Instrumentation of the Loss-of-Resistance Technique for Epidural Needle Insertion

Denis Tran*, King-Wei Hor, Allaudin A. Kamani, Victoria A. Lessoway, and Robert N. Rohling, *Member, IEEE*

***Abstract*—Epidural anesthesia is the most common form of anesthesia in obstetrics. The loss-of-resistance to saline injection is used to confirm when the needle tip enters the epidural space. This procedure is highly dependent on skill and expertise, so it is useful to quantify the tissue resistance during insertion. Sensors are used to measure the force and displacement of the plunger of the syringe and the pressure at the needle tip. A model is also developed to estimate the pressure from the force and displacement. Tests are first performed on porcine tissue to compare the continuous-pressure and intermittent-pressure versions of the technique and to compare the paramedian and midline needle approaches. The accuracy of the pressure model is 12% of peak pressure for the continuous technique and 20% for the intermittent technique. Significant differences in injection flow rate were also found for the muscle, interspinous ligament, and ligamentum flavum encountered in the two approaches. A small clinical study on human subjects was performed and again significant differences were found in flow rate for different tissues. These quantitative results improve the understanding of small differences in feel that have been previously known qualitatively and may help in the development of simulators.**

***Index Terms*—Anesthesiology, biomedical laboratories, modeling, transducers.**

I. Introduction

IN OBSTETRICS, a patient may require the use of anesthesia to ease the pain of labor or a cesarean section. Epidural anesthesia is the most common form of anesthesia used for these purposes. To administer the anesthesia, a needle is inserted into the lumbar epidural space located approximately 20–90 mm below the skin [1]. As anesthesia may be required to be injected at different times, a catheter is inserted through the epidural needle into the epidural space and remains there until anesthesia is no longer needed. Although epidural anesthesia has been practiced for decades, the failure rate remains 6%–25% [2], [3], and the procedure is considered more difficult than other regional anesthesia procedures [4]. A failed epidural needle insertion procedure, in which the needle punctures the dura mater just below the epidural space, may cause the patient to experience headaches, or in more severe cases, paralysis or death [5].

The needle insertion is considered a blind procedure. The standard method of confirming entry into the epidural space is through the feeling of loss-of-resistance (LOR) [6]. To begin, the patient's back is palpated, and by using external landmarks such as the iliac crest, the L2–L3 interspace (between lumbar vertebra 2 and lumbar vertebra 3) or L3–L4 interspace is located. The epidural needle is then partly inserted in the interspinous ligament and a saline-filled syringe is attached to the needle. Force is applied at the plunger to get a feel of the resistance to saline injection by the tissue at the needle tip. This haptic feedback helps the physician determine the location of the needle tip within the different tissues. The needle is further inserted until the tip reaches the ligamentum flavum, and a high resistance to injection is felt as feedback. As the needle tip traverses the ligamentum flavum, it enters the epidural space, a cavity, where the saline is easily injected, hence the LOR. The LOR is therefore an inferred phenomenon for detecting the epidural space [7].

There are several variations in the way the LOR technique can be performed. Some physicians use an air-filled syringe rather than a saline-filled syringe [8], [9], although saline is slightly preferred [7]. Furthermore, the pressure on the plunger of the syringe can be applied using a continuous technique or using an intermittent technique. In the continuous pressure technique, an approximately constant force on the plunger is maintained throughout the whole process, whereas in the intermittent technique, an oscillating force is applied on the plunger. In one study, 58% of physicians in the U.K. use the continuous pressure technique and 16% use the intermittent pressure technique [10]. Both pressure techniques normally consist of the epidural needle being inserted in the midline and traversing the interspinous ligament. Another variation uses a paramedian approach [6] in which the needle is inserted lateral, about 2 cm to the midline, and at an angle of 10°–25° [6] into the muscle and then into the ligamentum flavum and the epidural space, as shown in Fig. 1.

It is impractical to provide substantial training on animals or cadavers, and current simulators capture only a portion of the full realism of the actual tissue resistance [11], [12]. Practice on human subjects remains the standard and proficiency is

