Fiber-needle Swept-source Optical Coherence Tomography System for the Identification of the Epidural Space in Piglets

Wen-Chuan Kuo, Ph.D., Meng-Chun Kao, Ph.D. Student, Kuang-Yi Chang, M.D., Ph.D., Wei-Nung Teng, M.D., Ph.D. Student, Mei-Yung Tsou, M.D., Ph.D., Yin Chang, Ph.D., Chien-Kun Ting, M.D., Ph.D.

ABSTRACT

Background: Epidural needle insertion is traditionally a blind technique whose success depends on the experience of the operator. The authors describe a novel method using a fiber-needle–based swept-source optical coherence tomography (SSOCT) to identify epidural space.

Methods: An optical fiber probe was placed into a hollow 18-gauge Tuohy needle. It was then inserted by an experienced anesthesiologist to continuously construct a series of two-dimensional SSOCT images by mechanically rotating the optical probe. To quantify this observation, both the average SSOCT signal intensities and their diagnostic potentials were assessed. The insertions were performed three times into both the lumbar and thoracic regions of five pigs using a paramedian approach.

Results: A side-looking SSOCT is constructed to create a visual image of the underlying structures. The image criteria for the identification of the epidural space from the outside region were generated by the analysis of a training set (n = 100) of ex vivo data. The SSOCT image criteria for in vivo epidural space identification are high sensitivity (0.867 to 0.965) and high specificity (0.838 to 0.935). The mean value of the average signal intensities exhibits statistically significant differences (P < 0.01) and a high discriminatory capacity (area under curve = 0.88) between the epidural space and the outside tissues.

Conclusions: This is the first study to introduce a SSOCT fiber probe embedded in a standard epidural needle. The authors anticipate that this technique will reduce the occurrence of failed epidural blocks and other complications such as dural punctures. (Anesthesiology 2015; 122:585-94)
contrast agent or contact gels are necessary in the OCT system.

Further developments in the OCT include the transformation of the technology from the "time-domain" OCT to the "Fourier-domain" OCT. Fourier-domain OCT allows imaging at higher rates by an order of magnitude. In Fourier-domain OCT, it can be performed using a single detector by sweeping the source spectrum and detecting the intensity due to the component frequencies. Fourier-domain OCT of this type has been called swept-source OCT (SSOCT), which shows improved sensitivity and thus enables the rapid three-dimensional imaging of tissues.

An optical method using a forward-looking needle-fiber time-domain OCT system was proposed by Li et al. for guiding epidural anesthesia. Their report presented an OCT system based on a slow mechanical scanning time-domain setup that monitors the axial information in front of the needle by providing A-mode signals. However, the forward-looking probe is limited by the shallow OCT imaging penetration depth of several millimeters; it is not very useful for guidance purposes. Moreover, the ranging performance in their report was only investigated using a phantom.

Here, we propose a system that uses the method of guided epidural block by combining a side-looking fiber probe with an SSOCT, which can provide a visual image and thus mediate the needle-probe technique by identifying different biological tissues surrounding the needle. The fiber-needle–based SSOCT system not only displays the two-dimensional (2D) structure features and the average intensity of each image for distinguishing the ES from outside tissues but can also be operated by a single user.

**Materials and Methods**

**Needle Probe**

Figure 1A shows a photo of our SSOCT system working together with the needle probe. The optical probe was connected to a rotary motor, covered by a plastic tube, and placed into a puncture needle (with 1.2-mm inner diameter and 1.6-mm outer diameter; B. Braun Medical Inc., Saucon, PA) (fig. 1B). Figure 1C is an enlarged picture of the probe part from figure 1B. An arrow points to a “holder,” made using a rubber block, designed to keep the probe from moving in and out of the needle during the rotation. The optical probe was constructed by attaching a single-mode fiber to a gradient index lens and a prism (BK7 aluminum coated, beam direction angle <45°; Agiltron Inc., Woburn, MA), as shown in figure 1D, to guide and focus the light on the tissues. As the outer diameter of the plastic tube was only 0.9 mm, the probe fits into the hollow chamber of an 18-gauge epidural needle. The needle probe’s light output angle is approximately 90°, and a 2D OCT image was acquired by the circumferential scanning of the optical probe.

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**Fig. 1.** Photograph of our swept-source optical coherence tomography (SSOCT) system (A) working together with the needle probe (B and C) and schematic (D) of the SSOCT needle probe. GRIN lens = Graded-Index lens.
with a rotational motor. Thus, this design provides a “side-looking” image around the needle tip.

