

A New Technique to Assist Epidural Needle Placement

Fiberoptic-guided Insertion Using Two Wavelengths

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ABSTRACT

Background: Up to 10% of epidurals fail due to incorrect catheter placement. We describe a novel optical method to assist epidural catheter insertion in a porcine model.

Methods: Optical emissions were tested on *ex vivo* tissues from porcine paravertebral tissues to identify optical reflective spectra. The wavelengths of 650 and 532 nm differentiated epidural space from the ligamentum flavum. We then used a hollow stylet that contained optical fibers to place epidural needles in anesthetized pigs. Real-time data were displayed on an oscilloscope and stored for analysis. A total of 50 punctures were done in four laboratory pigs. Data were expressed as mean \pm SD.

Results: Paired *t* test shows significant optical differences between the epidural space and the ligamentum flavum at both 650 nm ($P < 0.001$) and 532 nm ($P = 0.014$). Mean magnitudes for 650 nm, 532 nm, and their ratio were 3.565 ± 0.194 , 2.542 ± 0.145 , and 0.958 ± 0.172 at epidural space and 3.842 ± 0.191 , 2.563 ± 0.131 , and 1.228 ± 0.244 at ligamentum flavum, respectively. There were no differences in the optical characteristics of the ligamentum flavum and epidural space at different levels in the lumbar and thoracic region (two-way ANOVA $P > 0.05$).

Conclusions: This is the first study to introduce a new optical method to localize epidural space in a porcine model. Epidural space could be identified by the changes in the reflective pattern of light emitted at 650 nm, which were specific for the ligamentum flavum and dural tissue. Real-time optical information successfully guided a modified Tuohy needle into the epidural space.

What We Already Know about This Topic

- ❖ Identification of the epidural space relies on manually sensing changes in tissue compliance and dispensability, relegating this method to a blind technique

What This Article Tells Us That Is New

- ❖ Optical reflective spectra were obtained in porcine tissues, and then optical fibers were inserted in an epidural needle for placement in pigs
- ❖ Real-time optical information successfully guided needle placement to the epidural space, suggesting a novel method to guide such placement

THE most common method used to identify epidural space is a loss of resistance (LOR) to either air or fluid.¹⁻³ However, up to 10% of epidurals fail to provide adequate analgesia because of incorrect catheter placement using the LOR technique.^{4,5} Factors such as the operator's experience and spinal anatomy influence the success of accurate placement.^{6,7}

Investigators have used ultrasound and nerve stimulation to improve the accuracy of placement.⁸⁻¹⁰ Ultrasound provides an estimate of the distance to the epidural space,¹¹ but the technique does not provide adequate resolution to distinguish the tissue layers that the needle travels through or to specifically identify the epidural space.¹² Therefore, epidural failure using sonographic-assisted neuraxial placement is still reported.¹² We therefore designed a method of epidural catheter placement using a technique that would specifically identify the ligamentum flavum and the dura. Our method uses tissue-specific reflected light signals emitted from optic fiber bundles contained within a standard epidural needle.

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Each type of tissue has its unique optical property that can be identified by its reflectance and absorption spectra. The quantity of light absorption or scattering in a tissue for particular wavelengths is highly dependent on the particle size and the molecular structure in the cells of the tissue (*e.g.*, muscle, fat, and ligamentum flavum are constructed by different kinds of cells with various sizes and shapes. Of course, the molecular structures that form the cells are also different). These characters of a tissue determine the optical properties (such as the refractive index, absorption, and scattering coefficients) of the tissue.^{13,14}

We hypothesize that the use of a light reflectance spectrum during epidural needle placement can be used to guide epidural needle placement. Because each tissue has unique light qualities, the path and site of a needle tip can be accurately localized. The changes in the magnitudes of reflected light can be analyzed in real time and are used to identify the specific tissues through which a hollow needle passes.

In this study, we describe an innovative adjunct technique for epidural needle placement that uses differences in light reflection between the ligamentum flavum and dural tissues to guide needle insertion into the epidural space of a porcine animal model. The technique uses a specialized stylet in the epidural needle to emit light and an optical receptor to image changes in the intensity of the reflected light amplitudes.

Materials and Methods

Study Design

This study was approved by the Institutional Animal Care and Use Committee of Taipei Veterans General Hospital. The study was conducted in two phases. We conducted the first part of our optical study in *ex vivo* porcine tissues. In the second part of our study, we applied information from the *ex vivo* analysis to our anesthetized porcine model. We analyzed the reflected light in two different applicable wavelengths in the reflective spectra. Wavelengths that provided accurate information on the optical characteristic of the individual tissue in both the *ex vivo* and *in vivo* parts of our study were selected.