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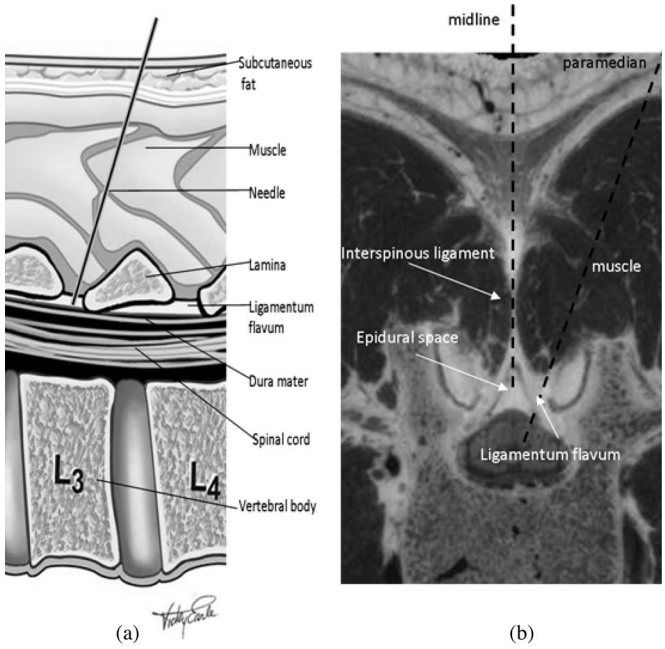


Fig. 1. Lumbar anatomy with epidural needle trajectory to the epidural space between L3 and L4. (a) Midline and paramedian approaches in a transversal slice [22]. (b) Paramedian approach in a parasagittal slice.

gained slowly (e.g., more than 60 attempts). Instrumentation of the technique of LOR would help gain a better understanding of the variations in feel, including subtle changes in resistance that experienced physicians report. Instrumentation would also provide quantitative differences in technique. Finally, instrumentation would also provide more information for the next generation of haptic epidural simulators.

The pressure in the epidural space has been measured in the past [13], [14]. Vas *et al.* [13] studied the pressures for infants and measured a pressure of about 9.2 kPa when the needle tip is in the ligamentum flavum and 0.13 kPa when the needle tip reaches the epidural space and the LOR is felt. In [14], measurements of the pressure when the needle is in the epidural space are taken, but no data are given about the ligaments preceding the epidural space, which are essential for quantifying the feeling of LOR. In [15], the pressure is measured throughout the epidural needle insertion and converted to an acoustic signal, with the pressure associated to the pitch of the acoustic signal; a drop in pressure at the LOR is clearly detected. The resistance sensed at different tissues throughout the procedure, using conventional LOR apparatus, has not been reported previously in the literature.

For instrumentation of the LOR, three measurements are of interest: the pressure at the tip of the needle, the force applied on the plunger of the syringe, and the volume of saline injected into the tissue. The force can be measured by a force sensor, the pressure by a pressure sensor, and the volume by a displacement or position sensor attached to the plunger of the syringe [Fig. 2(a)]. The force sensor can be worn under the glove of the physician during data capture and the position sensor can be mounted to the syringe, both maintaining sterility; however, the pressure sensor requires the saline to flow through the sensor and cannot be sterilized conveniently. The pressure sensor is also cumbersome. Therefore, there is a need to model the pressure from force and displacement alone, thus allowing the omission of the pressure sensor in the clinical trials on human subjects.

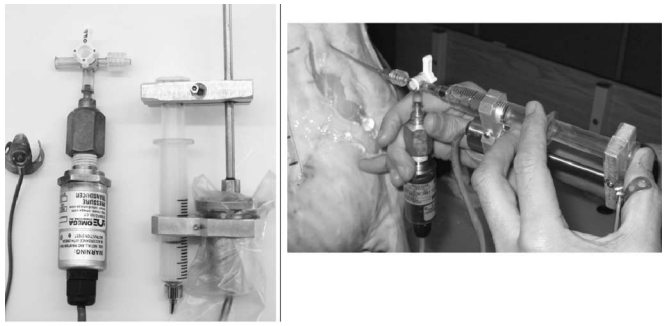


Fig. 2. (a) Three sensors, from left to right: force, pressure, and displacement sensor mounted to the syringe. (b) Experimental setup with the three sensors mounted on the syringe and epidural needle. The needle is inserted into an interspinous space in the lumbar region of the porcine tissue in a seated position.

In the first part of this research with porcine tissue, the goal was to show that the set of three sensors can be used in a reliable and consistent manner for quantifying the LOR endpoint. This was done by comparing the times of LOR on the graphs to the verbal signal from the physician. The second part consisted of deriving a model to estimate the pressure at the tip of the needle in terms of the displacement and force signals as the pressure sensor was to be omitted from clinical trials. Intermittent and continuous pressure techniques were compared to choose which is more suitable for the measurements and more accurate modeling of the pressure. The paramedian approach was then compared to the midline approach to quantify the differences between the "feel" of each approach. Finally, the force and displacement sensors were used in a clinical setting to quantify the tactile feedback or "feel" of LOR in human subjects *in vivo*. Preliminary results of portions of these tests were previously reported in [16]–[18].