SSOCT System

Figure 2A shows the setup of our fiber-needle–based SSOCT. The system incorporates a 16-kHz frequency swept laser (Thorlabs Inc., Newton, NJ), which has a 1,310-nm center wavelength and 3-dB spectral bandwidth (>100 nm), as well as an average output power of 10 mW. Accordingly, the SSOCT system has an axial resolution of approximately 17.5 μm in the air (corresponding to 15 μm in tissue), as shown in figure 2B. The swept source contains a built-in Mach-Zehnder interferometer (Thorlabs Inc.) that provides a frequency clock for the laser to resample each individual record from the sample signal to an equidistant spacing in the frequency. The main output of the laser is coupled into a fiber-based Michelson interferometer and split into the reference and sample arms using a broadband 50/50 coupler. The sample arm of the SSOCT system was constructed with a single-mode fiber and the needle probe, as demonstrated in figure 1.

Two-dimensional OCT imaging was performed by circularly scanning the optical probe within the puncture needle using a rotary motor. The reflected light from the measured sample and the end mirror of the reference arm were incident onto the coupler. The reflected light, propagating backward through the coupler and circulator, exhibited a phase shift of π and were guided onto a balanced detector. The balanced detection doubled the signal and minimized the common excess noise. Finally, the fringe signals from the OCT interferometer and the output of the Mach-Zehnder interferometer were simultaneously recorded using a high-speed analog-to-digital converter (Alazar Technologies Inc., Quebec, Canada) operating at 10⁸ samples per second with a 14-bit resolution.

For the optimal resolution in OCT imaging, several post-processing steps were performed following the data acquisition. Further details and principles can be found in our previous proposed method. In brief, in the first step, each individual record from the sample signal was resampled to obtain an equidistant frequency spacing. In the second step, we applied a numerical compensation to offset the dispersion mismatch between the two arms of the interferometer. Next, after the application of zero padding and the windowing method to calibrate the spectrum side lobes, the A-scan signal was obtained by taking the inverse Fourier transform. Including all the processing stages described above, the image was displayed at a rate of two frames per second. Each frame comprised 720 A-lines, with an imaging depth of approximately 2 mm in water.

Epidural Insertion Protocol

First, we performed an ex vivo study to evaluate whether the characteristic features of different tissues are visible in our
needle-probe–based SSOCT images. The spinal region of a swine, centered in the lower lumbar region, was obtained from a local abattoir operated in accordance with the relevant legislation. Because different tissue layers were exposed, tomograms from the muscle, ligamentum flavum (LF), and ES were acquired as the needle tip progressed through the tissues. During the acquisition of the images, the needle was held manually and was maintained in fixed positions.

The in vivo study was approved by the Institutional Animal Care and Use Committee of Taipei Veterans General Hospital (Taipei, Taiwan). Five Chinese native pigs with an average weight of 25 kg were studied. The animals were intubated after the induction of general anesthesia with Zoletil 50 (Virbac, Carros, France) and mechanically ventilated with isoflurane. They were placed in the left lateral position for the epidural placement. The needle probe was inserted three times in both the lumbar and thoracic regions 35 to 40° from the midline using a paramedian approach. Six insertions were performed in each of the five piglets. During the needle probe insertion, a series of 2D OCT circumferential images was built up by continuously rotating the optical probe with a rotary motor (at a speed of two rounds per second) within the needle while acquiring image lines, until the ES was identified by directly observing the signal-free regions or adipose tissue structures in the ES. At that time, the conventional LOR technique was also used to confirm the ES. Once the ES region was suspected, we opened the “holder” and pushed the fiber probe beyond the needle tip by approximately 10 cm and obtain a circular image within the ES to double-check the ES region. The needle probe placement was also confirmed by ultrasound (Vivid e; GE Healthcare, London, United Kingdom) and radiograph (KXO-50R; Toshiba, Tokyo, Japan) with 5-ml contrast (ioxitalamic acid). The animals were euthanized after the procedure.

Quantitative Parameter Measurement and Statistical Analysis
To nonsubjectively discriminate the ES from outside tissues, the average OCT signal intensities in each image were calculated. A linear mixed-model analysis with compound symmetric covariance structures for repeated measures was used to evaluate whether the average signal intensity in the OCT images of the inside ES differed from that of the outside ES. The difference in average intensities of the distinct repeated measures in the ES and outside tissues was also tested. A P value less than 0.05 was considered to be statistically significant. The receiver operating characteristics curves were used to show the capacity for using this mean value to discriminate between the two sample populations. The measured ratio of the A-scan peak height to the mean noise floor was achieved as greater than 36 dB for the peaks within 1.5 mm. The optical path difference was defined as the difference in the path length between the reference and sample arm. The axial resolution of 17.5 μm measured at 1.5 mm was degraded to 28.7 μm in air.