Ex Vivo Study (Part 1)

We used porcine *ex vivo* tissues that were anatomically similar to tissues that an epidural needle would course through during neuraxial placement. The reflective spectra of these tissues were collected and analyzed to identify the specific wavelengths of each tissue type. This allowed us to create a reference library for subsequent analysis.

The study of *ex vivo* porcine tissues was performed as follows. We used a xenon lamp light source with a monochromator to generate a single-wavelength scanning system. The output light was emitted by a monochromator to transmit a selectable band of light wavelengths. The light from the monochromator was aimed through an arm of a Y-shaped optic fiber bundle that formed the inner core bundle illuminating the tissue. A fraction of the reflective light from the

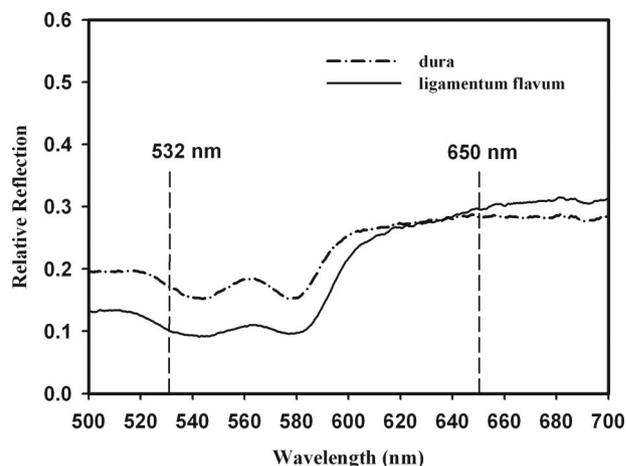


Fig. 1. The reflective spectra of *ex vivo* swine spine tissues (dura and ligamentum flavum).

tissue was transmitted to optic fibers around the core fibers of the optic probe and to an avalanche photodiode (S5345, Hamamatsu Photonics K.K., Shizuoka Pref., Japan) to convert the light to an electrical signal. The signal was then amplified to analyze the reflective spectrum of this tissue. We used barium sulfate (BaSO_4) to correct the reflective spectra of the *ex vivo* swine tissues. This is because it is a near perfect diffuser when measuring light sources in the range of visible wavelengths.¹⁵ The results of the reflective spectra of the dura and ligamentum flavum are shown in figure 1. We found that the two tissues have unique reflective spectra and could therefore be individually identified. Two commercially available laser diodes (532 and 650 nm) were chosen in our study because both are readily available and can distinguish the two tissues (fig. 1).

The ratios of the reflective lights for 650–532 nm were 1.5882 ± 0.1403 and 2.8191 ± 0.2711 ($n = 5$) for dura and ligamentum flavum, respectively. The statistically significant difference is shown ($P = 0.043$) by the application of Wilcoxon signed rank test. In addition, the sensitivity and specificity of the reflected signals were explicitly apparent. Therefore, we concluded that the reflection signals could be used for part 2 of our study, which aimed to locate the epidural space in a living porcine model.

In Vivo Study (Part 2)

Porcine Model. Four Duroc and Landrace, Chinese native pigs with an average weight of 20 kg were used in this study. The animals were intubated and ventilated after induction of general anesthesia. Tiletamine–zolazepam (5 mg/kg) was given intramuscularly for induction of general anesthesia. Anesthesia was then maintained with an intravenous infusion of pentobarbital sodium ($15 \text{ mg} \cdot \text{h}^{-1} \cdot \text{kg}^{-1}$) for the duration of the study.

Study animals were placed in the left lateral position for epidural placement. A 17-gauge insulated Tuohy needle (Arrow, Teleflex Incorporated, Limerick, PA) containing the fiberoptic-modified stylet was inserted into the back of the pig, in the lumbar, low thoracic, and mid-thoracic region. The needle