II. Method

The first experiments were performed in a laboratory environment on excised porcine tissue (*Sus scrofa domestica*). The porcine lumbar spinal anatomy is similar to the human anatomy with the main difference being that the porcine lumbar region contains six vertebrae rather than five in humans. Additionally, the porcine subjects were slaughtered one or two days prior to the tests, causing some dehydration and increased stiffness in the tissue. The porcine tissue was prepared and fixed in a vertical orientation to mimic a seated position of human subjects, as shown in Fig. 2(b). The excised portion of tissue contained the entire spine, muscle, and ligaments. The advantage of using porcine tissue is that multiple needle insertions can be performed for repeated measurements on the same subject. The porcine tissue was obtained through a certified butcher, following guidelines and notification of the University of British Columbia (UBC) Animal Care and Biosafety Committee.

There were three sensors used to quantify the LOR: the force sensor, the pressure sensor, and the displacement sensor, as shown in Fig. 2(a). The SLB-25 force sensor (Transducer Techniques, Temecula, CA) was mounted on a custom-built stainless steel harness and fitted to the physician's thumb to measure the force applied to the plunger of the syringe. The CSPR IP65 magnetostrictive displacement sensor (MTS System, Cary, NC) was attached to the body of the syringe and the ring magnet used to track the position is attached to the plunger of the syringe. The change in displacement measurements was converted into the change of volume of saline remaining in the syringe by multiplying the displacement by the cross-sectional area of the syringe. The ring magnet did not touch the rod, and therefore, the friction was negligible. The PX302 pressure sensor (Omega Engineering, Stamford, CT) was connected to a three-way stopcock between the syringe and the epidural needle so that the pressure measurements were approximately equal to the pressure at the tip of the needle. The three sensors were connected to a computer workstation and data were acquired using a Q8 data acquisition board (Quansar, Markham, ON, Canada) at a sampling period of 0.01 s. From the manufacturers' specifications, the position sensor accuracy is 0.2 mm (when mounted to the syringe, the saline volume accuracy is 24 mm^3), the force sensor accuracy is 0.018 N (0.6% of the maximum force of around 30 N), and the pressure sensor accuracy is 0.25 kPa (0.25% of the maximum pressure of around 100 kPa). Glass syringes (JH-0550 Epidural Catheterization Kit, Arrow International, Reading, PA) were used as they provide minimal friction when properly wetted and are commonly used.

A. Experiment 1: Confirmation of LOR Endpoint on Porcine Tissue

The sensors were first evaluated to ensure the reliability of detection of the LOR endpoint. For these tests, the physician performed a needle insertion using LOR with the sensors measuring the three parameters of interest at L2–L3 and L3–L4. Upon entry into the epidural space, the physician verbally communicated the success and a time stamp was recorded on the computer recording the sensor measurements. This time stamp was then compared to the time LOR was observed on the sensor signals. Both the continuous and the intermittent techniques were evaluated by performing five needle insertions with each technique at each of the two lumbar intervertebral spaces (L2–L3 and L3–L4). This gives $n = 10$ for each technique. The midline approach was used for all insertions. Since the LOR could be clearly observed as a rapid drop in all three sensors, the times of the drops were averaged and compared to the time the physician indicated LOR.

B. Experiment 2: Pressure Estimate for Both Continuous and Intermittent Techniques on Porcine Tissue

The pressure is believed to be more closely related to the properties of the tissues where the needle tip is located because it is what the physician attempts to feel when using the LOR technique. The saline comes in contact with the pressure sensor, so sterilization is difficult and the pressure sensor cannot be used for clinical trials on human subjects. By deriving a model, it may be possible to estimate the pressure from the measured force and displacement. The simplest model is a static model defined by

$$P(t) = \frac{k_{\mathrm{a}} F_{\mathrm{a}}(t)}{A} \tag{1}$$

where $P(t)$ is the estimated pressure, $F_{\mathrm{a}}(t)$ is the force applied from the thumb to the plunger, A is the area of the cross section of the syringe, and k_{a} is a unitless constant that accounts for losses such as friction, viscosity, and off-axis forces. k_{a} is determined empirically from bench-top tests using a range of test forces to be 0.900 [18]. The value of k_{a} is determined by correlating three applied forces (0.617, 1.516, and 2.133 kg) and the associated measured pressure, taking into account the dimensions of the syringe. A linear fit is applied to the points and the slope is found to be 0.900.

