

Trans-Sacral Epiduroscopic Ho:YAG Laser Ablation of the Ligamentum Flavum in a Live Pig

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Abstract:

Introduction: For the aging population, surgery for lumbar spinal canal stenosis (LSCS) requires minimally invasive procedures. Recently, trans-sacral epiduroscopic laser decompression for lumbar disc herniation has been reported with good results. In this study, we devised a new method to perform trans-sacral epiduroscopic laser ablation of the ligamentum flavum (LF), known to be the major cause of LSCS. Using a live pig, this study aims to evaluate the efficacy, safety, and drawbacks of this procedure.

Methods: Using an epiduroscope, we observed intra-spinal canal structures and then examined the feasibility and problems of a decompression procedure to ablate the LF using holmium:YAG (Ho:YAG) laser. The pig was observed for behavioral changes and neurological deficits after the procedure. Histological analysis was performed to evaluate the amount of tissue ablation and damage to surrounding tissues.

Results: Although it was possible to partially ablate the LF using the Ho:YAG laser under epiduroscopy, it was difficult to maintain a clear field of view, and freely decompressing the target lesion has been a challenge. After the first two experiments, the pig neither showed abnormal behavior nor any signs of pain or paresis. However, in the third experiment, the pig died during the operation. On autopsy, no thermal or mechanical injury was noted around the ablated site, including the dura mater and nerve root. Histological analysis showed that the LF and lamina were deeply ablated as the laser power increased, and no damage was noted on surrounding tissues beyond a depth of 500 μm .

Conclusions: Although Ho:YAG laser could ablate the ligamentum and bone tissues without causing damage to surrounding tissues, it was difficult to completely decompress the LF under epiduroscopy. This method is a potentially highly invasive procedure that requires caution in its clinical application and needs further improvement in terms of the instruments and techniques used.

Keywords:

Epiduroscopy, Ho:YAG laser, trans-sacral epiduroscopic laser decompression, lumbar spinal canal stenosis, ligamentum flavum

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Introduction

Lumbar spinal canal stenosis (LSCS) has been determined as a common spinal disorder in elderly individuals. LSCS often causes pain, numbness, and paresis in the lower extremities, which could impair walking and activities of daily living^{1,2)}. Although chronic intervertebral disc degeneration and bony hypertrophy can both contribute to the narrowing of the spinal canal, the major cause of LSCS has been identified as the hypertrophy of the ligamentum flavum (LF)^{3,4)}.

Most patients with LSCS are usually treated conservatively with drugs, physiotherapy, epidural injections, and multidisciplinary rehabilitation^{5,6)}. Patients who do not improve with conservative treatment are treated with surgery⁷⁾. The most common surgical procedure for LSCS is laminectomy and resection of the LF via detachment of the paravertebral muscles from the bone by the posterior approach to decompress the neural structures⁸⁾. Although laminectomy is a good technique for efficient decompression of neural structures, it can cause muscle damage and iatrogenic insta-

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bility associated with excessive facet joint resection^{9,10}. In recent years, minimally invasive decompression surgery for LSCS has become popular with the aging of the population. Good clinical results have been obtained with the development of microendoscopic technology and surgical techniques¹¹⁻¹⁵. Although significantly less invasive than the classic procedures, these minimally invasive surgical techniques still require general anesthesia and hospital admission and could damage normal tissues such as the paravertebral muscles and bones. Some elderly individuals with various comorbidities have a difficult time under general anesthesia, and further minimally invasive methods with local anesthesia are thus required.

The spinal canal is a luminal structure that connects to the sacral hiatus. Recently, percutaneous epidural neuroplasty (PEN), using catheters via the sacral hiatus under local anesthesia, has been widely performed as an interventional pain management technique to treat chronic low back pain and/or lumbosacral radiculopathy. This technique aims to eliminate fibrous adhesions and ensure the delivery of high concentrations of injected drugs to targeted areas^{16,17}. There is strong evidence for short-term efficacy (3 months) and weak evidence for long-term efficacy (greater than 3 months)¹⁸. Randomized, double-blind trials showed that PEN was superior to epidural steroid injections¹⁹ and physiotherapy²⁰, but might be inferior to surgical treatment in the long term. We believe that physical nerve compression by the LF should be removed to improve the long-term results.