Results
To test the system performance for the reflected signal measurement as a function of the ranging depth, a mirror was used to represent the sample. Figure 3 shows the depth-dependent signal decay for the mirror at different optical path difference positions (linear scale in arbitrary units), where the measured ratio of the A-scan peak height to the mean noise floor was achieved as greater than 36 dB for the peaks within 1.5 mm. The optical path difference was defined as the difference in the path length between the reference and sample arm. The axial resolution of 17.5 μm measured at 1.5 mm was degraded to 28.7 μm in air.

Figure 4 shows several representative images of the ex vivo experiments selected to illustrate the characteristic features visible in the OCT. The two signal-rich bands in the upper part of the OCT images are due to backscattering from the plastic protection tube. In the muscle tissue (fig. 4A), the layered structure resulting from the muscle fascicles can be identified. In addition, the inclusion of dispersed adipose tissues leads to a nonuniform signal distribution. The LF (fig. 4B) has strong and homogeneous signal distributions with a smaller imaging penetration depth than that for the muscle tissue (fig. 4A). This may be because the LF tissue is mainly comprised of elastin, which is far denser than muscle tissue. Thus, the light scattering from the LF is stronger than that in muscle. Moreover, numerous empty spaces construct a lattice-like structure, which results from the large amounts of the attached adipose tissue in the ES (fig. 4C). Figure 4D shows another case with a needle inside the ES, without the adipose tissue attached. Because no reflective light can be detected, the ES in the OCT image is revealed as a signal-free region.
These visual details regarding the morphological information obtained from the \textit{ex vivo} OCT images are summarized in table 1 and were used to establish the OCT image criteria for distinguishing the ES from the outside tissues. A total of 100 \textit{ex vivo} OCT 2D scans were obtained and quantitatively analyzed: 50 images were from the sites identified as ES and the other 50 were from the outside ES regions (including the LF and muscle tissues). The population means of the average intensities are smaller in the ES areas (−10.70 ± 1.23 dB) compared with the outside tissues (−7.92 ± 1.80 dB), which are statistically significantly different (\( P < 0.01 \)).

After the \textit{ex vivo} experiment, six insertions were performed in each of the five piglets, during which guidance to the ES location was performed with the characterization of OCT images by using the criteria summarized in table 1. The average intensity of each image was calculated simultaneously. Figures 5 and 6, A–D, show representative tomograms where different structures can be observed as the needle probe moves from the skin hypoderm toward the ES in the lumbar and thoracic regions, respectively. The hypoderm, exhibiting numerous empty spaces, comprises subcutaneous adipose tissue and can only be observed when the needle tip positions are in the skin surface (figs. 5A and 6A). The ES (figs. 5D and 6D) was confirmed using a conventional LOR technique. The muscle layer (figs. 5B and 6B) and LF (figs. 5C and 6C) could also be easily recognized by the criteria listed in table 1. When our OCT needle probe was inserted into the ES, we opened the “holder” and pushed the inner optical fiber tip out of the needle tip so that we could obtain a whole circular image within the epidural channel. The result is shown in figure 7A. The ES and cerebrospinal fluid reveal no backscattering signals.

\begin{table}
\centering
\caption{OCT Criteria for Identification of ES and Outside Tissues}
\begin{tabular}{|l|l|l|}
\hline
Tissue Type & Characteristic Features Visible in OCT Image \\
\hline
Outside ES & Nonuniform signal distribution, presence of layered structures \\
tissues & Strong and homogeneous signal distribution, less imaging penetration depth than that in muscle tissue \\
\hline
Inside ES & Appearance of numerous empty spaces, presence of a lattice-like structure, or no reflective signal \\
region & \\
\hline
\end{tabular}
\end{table}
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SSOCT-embedded Epidural Needle

posterior dural shows a signal-rich layer, and the adipose tissue attached to the LF in the ES can be easily differentiated. Figure 7B shows the surface ultrasound image of the lumbar and the thoracic regions in the ES. The ultrasound image in figure 7B reveals the empty space between the two signal-rich layers (LF and posterior dural), that is, the ES.

Finally, a total of 60 in vivo OCT 2D scans were obtained and analyzed; 30 images were from the sites identified as ES and the other 30 were from the outside regions. All 60 of the OCT 2D images were obtained from the five piglets. One inside-ES and one outside-ES images were obtained from each insertion attempt. Six insertions were successfully performed for each of the five piglets without any difficult or failed attempts. The independent validation of OCT criteria for the ES identification by 10 OCT readers for the in vivo data demonstrated the sensitivity and specificity, which ranged from 0.867 to 0.965 and 0.838 to 0.935, respectively, as shown in table 2.