It is observed that there is some leakage at the plunger–barrel interface, which causes a drop in the pressure over time for a constant force. The pressure decays in regions where there is force on the plunger but no displacement. A decay term is added to the model in order to more closely estimate the pressure defined by

$$P(t) = \begin{cases} \dfrac{k_{\mathrm{a}} F_{\mathrm{a}}(t)}{A}, & \dfrac{dD}{dt} \neq 0 \\ \dfrac{k_{\mathrm{a}} F_{\mathrm{a}}(t)}{A} e^{-(t-t_i)/\tau}, & \dfrac{dD}{dt} = 0 \end{cases} \tag{2}$$

where t_i is the time at which the plunger stops moving and τ is a decay time constant determined empirically on bench-top tests with a closed needle to be 23 $\pm$ 8 s [18]. The plunger is considered stationary for plunger displacements smaller than 0.18 mm/s (or 21 mm^3/s), just beyond the noise level of the sensors.

As mentioned, there are two standard methods of applying pressure with the saline-filled syringe: the continuous pressure technique and the intermittent pressure technique. Given two models and two techniques, tests were performed on excised porcine tissue to determine the most accurate of the four combinations. Using a protocol similar to experiment 1 for tissue preparation, the estimated pressure values were compared to the actual pressure measurements. Needle insertions ($n = 5$) were performed using each of the continuous and intermittent technique at L2–L3 and L3–L4. Knowledge of the porcine anatomy and verbal indication from the physician allowed different portions of sensor measurements to be associated with the interspinous ligament, ligamentum flavum, and the epidural space where the LOR occurred. Volume flow rate was calculated for each point in time by multiplying the rate of change of displacement by the syringe cross section (a constant). Average flow rate was then calculated for each tissue type.

C. Experiment 3: Comparison of the Midline Approach and Paramedian Approach on Porcine Tissue

Two approaches are used by physicians for performing a needle insertion [19]. The two approaches were compared by performing needle insertions on excised porcine tissue using a

protocol similar to experiment 1 ($n = 10$ for midline, $n = 20$ for paramedian). The "feel" of LOR is inherently different in the two techniques because, in the midline case, the epidural needle first traverses interspinous ligament, and, in the paramedian case, the needle first traverses muscle. Knowledge of the anatomy allowed the measurements to be divided into portions and each portion associated with the interspinous ligament/muscle (midline/paramedian), ligamentum flavum, or epidural space at the LOR. The continuous LOR to saline technique was used.

D. Experiment 4: Instrumentation of Human Subjects

The human subjects were recruited ($n = 11$) using signed consent. This study was approved by the clinical review ethics boards of both the UBC and the British Columbia Women's Hospital (C05-0409). Subjects were women in labor prior to vaginal delivery or women scheduled for cesarean section. The subject biometrics were as follows: average age of 33.8 $\pm$ 4.6 years, weight of 73.6 $\pm$ 16.5 kg, height of 162.6 $\pm$ 8.2 cm, and skin-to-epidural depth of 51.9 $\pm$ 11.8 mm.

Sterility is critical for percutaneous procedures, so a protocol for assembly of the sensorized needle was developed in coordination with the hospital's sterilization unit. A standard catheter, an epidural needle, and a syringe were supplied in a sterile package (FlexTip Plus Catheter, model JH-05500, Arrow International, Inc., Reading, PA). The force sensor was worn on the physician's thumb and a sterile glove was worn on top of it to ensure sterility. Since the position sensor contains sensitive electronics not suitable for high-temperature sterilization, the position sensor was covered by a general-purpose ultrasound cover (Cone Instruments, Solon, OH). The covered position sensor was then connected to the syringe by a set of aluminum clamps. The clamps, screws, and tools were sterilized after every procedure using steam at high temperature (132 °C) and high pressure (186 kPa) for 4 min, and wrapped and stored until assembled. Because of the 3-h sterilization processing time, duplicate sets of components were used to ensure availability. The clamps, position sensor, and syringe were assembled in the operating room during the time the physician prepared the subject.

The epidural needle insertions were performed using the midline approach as it is the standard of practice in the hospital where the experiments were conducted. The patients were placed in the seated position. A 17-gauge epidural needle was inserted, and the continuous pressure technique was used while measuring force and displacement.

For all tests, the physician gave a verbal indication of which tissue the needle tip was believed to be traversing. The times of each verbal indication were used to help segment the graphs into the following regions: interspinous ligament, ligamentum flavum, and the epidural space where LOR occurred.