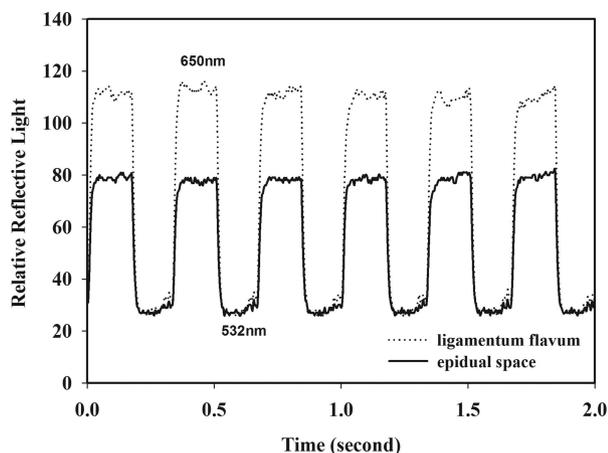


Fig. 2. The reflective signals at 650 nm and 532 nm are shown while the stylet reached ligamentum flavum and epidural space in an *in vivo* study. The y-axis is the magnitude of light reflected from the tissues (the peaks represent 650 nm wavelength whereas the troughs indicate the 532 nm wavelength). The x-axis indicates the time course of the modulation for 650 and 532 nm during the insertion of the needle into the tissue. (Dotted line) The reflected light when the needle is located in the ligamentum flavum and (solid line) the light reflected from the epidural space. The two lines illustrate the reflectance that are obtained at different times (*i.e.*, when the needle is in two different locations) but are superimposed to provide a visual comparison.

was advanced through the tissue planes until the ligamentum flavum was identified. Needle advancement was stopped once the ligamentum flavum–reflected light was lost. The needle was deemed to be in the epidural space when this criterion was met.

We performed approximately 12 needle passes on each study animal. We compared the optical properties of the tissues at different interspace levels in the thoracic and lumbar spine to determine whether the tissues of interest had consistent optical properties throughout the longitudinal axis of the spine.

We analyzed the mean and SD for the magnitudes of the reflective lights at 650 and 532 nm for the ligamentum flavum and epidural space. A second reading was collected for the ligamentum flavum after the needle was pulled back from the epidural space. We collected dual wavelength magnitudes and their ratio (red light magnitude over green light magnitude) for each of the epidural insertions performed.

The stylet of the needle was removed when the optical properties of the tissues indicated that the needle had passed through the ligamentum flavum (fig. 2). An epidural catheter was then inserted. The catheter in the epidural space was identified by using ultrasonography (Vivid e, GE Healthcare, London, United Kingdom; fig. 3). A radiography with contrast medium was then performed to confirm the epidural location of the catheter (fig. 4). The animals were killed after the procedure.

Optical Analysis of Tissues. We used a 17-gauge Tuohy needle from a standard catheterization set for epidural placement in our porcine model. The stylet supplied in the kit was replaced with a hollow stylet that was designed to accommodate the light source for the study. It had the same size and shape as the original stylet, with an internal diameter of 0.80 mm to allow the insertion of a total of six optic fibers (each 250 μm in outer diameter and 62.5 μm in core diameter). At