Figure 8A indicates that the population means of the average intensities in the ES and outside tissues are \(-10.71 \pm 0.91\) and \(-8.87 \pm 1.44\) dB, respectively, which are statistically significantly different (i.e., \(P < 0.01\)). No significant difference in the average intensities was noted among the distinct repeated measures in either the ES or outside tissues (\(P = 0.47\)). The receiver operating characteristics curves (fig. 8B) demonstrate the prospective use of the average intensities for discriminating between regions inside the ES and adjacent regions. The AUC for the receiver operating characteristics curve indicates that the average intensities have a high discriminatory capacity (AUC = 0.88) for discriminating between the ES and outside tissues.

Discussion

Currently, there is no commercially available OCT system for epidural needle insertion although Li24 and Tsen27 have addressed this possibility. The epidural and spinal spaces are surrounded by a complex bony structure, which limits the use of ultrasound to clearly identify the LF, ES, and dura well in adults, whose bones are fully calcified. Thus, ultrasound can only assist in landmark identification and reducing the contact with the bony structure. Clinicians are still searching for practical neuraxial techniques that allow “real-time” observation of the epidural catheter introduction and drug deposition.27

In this study, a side-looking, fiber-needle–based SSOCT that can provide a visual image of the underlying structure is presented. The OCT image criteria for the identification of the ES from the outside region were formulated by the analysis of a set (n = 100) of ex vivo data. The OCT images
of the ES were characterized by signal-free regions or by the appearance of several numerous empty spaces, forming a lattice-like structure. The empty spaces in the ES are adipose tissues and are possibly due to the existence of large amounts of epidural fat in the ES. A quantitative assessment of the OCT signals showed that the average intensities are smaller in the ES compared with that in the outside tissues. A previous report, which used an optical spectroscopy method to identify the ES, indicated that there was an increased lipid volume fraction when the needle tip was moved from an

Fig. 6. In vivo optical coherence tomography images of (A) hypoderm, (B) muscle, (C) ligamentum flavum, and (D) epidural space in the thoracic region acquired using the side-imaging optical coherence tomography needle probe.

Fig. 7. (A) Optical coherence tomography whole circular image within the epidural channel. (B) In vivo surface ultrasound image. CSF = cerebrospinal fluid; EF = epidural fat; ES = epidural space.
adjacent tissue structure to the ES. In our study, the ES was identified in real time by the direct observation of the adipose structures from the epidural fat. Our SSOCT probe presents “live” 2D images, which assists the navigation toward the ES, similar to the transesophageal ultrasound transducers currently used for cardiac imaging. Our proposed method can also be used to decrease the training time and learning curve. Moreover, it can help to confirm the ES once the ES has been identified by the LOR technique.

To see is to believe, images are always a better tool for humans to understand a new concept than a verbal description. People can easily recognize the ES and outside tissue by the OCT images after a brief training on the criteria and images. However, the analysis using only the average OCT intensity in each image will lose the information on structures and thus reduce the discriminant ability; this is why the sensitivity and specificity are so high in the test, but the AUC for the quantitative analysis is relatively low (0.88) although the statistical significance was still existed. However, the AUC of the average signal intensity in this report is very close to the result for the AUC (0.89) obtained using 650-nm visible light in our previous report. This is due to not only its physical nature but also its reproducibility. Moreover, the near-infrared light offers the greatest potential for optical imaging penetration owing to the weak scattering and absorption in soft tissue. The optical attenuation in blood at 1,310 nm in the near-infrared light is 1 to 2 orders of magnitude less than that in the visible range; the absorption in water is also very low (i.e., absorption coefficient is 1.2 cm$^{-1}$ at a 1,310-nm wavelength). Thus, the image quality may not be severely influenced when our needle is filled with anesthetic fluid, blood, and/or blood clots.