III. RESULTS

A. Experiment 1: Confirmation of LOR Endpoint on Porcine Tissue

The time believed to be associated with the detection of the LOR using each of the three sensors is compared to the physician's confirmation of entry into the epidural space. Both the intermittent and continuous techniques show a clear LOR, as shown by a rapid fall in values. The errors are similar for both techniques. Combining all measurements, the overall average of the difference between the time indicated by the sensors and the physician is 0.8 $\pm$ 0.3 s.

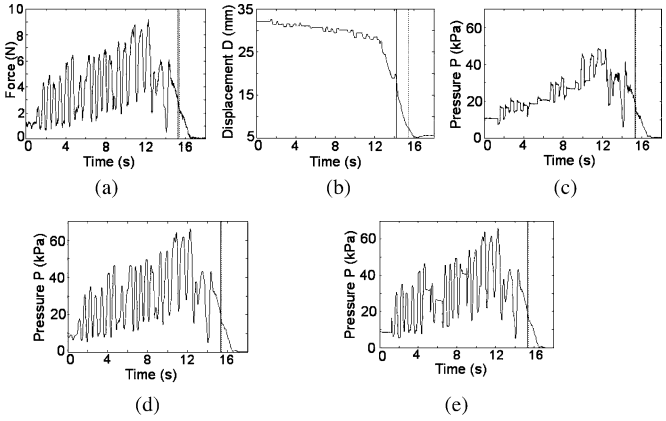


Fig. 3. Example of epidural needle insertion on porcine tissue using the intermittent technique of (a) force, (b) displacement, (c) measured pressure, (d) estimated pressure using the static model, and (e) estimated pressure using the decay model.

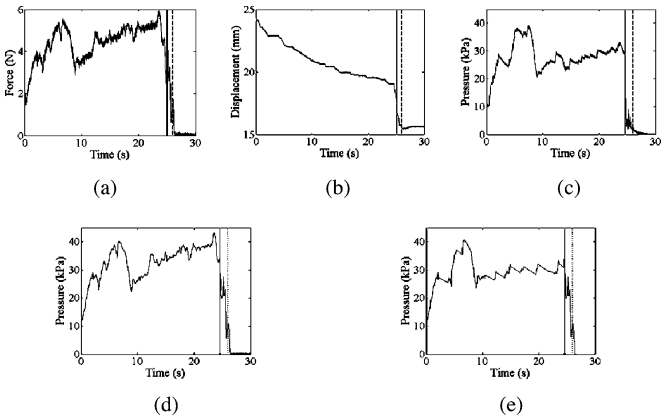


Fig. 4. Example of epidural needle insertion on porcine tissue using the continuous technique of (a) force, (b) displacement, (c) measured pressure, (d) estimated pressure using the static model, and (e) estimated pressure using the decay model.

B. Experiment 2: Pressure Estimate for Both Continuous and Intermittent Techniques on Porcine Tissue

Examples of the sensor signals when using the intermittent technique and the continuous technique are shown in Figs. 3 and 4, respectively. For comparison, Fig. 3(d) shows the estimated pressure using the static model and Fig. 3(e) shows the estimated pressure using the decay model. Fig. 4(d) and (e) can be compared similarly. The errors for each of the ten trials are shown in Fig. 5 and are summarized in Table I. It is observed that when using the continuous pressure technique for LOR to saline, the error of the estimated pressure from the static model compared to the actual pressure sensor signal (6.89 kPa rms error) is significantly larger ($p < 0.05$ using the paired t-test)

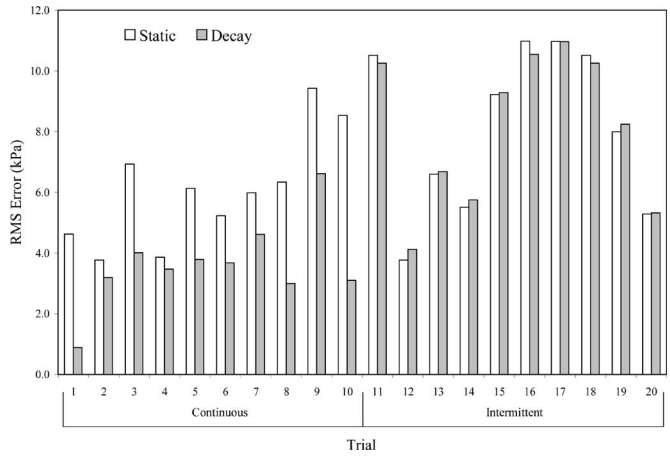


Fig. 5. rms error between the measured pressure and the pressure calculated from the decay model and between the measured pressure and the pressure calculated from the static model. Both the continuous and intermittent techniques are compared on porcine tissue.