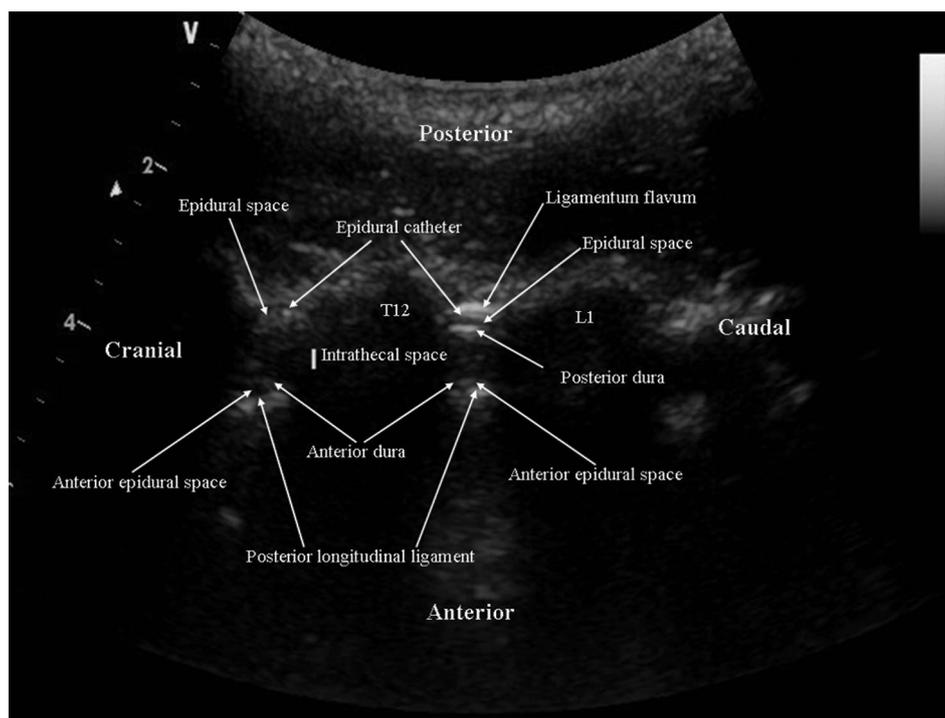


Fig. 3. The paramedian oblique ultrasound image of the swine lumbar spine. The curved linear ultrasound probe is placed laterally to the spinal process and directed medially to the spinal canal to get the paramedian oblique view. The inclined hyperechoic bony structures are the lamina of each swine spine. There is a narrow acoustic window cephalic to the lamina, including ligamentum flavum, hypoechoic epidural space, posterior dura, spinal canal, and anterior dura from posterior to anterior. The indwelled epidural catheter is visualized by the ultrasound within the epidural space as a traceable hyperechoic line or spot. L1 = lamina of L1 vertebra; T12 = lamina of T12 vertebra.

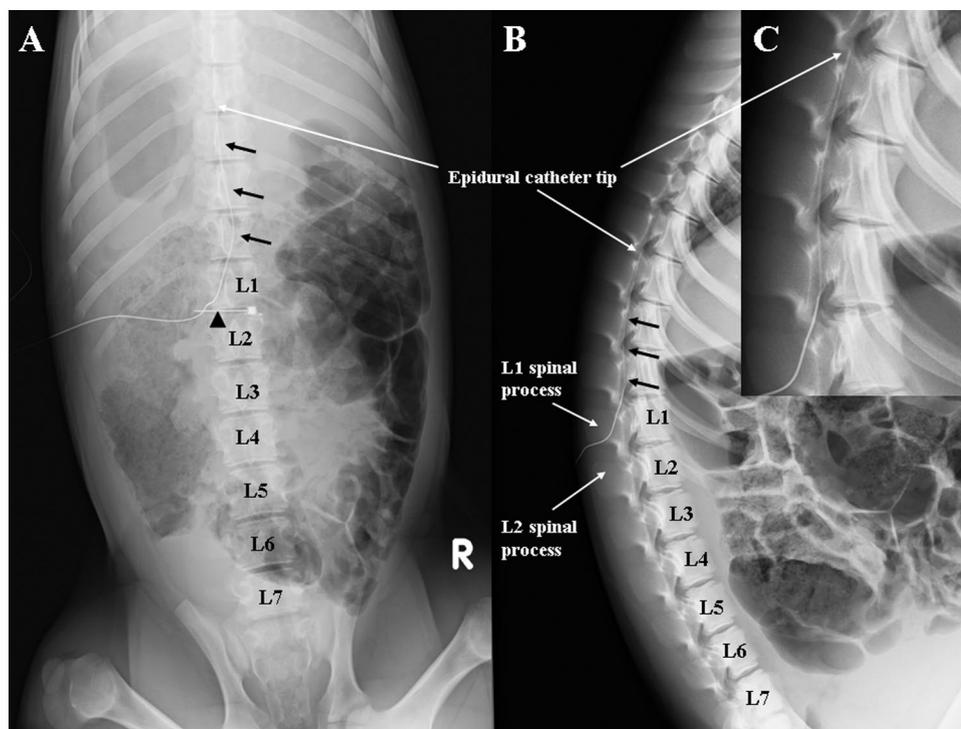


Fig. 4. The radiography with contrast medium of swine spine: (A) posteroanterior view, (B) lateral view, and (C) zoom of the epidural catheter. Arrow: epidural catheter, triangle: the marking needle for the insertion level of the epidural needle.

the tip of the needle, the fibers were sealed together and shaped similar to the needle bevel. The central fiber was designed to deliver two counter-phased laser lights (3 Hz, square wave) at wavelengths of 650 and 532 nm. These particular wavelengths were tested because they are commercially available for laser diodes and our *ex vivo* data show that they fit the parameters of this study.

We used a 5- and 10-mW power source for the 650 and 532 nm laser diodes, respectively. The reflected light was sent to a photomultiplier tube (model H5773-20; Hamamatsu Photonics K.K.) through the fibers surrounding the core fiber at the tip of the stylet. The photomultiplier tube multiplied the current produced by the incident light to improve the signal analysis. The current was converted to an electrical signal and was displayed on an oscilloscope (GW Instek, Hsinchu City, Taiwan; model GDS2104, 100 MHz, 4ch). The data were then electronically stored for analysis. Figure 2 shows the typical waveform of reflective light when the needle was located at the ligamentum flavum and after it passed into the epidural space.