The linear mixed-model analysis indicated that there was no significant difference in the OCT signals obtained among the six different spine levels in the thoracic and lumbar regions in our porcine model. Ultrasound studies confirmed the correct placement of all the needle probes in the ES of the lumbar and thoracic areas of the spine. Moreover, because the OCT provides noninvasive imaging at a high resolution, the adipose tissue attached to the LF in the ES can be easily differentiated, as demonstrated in figure 7A. In addition, the dura mater was identified between the

| Table 2. Independent Validation of OCT Criteria for Epidural Space Identification by 10 OCT Readers for the In Vivo Data |
|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
|                | 1               | 2               | 3               | 4               | 5               | 6               | 7               | 8               | 9               | 10              | Mean            | SD              |
| Sensitivity    | 0.867           | 0.96            | 0.931           | 0.965           | 0.896           | 0.93            | 0.94555         | 0.962264        | 0.94            | 0.901961        | 0.929868        | 0.0306868       |
| Specificity    | 0.878           | 0.866           | 0.838           | 0.709           | 0.935           | 0.871           | 0.911111        | 0.914894        | 0.82            | 0.857143        | 0.8700148       | 0.0613368       |
| PPV            | 0.866           | 0.887           | 0.843           | 0.756           | 0.928           | 0.831           | 0.928571        | 0.927273        | 0.921569        | 0.867925        | 0.8756338       | 0.05288859      |
| NPV            | 0.899           | 0.955           | 0.82            | 0.95            | 0.935           | 0.871           | 0.931818        | 0.955556        | 0.938776        | 0.893617        | 0.9149767       | 0.04170391      |
| ACC            | 0.87            | 0.94            | 0.88            | 0.83            | 0.91            | 0.9             | 0.93            | 0.94            | 0.93            | 0.88            | 0.901           | 0.03419064      |

ACC = accuracy; NPV = negative predictive value; OCT = optical coherence tomography; PPV = positive predictive value.

Fig. 8. (A) Distributions of the optical coherence tomography average intensities (Intensity_ave) from regions in epidural space (ES) and outside tissues. (B) Receiver operating characteristics (ROC) curves showing the capacity of using the optical coherence tomography average intensities for discrimination between ES and outside tissues.
signal-free ES and cerebrospinal fluid. This made the boundaries of the dura mater more distinct than the LF. Thus, the area between the top surface of the LF and the dura mater was measured as approximately 2 to 3 mm wide and identified as the ES (fig. 7A).

An advantage of this new technique is that it can be used by a single operator, similarly to our previous A-mode ultrasound technique and commercially available spring-loaded syringe systems\(^9,30\) (Episure AutoDetect LOR Syringe; Indigo Orb, Irvine, CA). Compared with our previously proposed A-mode ultrasound technique, the present technique provides not only the signal amplitude but also a visual image of the underlying structure with a good axial resolution. The OCT image provides a more specific method than the amplitude in the A-mode ultrasound. In clinical application, a disposable OCT probe allows a safe procedure. Moreover, the side-looking design and circumferential scanning ensure that the probe is not limited by the different angles of the needle insertion and the shallow optical imaging penetration depth.

There are several limitations to our new technique. First, although this new technique provides a good differentiation between the ES and outside tissues, it is possible that it may not reduce the number of insertion attempts, as it does not provide guidance of the trajectory path for the needle placement or an overview of the axial anatomy, as do surface ultrasound techniques. However, a surface ultrasound probe can be used together with our SSOCT needle if the anatomical landmarks of the subject are difficult to define. Second, it is difficult to differentiate from the images whether the needle tip is at supraspinous ligament, interspinous ligament, or LF. Thus, in this study, we only discriminate the ES region from the surrounding tissues. Third, the cost of the OCT equipment currently is close to a surface ultrasound system. However, because of the rapid pace of innovation in the OCT field, the cost and ease of use of such modalities is improving rapidly.

In conclusion, the first study to introduce a new needle-probe method to identify the ES in real time. The OCT image criteria are highly sensitive and specific for distinguishing the ES from the outside tissues. Quantitative parameters by using the average intensity in the OCT images can provide a complementary (AUC = 0.88) method for aiding the ES identification. The current image display rate of two frames per second cannot be affected by slow motion, such as the patient’s breathing. Further improvements in the signal-to-noise ratio and image display rate are currently under development that can be used for preventing the image quality degradation due to a large amount of patient movement. Improving the image display rate also reduces the time required for performing the procedure. These improvements may result in the actual use of the system for epidural anesthesia in the near future. Although our findings indicate that such devices can be used in clinical practice, additional studies with human subjects are required to confirm our hypothesis.

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Competing Interests
The authors declare no competing interests.

Correspondence
Address correspondence to Dr. Ting: Department of Anesthesiology, Taipei Veterans General Hospital and School of Medicine, National Yang-Ming University, Taipei, Taiwan. cktng@vghtpe.gov.tw. Information on purchasing reprints may be found at www.anesthesiology.org or on the masthead page at the beginning of this issue. ANESTHESIOLOGY’s articles are made freely accessible to all readers, for personal use only, 6 months from the cover date of the issue.

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