TABLE I
EXPERIMENT 2: RMS ERROR FOR CONTINUOUS AND INTERMITTENT TECHNIQUES USING STATIC PRESSURE MODEL AND DECAY PRESSURE MODEL

	Mean Error Static model (kPa)	RMS Error Static model (kPa)	Mean Error Decay model (kPa)	RMS Error Decay model (kPa)
Continuous	0.69±5.5	6.89	-0.69±4.1	4.8
Intermittent	1.4±6.89	8.3	1.2±6.89	8.3

than the error of the estimated pressure from the decay model compared to the actual pressure sensor signal (4.8 kPa rms error). These represent 20% and 14% errors of the peak pressure for the static and decay models, respectively. When using the intermittent technique, both models estimate the pressure sensor with a higher level of error (8.3 kPa rms error), which is 24% of the peak pressure.

Table II shows the different average flow rates, forces, and pressures as well as the estimated pressures using the decay model for the porcine tissue. The flow rate is shown to be significantly higher ($p < 0.05$ using the paired t-test) for the interspinous ligament (29 ± 9 mm^3/s) compared to the flow rate in the ligamentum flavum (9 ± 7 mm^3/s). The force and pressure are not significantly different, so the differences come from the tissue properties, not the operator. The estimated pressure is also not significantly different from the measure pressure from the sensors giving confidence that the decay model can accurately estimate the tip pressure using the force and displacement measurements.

C. Experiment 3: Comparison of Midline Approach and Paramedian Approach on Porcine Tissue

Table III shows sensor data for the three regions of interest: before ligamentum flavum, at ligamentum flavum, and in the epidural space (i.e., when LOR is felt). Before the ligamentum flavum, in the midline approach, the needle tip is in the interspinous ligament and the flow rate (131 ± 86 mm^3/s) is smaller than the flow rate in the paramedian approach where the needle tip is in the muscle (172 ± 133 mm^3/s). The force and pressures are not significantly different for the two approaches at this point of insertion, so the differences are again mainly due to the tissue properties, not the operator. When the needle tip is on the ligamentum flavum, the flow rate in the paramedian plane is 147 ± 141 mm^3/s, which is again significantly larger than the flow rate in the midline of 92 ± 48 mm^3/s, so the differences arise from the tissue. This is an unexpected result since the tissue type is the same for both approaches. Although the force is slightly higher paramedian than midline, the pressure is not significantly different. Finally, when the needle tip is in the epidural space and the LOR to saline is felt, the flow rates are not significantly different (1077 ± 530 mm^3/s in the midline compared to 1064 ± 723 mm^3/s in the paramedian approach). Again, the force is not significantly different for the two approaches although the pressure is slightly higher paramedian than midline. Fig. 6 shows typical force, pressure, and displacement measurements obtained when performing midline and paramedian epidural needle insertion in the same subject.

D. Experiment 4: Instrumentation of Human Subjects

In the clinical trial, the measurements in the interspinous ligament can be compared to the ligamentum flavum. Sample measurements are shown in Fig. 7. Table IV shows the average flow rate and force applied. The flow rate at the interspinous ligament is 60 ± 30 mm^3/s, which is significantly larger than the flow rate in the ligamentum flavum at 12 ± 13 mm^3/s. The average force is also significantly larger in the ligamentum flavum (5.0 ± 3.0 N) than in the interspinous ligament (2.0 ± 1.4 N) despite the lower flow. The maximum force applied is 6.0 ± 3.0 N in the ligamentum flavum and is also significantly larger than in the interspinous ligament at 4.6 ± 1.3 N. Since the continuous pressure technique is used, the pressure can be reliably approximated as a function of the force and displacement. The estimated pressures are calculated to be around 15.0 ± 5.3 kPa for the interspinous ligament and 37.5 ± 20.0 kPa for the ligamentum flavum.

IV. DISCUSSION

The elapsed time between the sensors detecting the LOR and the physician detecting the LOR is small. In fact, the physician consistently confirmed the LOR slightly after the sensors detected it, suggesting that the small delay could simply be the time it takes for the physician to feel the LOR and react verbally (about 1 s).