Statistical Analysis. Parametrical data are presented as the mean \pm SD. Puncture sites were classified into three levels based on their anatomic locations (lumbar, low, and high thoracic). A linear mixed model was used to compare the signals of ligamentum flavum and epidural space at different puncture sites, with random effects to account for the correlation in each measurement from the same pig. Interaction between the two tissues and puncture sites was also checked. If there was no significant difference in distinct puncture sites, a paired *t* test was used to compare the signal amplitude

of 650 nm, 532 nm, and their ratio between the epidural space and the ligamentum flavum before and after dura puncture. The results were considered to be statistically significant for *P* values less than 0.05. A receiver operating characteristic curve (ROC) was used to determine the optimal cutoff values for signal amplitudes of 650 nm, 532 nm, and their ratio to differentiate the epidural space from the ligamentum flavum. Area under the ROC curve with its 95% CIs was also calculated to evaluate the predictive validity of 650 nm, 532 nm, and their ratio. All statistical analyses were performed with SPSS software (v.15; SPSS Inc., Chicago, IL).

Results

The needle was advanced until we entered the ligamentum flavum. The needle was then advanced just beyond this point until there was a change in light signals. The light emission at this point was probably due to reflection from the dura. The low variability in our readings supports this point. However, we cannot guarantee that other tissues did not influence the exact optical measurements. Therefore, we refer to this reading as the epidural space. Figure 5 illustrates a total of 50 needle insertions that were performed in the four pigs. Linear mixed model analysis showed that there was no significant difference at different puncture sites along the longitudinal axis of the spine for the ligamentum flavum and epidural space ($P = 0.9$ for 650 nm and $P = 0.35$ for 532 nm). Because the optical characteristics of the tissue were consistent regardless of axial position on the spine, we statistically compared data obtained from different puncture sites. We

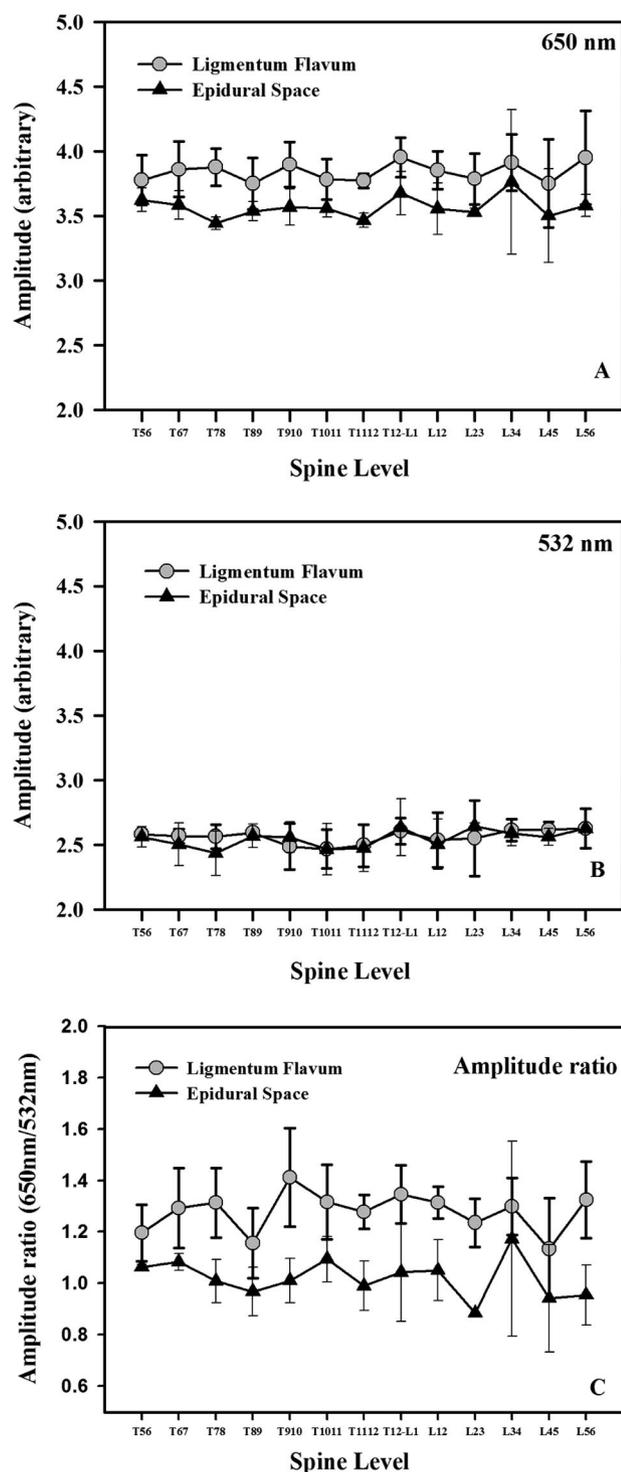


Fig. 5. The reflective amplitudes at different spine levels in a porcine model: (A) 650 nm, (B) 532 nm, and (C) 650 nm/532 nm (mean \pm SD).

