tuning session was conducted with help of 2 expert surgeons and four scenarios were created to simulate the complex events that can happen in a real surgery. There were 10 other surgeons who were asked to conduct in a clinical study.

By using linear regression analysis on incorrect recognition and incorrect breach recognition with respect to surgeon's experience, it was concluded that there is no statistically significant relationship between the wrong breach recognition rate and surgical experience. In addition, there is no statistically significant relationship between the total wrong recognition rate and surgical experience.

Further analysis was conducted using the collected measurements. In the hard probing scenarios, it was found that surgical experience has an effect on vertical force variance, where the more experienced surgeons tend to have a larger operating range. The soft probing's force variance is also very close to statistically significant. With help of more data, it may be possible to reject the null hypothesis.

The difference between the trials of the same scenario were also analysed. This was used to evaluate whether the simulator is an effective training tool and if the surgeons did adapt over the study time. One of the most important indicator for this analysis is the breach data. By using ANOVA, it was found that the p-value for breach velocity is 0.0627. The p-value for breach mean force is at 0.0693. Although both are not considered statistically significant, they are close and could be interesting to further analyse the data with a larger sample size.

In terms of future research, this project should continue collecting data from more surgeons. Currently, there are only 10 participants conducted the clinical study. Many analyses such as the breach velocity regression analysis are close to statistically significant. A larger sample size could potentially help reject the null hypothesis. Furthermore, the larger sample size could lead to new finding that were previously ignored due to Type I error. Lastly, it would be interesting to re-conduct the study with the participants after a certain period of time. Since many participating surgeons currently have minimum experience in the pedicle screw insertion surgery, it may be interesting to find if there is any progression or regression in their surgical skill after a period of study in pedicle screw insertion.

The current haptics sensation tuning and scenario design was only completed by two expert surgeons. From the clinical study, it was clear that many surgeons operate differently, and even expert surgeons can have significant different operating techniques. The simulator could be greatly improved if more expert surgeons were involved in the tuning process. This can lead to creation of a universal scenario.

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