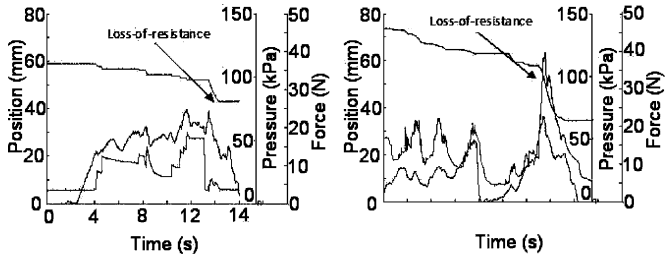
In experiment 2, when using the continuous pressure technique, both the static model and the decay model perform reasonably well. The decay model builds on the static model and adds a decay term where the plunger is stationary. These portions of exponential decay are observed in the measured pressure signals, and therefore, the longer the plunger stays immobile, the more the pressure will drop compared to the static model and the more accurate the decay model will be. This effect is most important in the ligamentum flavum as it is very resistant to injection, so plunger movement is small. Given similar exponential pressure decays in tissue compared to the bench tests

TABLE II
EXPERIMENT 2: FLOW RATE, FORCE (F_a), AND PRESSURE (P) FOR INTERSPINOUS LIGAMENT AND LIGAMENTUM FLAVUM FOR PORCINE SUBJECTS USING MIDLINE APPROACH

	Flow rate (mm^3/s)	F_a (N)	Max F_a (N)	P (kPa)	Max P (kPa)	P_{est} (kPa)	Max P_{est} (kPa)
Interspinous ligament	29±9	2.7±1.6	4.5±1.6	20±10	31±13	20±11	34±13
Ligamentum flavum	9±7	3.3±1.4	4.1±1.5	27±6	30±7	25±7	32±10

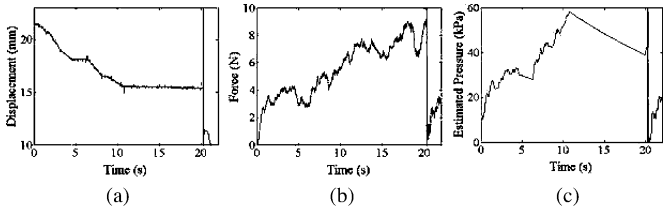
TABLE III
EXPERIMENT 3: FLOW RATE, FORCE (F_a), AND PRESSURE (P) FOR INTERSPINOUS LIGAMENT, MUSCLE, LIGAMENTUM FLAVUM, AND EPIDURAL SPACE (LOR) FOR PORCINE SUBJECTS USING MIDLINE AND PARAMEDIAN APPROACHES

Region	Flow rate (mm^3/s)	F_a (N)	Max F_a (N)	P (kPa)	Max P (kPa)
Midline: interspinous ligament	131±86	8.9±5.3	14.7±6.6	31.3±12.8	59.4±24.1
Paramedian: muscle	172±133	9.4±5.4	13.7±7.0	34.0±17.4	56.2±31.3
p-value	<0.175	>0.25	>0.25	>0.25	>0.25
Midline: ligamentum flavum	92 ± 48	8.9±5.3	14.7±6.6	31.3±12.8	59.4±24.1
Paramedian: ligamentum flavum	147 ± 141	12.9±5.3	16.1±5.3	50.4±25.8	65.6±33.5
p-value	<0.02	<0.075	<0.175	>0.25	>0.25
Midline: LOR	1077 ± 530	11.4±8.3	18.2±9.6	40.1±32.7	61.2±40.0
Paramedian: LOR	1064 ± 723	12.9±5.1	17.4±5.5	57.9±28.1	82.0±34.7
p-value	>0.25	>0.25	>0.25	<0.125	<0.125



(a) (b)

Fig. 6. Sample graph of force (middle), pressure (bottom), and displacement (top) measurements using continuous pressure. (a) Midline approach. (b) Paramedian approach. Note the several bone contacts in the paramedian approach that occur occasionally when performing the needle insertion in the paramedian plane.



(a) (b) (c)

Fig. 7. Sample graph of a midline approach using the continuous pressure technique on a human subject. (a) Displacement. (b) Force. (c) Estimated pressure from the decay model.

with a closed needle tip, the decay is assumed to arise mainly from leakage past the plunger and the amount of saline injected into the tissue with a stationary plunger is negligible.

When comparing the interspinous ligament and the ligamentum flavum (on the excised porcine tissue), it is evident that the ligamentum flavum is more resistant to saline injections: the flow rate is significantly smaller for a comparable force and pressure. This is to be expected as the ligamentum flavum is much stiffer than the interspinous ligament (50 N compared to 7 N at a strain of 5%) [20].