observed that when the beveled blade was oriented parallel to the midline of the spine, the amplitude of the reflective light was stronger than when it was oriented to face cephalic. However, the difference became minimal with the increase in the number of studies performed.

The averaged magnitude of the reflective signals at the epidural space was 3.565 ± 0.194 at 650 nm, whereas it was

2.542 ± 0.145 at 532 nm wavelength. The calculated ratio between the two wavelengths was 0.958 ± 0.172 . The magnitudes and ratio of the two wavelengths at the ligamentum flavum were 3.842 ± 0.191 , 2.563 ± 0.131 , and 1.228 ± 0.244 , respectively. A paired *t* test showed significant differences between the averaged magnitudes and ratios for the light reflected from the ligamentum flavum and the epidural space. There were significant differences between epidural space and ligamentum flavum in both the 650 nm ($P < 0.001$), 532 nm ($P = 0.014$) wavelengths, and their ratio ($P < 0.001$; table 1).

However, there was no significant difference when comparing the characteristics of epidural spaces and ligamentum flavum when the needle was pulled back (Lig, POST; all $P > 0.05$).

ROC analysis verified the difference in optical properties between the ligamentum flavum and epidural space at wavelengths of 650 and 532 nm based on the sensitivity and specificity.^{16,17} Figure 6 shows the ROC curve of the three tests. The test showed good discrimination between the epidural space and ligamentum flavum (table 2). The area under curve for 650 nm was 0.887 (95% CI 0.813–0.9). Although the paired *t* tests of the magnitudes and ratios for the 532 nm wavelength suggested that this wavelength could be used to distinguish tissue planes, the ROC did not. In contrast to the 650 nm wavelength, the 532 nm area under curve was only 0.549 (95% CI 0.4275–0.6), whereas the ratio was 0.809 (95% CI 0.7180–0.9).

Discussion

Our studies show that optical technology can be used to guide epidural catheter placement. The technique is easily adapted for use in standard epidural needles. The procedure of epidural needle placement using this technique is almost the same as that of traditional epidural needle placement, which is familiar to the anesthesiologists, except there is a fiber bundle extended from the end stand of the stylet needle, and information for localizing epidural space is obtained by observing the signal change from an oscilloscope. Analysis of dual wavelengths optical data in the porcine model showed that the dura and ligamentum flavum have characteristics that are unique. Using this information, we were able to reliably identify the epidural space at multiple levels along the vertebral axis. We did not test the rate of successful epidural placement using this novel technology in an independent arm of the study. Thus, the practical application of this technology would require additional testing to include factors that we did not analyze in this study. However, our data suggest that the 650-nm wavelength alone can successfully identify the epidural space.

Epidural blockade is an effective technique to control chronic and acute pain caused by a wide variety of surgical procedures.^{1,2,18} However, up to 10% of epidurals fail when LOR is used to identify the epidural space. This can be due to irregularities in the interspinous ligaments, fat planes, or the

Table 1. Reflected Signals and Paired *t* Test

	ES	LF	LF after Punctured	P1 (ES vs. LF)	P2 (ES vs. Lig. Post)
N	48	43	20	42	19
650 nm	3.565 ± 0.194	3.842 ± 0.191	3.586 ± 0.162	<0.001	0.243
532 nm	2.542 ± 0.145	2.563 ± 0.131	2.558 ± 0.136	<0.014	0.4270
650 nm/532 nm	0.958 ± 0.172	1.228 ± 0.244	1.03 ± 0.224	<0.001	0.375

Data are expressed in mean ± SD.

ES = epidural space; LF = ligamentum flavum; Lig. Post = ligamentum flavum after punctured; P1 and P2 = *P* values of statistical paired *t* test.

inadvertent entry into the paravertebral space.¹⁹ Additional risks include dural puncture, total spinal anesthesia, or even significant neurologic deficits as a result of unintentional spinal cord trauma.^{20,21} The use of air can cause pneumocephalus with resultant headache.^{22–25} The air bubbles in the epidural space may also interfere with effective spread of local anesthetic and with the quality of the block.^{3,25} This is exemplified by an increase in ineffective labor analgesia when air is used to determine LOR.²² One of the advantages of our novel optical technique is that no air or saline is injected when the tip of the Tuohy needle enters the epidural space. This could reduce complications and improve the quality of epidural blockade.

Ultrasound visualization of the spinal column and surrounding structures has also been used to obtain more detailed anatomical information during placement. It significantly reduced failed neuraxial block by identifying the optimal skin puncture site, estimating a direction of needle advancement and providing additional information about the skin-to-epidural space distance.²⁴ However, the technique usually requires two people; one to handle the ultra-

sound probe and the other to perform the LOR. However, Karmakar *et al.*¹² recently reported that they could omit the need of a second operator using a new spring-loaded syringe system (Episure AutoDetect LOR Syringe; Indigo Orb, Irvine, CA).

In contrast, our technique requires a single operator and can be accomplished by the use of a single wavelength of 650 nm. Although *ex vivo* data suggested that both the 532 and 650 nm wavelengths could be used for optical analysis, the *in vivo* study showed that only the 650 nm wavelength has practical application. The ROC analysis suggests that the 532 nm wavelength fails to adequately distinguish tissue types. This conclusion is based on the observation that the area under curve of the ROC is less than 0.6. However, our *in vivo* analysis confirmed that the 650 nm wavelength had optically discriminating properties. Therefore, optical placement could be achieved by using the 650 nm wavelength as a single probe.

Our findings do confirm that more 532 nm light is absorbed in the *in vivo* than the *ex vivo* tissue. We reason that the failure of 532 nm wavelength to discriminate tissue types was due to variations in the content of oxyhaemoglobin and deoxyhaemoglobin of *in vivo* tissues compared with *ex vivo* tissues. The absorption spectra of oxyhaemoglobin and deoxyhaemoglobin^{26,27} (fig. 7) are only displayed in the range of 400–700 nm of the visible-wavelength spectrum. Thus, the profiles of the above two hemoglobin subtypes are magnified in the wavelength range of 500–660 nm. We did not directly study the cause of differences in light absorption between the two wavelengths. Therefore, why 532-nm wavelength failed to discriminate tissue types will require further testing.

The novel technology of optical epidural placement is an alternative to the use of LOR for correct epidural needle

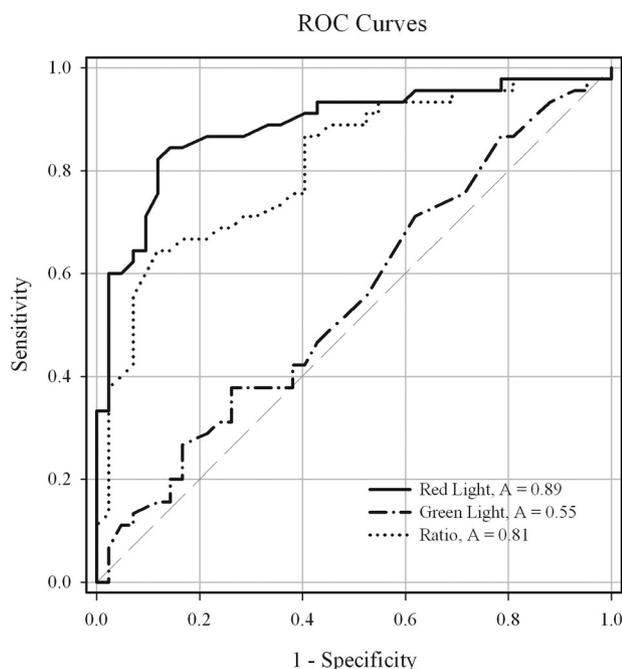


Fig. 6. The receiver operating characteristic (ROC) curve of the three tests in the porcine model. The area under curve for 650 nm, 532 nm, and their ratio are 0.89, 0.51, and 0.81, respectively.

Table 2. Receiver Operating Characteristic Curve Analysis

Test Variables	650 nm	532 nm	650 nm/ 532 nm
ROC curve area	0.887	0.549	0.809
Standard error	0.037	0.062	0.047
95% CI	0.8131–0.9	0.4275–0.6	0.7180–0.9
<i>P</i> Value	<0.001	0.427	<0.001

CI = confidence interval; ROC = receiver operating characteristic.