In experiment 3, the epidural needle traverses the interspinous ligament in the midline approach and muscle in the paramedian approach. For a comparable force and pressure, the flow rate is higher in muscle than in interspinous ligament; therefore, the interspinous ligament is more resistant to injection and a physician performing a needle insertion should be careful, not to mistake the relative ease of injection in muscle to be an indication of LOR in the epidural space. Also, when the needle

TABLE IV
EXPERIMENT 4: FLOW RATE, FORCE (F_a), AND ESTIMATED PRESSURE (P_{est}) FOR HUMAN SUBJECTS USING MIDLINE APPROACH

Region	Flow rate (mm^3/s)	F_a (N)	Max F_a (N)	P (kPa)	Max P (kPa)
Interspinous ligament	60±30	2.0±1.4	4.6±1.3	15.5±12.0	34.9±17.4
Ligamentum Flavum	12±13	5.0±3.0	6.0±3.0	31.5±28.0	39.5±30.3
p-value	<0.05	<0.05	<0.05	<0.05	>0.25

is in the ligamentum flavum, a similar level of force and pressure produces a greater flow rate in the paramedian approach than in the midline approach. This phenomenon was unexpected as the needle tip is in the same ligamentum flavum. However, it is noticed that the needle does not smoothly penetrate the ligamentum flavum but instead "pops" through. This means that the needle tip is still partially in the interspinous ligament in the midline approach and in the muscle in the paramedian approach. When the needle tip is in the epidural space, similar forces, pressures, and flow rates are measured for both approaches. Because the flow rate is higher in the paramedian approach than in the midline approach prior to the LOR region, it is said that the LOR is more subtle in the paramedian approach.

Experiment 4 showed that the ligamentum flavum in live human subjects is more resistant to injection (12 ± 13 mm^3/s) than excised porcine tissue (92 ± 48 mm^3/s) for the same midline approach. The applied force was less on human subjects (5.0 ± 3.0 N) than porcine tissue (8.9 ± 5.3 N), but the very large difference in flow rate cannot be completely attributed to differences in applied force. The differences between excised porcine tissue and human tissue *in vivo* include changes in temperature, blood pressure, perfusion, and dehydration, among others. This means that excised porcine tissue cannot adequately replicate human tissue *in vivo* for the purposes of training and that practice of human subjects will likely remain the gold standard. The overall relationship between interspinous ligament and ligamentum flavum in human subjects is similar to the relationship between interspinous ligament and ligamentum flavum in porcine tissue. The estimated pressure generated from the decay model is similar to the pressures previously published. Previous research has reported a pressure of 67.6 ± 12.2 kPa when the needle tip is in the ligamentum flavum for adults [21] and 9.22 ± 4.93 kPa for infants [13].

The Tuohy needle used for these tests facilitates the introduction of the catheter into the epidural space with the exit orifice perpendicular to the central axis of the needle. This allows some lateral leakage of saline into the surrounding tissues in the interspace between muscle tissue fibers that are perpendicular to the needle. The leakage of saline into the tissues, especially when performing a paramedian needle insertion, was not taken into account in the modeling.

Also, as more saline is injected, the surface of contact between the plunger and the barrel increases, and this, in turn, increases the friction. The friction force is, therefore, nonlinear. However, this effect is considered small enough to be negligible. More research should be performed to address more realistic friction models.

Additionally, modeling of the pressure by incorporating the instantaneous flow rate may be more accurate than the current method. For instance, in the region of LOR, the pressure is low, but one could apply a high force. Only when looking at the high flow rate, one would realize that the pressure is low and not dependent only on the force. The commonly used air bubble in the syringe for LOR to saline also affects the pressure readings as air is compressible.

Errors from the presence of the glove between the sensor and the thumb are very small. For the relatively slow movements of the plunger, the inertial effects of the glove material are negligible. If the glove is modeled as an elastic element in series with the plunger and the thumb, then the force is unchanged by the transmission through the glove. This also applies to the compressible portion of the thumb. As long as the thumb, glove, sensor, and plunger are modeled as a series connection, and inertial effects are ignored, the force is the same in all elements at all times.

V. CONCLUSION

The data collected from this study can be used to implement a more accurate haptic simulator for anesthesiology training, which would contain force, pressure, and displacement components to characterize the feel of LOR. To further refine the models, a larger clinical trial is needed to detect differences among the subjects.

The data captured also improve the overall understanding of the LOR. Using these data, the difference often reported by anesthesiologists between several techniques can be quantified. This includes differences between techniques using intermittent pressure versus continuous pressure applied to the plunger. The claim that anesthesiologists often make about the abruptness of the LOR in the paramedian versus midline approaches is also quantified by the flow rate data. The sensors used in this paper can be used for education by senior physicians as an additional visual cue since they now have a way to quantitatively gauge how much force a student is applying in the procedure.

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