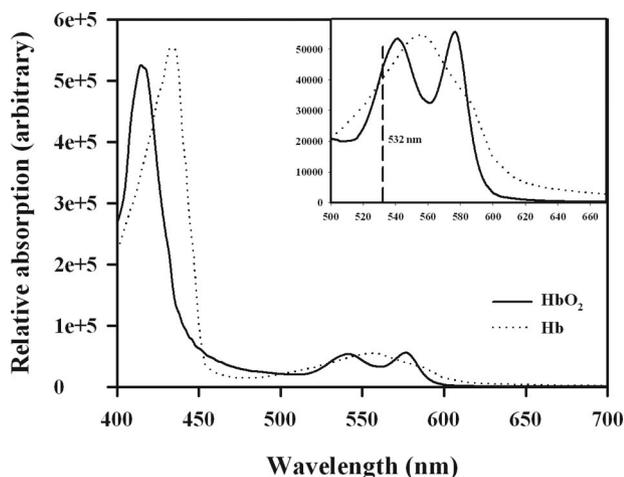


Fig. 7. Relative absorption spectra of oxyhemoglobin (HbO_2) and hemoglobin (Hb) in the visible wavelength range. The plot on the upper corner shows magnified profiles for HbO_2 and Hb in the range of 500–660 nm. The absorptions of HbO_2 and Hb at 532 nm are particularly indicated by a broken line.

placement. With this technique, the advancing needle is stopped after entering the ligamentum flavum. There is a distinct change in the optical signal that the operator can identify in real time. The use of two signals (ligamentum flavum and dural tissues) provides a greater degree of discrimination. This simple and sensitive technique can be performed with inexpensive equipment and can be applied in the operating room or ward without radiation. It is possible that the advantage of direct visualization of reading the amplitude change of the lights reflected from the tissues through an oscilloscope screen may also enhance training efficacy because both the instructor and students can acquire the same information while guided epidural placement is performed.

The use of an optically guided technique requires that the operator can distinguish signals of the different paravertebral tissue with a high degree of discrimination. There were no previous studies to identify optical characteristics and to confirm whether the optical measurements of the connective tissues surrounding the epidural space were uniform at all vertebral levels. Our studies show that the optical characteristics of the *in vivo* ligamentum flavum and epidural space using a 650-nm wavelength are significantly different. In addition, a linear mixed model analysis of our data shows that there is no significant difference ($P = 0.9$ for 650 nm and $P = 0.35$ for 532 nm) in the optical properties of the ligamentum flavum or epidural space at the lumbar and thoracic levels with the wavelengths we used. Therefore, it is likely that a similar optical analysis could be performed at other vertebral level, such as cervical spine, using a single set of cutoff values to distinguish the epidural space from the ligamentum flavum. Based on our data, the technique can be used for both thoracic and lumbar epidural catheter insertions. Further testing is required to identify the optical cutoff values for epidural placement in the cervical region.

We also observed optical characteristics while withdrawing the needle from the epidural space to a point just dorsal to

the ligamentum flavum. These data are noted as the ligamentum flavum after punctured. There was no statistical difference in optical characteristics in the tissues surrounding the epidural space when the needle was pulled back. This finding might be caused by imaging the path created by the Tuohy needle. The light would be able to leak into the hollow path created by the needle, and this path likely has characteristics similar to the epidural space. This could limit the application of our two wavelength optic approach to epidural placement if more than one pass is necessary.

Another limitation of our technique is that the direction of the beveled blade influenced the results while approaching the epidural space. The amplitude of the reflective light was stronger than when it was oriented to face cephalic. The fact that this difference became minimal with the increase in the number of studies performed suggests that there could be a learning curve for the reliable use of this technique.

Failure to identify the epidural space could also cause dural puncture using our optical method. Therefore, we studied the sensitivity in addition to the specificity of our optical values that we used as a cutoff for tissue identification. We found that our technique had a sensitivity of approximately 95% with an acceptable specificity; the cutoff value can be easily identified in the curves of 650 nm light and the ratio.

In conclusion, this is the first study to introduce a new optical technique to localize the epidural space. The technique uses unique optical properties in different tissues to identify the location of an epidural needle. This provides the operator with real-time information that can be displayed as a visual electronic signal to assist in epidural placement. Our technique will require further testing to compare the rate of successful insertion to techniques that use LOR. Further, our evidence indicates that only the 650-nm wavelength is consistently useful. This could limit the amount of information obtained using our technique. Finally, there seems to be a distinct but rapid learning curve similar to other techniques of epidural placement.

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