Recently, trans-sacral epiduroscopic laser decompression (SELD) for herniated lumbar discs has been introduced as a promising alternative to PEN²¹. Moon et al.²² have reported that SELD was superior to PEN in terms of the degree of improvement in clinical and functional outcomes, as SELD could directly decompress nerves as well as induce adhesiolysis. Epiduroscopy is also a new minimally invasive technique and a very useful method for the management of lumbar spinal disease because it provides direct visualization of spinal structures, which allows for focused adhesiolysis and targeted injection by identifying the pathology²³. Moreover, laser decompression with epiduroscopy can be a more effective method for treating intra-spinal pathologies, such as herniated nucleus pulposus, painful epidural adhesions, and hypertrophy of the LF.

We then devised a new method to perform trans-sacral epiduroscopic laser ablation of the LF, which is the major cause of LSCS. The clinical application of lasers has been widely used in orthopedics, including spinal surgery^{24,25}. To date, various types of lasers in spinal surgery have been reported in clinical or experimental studies, including the neodymium:yttrium-aluminum-garnet (Nd:YAG) laser^{26,27}, holmium:YAG (Ho:YAG) laser²⁸⁻³⁰, and CO₂ laser³¹. Among them, Ho:YAG laser has a wavelength of 2.1 μm and reaches a depth of <0.5 mm in tissue^{29,32}. Ho:YAG laser has good tissue vaporization but low tissue permeability, which can lessen damage to the surrounding tissues. Therefore, the

Ho:YAG laser may cause less damage to the surrounding tissues such as the dura mater and nerve roots in a small enclosed space compared with other types of lasers. We hypothesized that the Ho:YAG laser would be most suitable for epiduroscopic laser ablation.

The purpose of this study was to evaluate the efficacy, safety, and drawbacks of trans-sacral epiduroscopic Ho:YAG laser ablation of the LF using a pig, whose spinal morphology is anatomically similar to that of humans. To our knowledge, this is the first study to attempt trans-sacral epiduroscopic laser ablation of the LF in a live pig.

Materials and Methods

All procedures were conducted in accordance with the protocols approved by the experimental animal ethics committee in our university. We used a female pig obtained from the National Federation of Agricultural Cooperative Associations, Tokyo, Japan. After the pig was placed in the prone position under general anesthesia, a small incision was made to expose the dorsal side of the sacrum (Fig. 1A). As the pig does not have a sacral hiatus, a MyeloCath (Biomedica Healthcare, Tokyo, Japan) was inserted into the caudal epidural space through the interlaminar space of the sacrum (Fig. 1B). The MyeloCath is a double-lumen steerable catheter for epidural space access with a flexible mobility of more than 90 degrees to the right and left. A MyeloCath was advanced to the targeted lumbar region under fluoroscopic guidance (Fig. 2). One lumen of the 2.7 mm diameter catheter shaft had a 1.4 mm inner diameter, into which a 1.2 mm outer diameter epiduroscope (1.2 mm Flexible Fiber Optic Endoscope, Myelotec, Roswell, GA, USA) was inserted, and the other lumen had a 0.7 mm inner diameter, into which a Ho:YAG laser fiber (Lumenis Pulse 30H, Lumenis, Tokyo, Japan) was inserted and irrigated with saline. The Flexible Fiber Optic Endoscope has a 1.2 mm outer diameter with a 15 K pixel fiber bundle and approximately 40x magnification (Fig. 3A). The Ho:YAG laser system had a maximum output power of 30 W, pulse energy that could be set from 0.2 to 3.5 J, and repetition rate that could be set from 3 to 25 Hz. Through the epiduroscope, we observed intra-spinal canal structures and examined the feasibility and problems of a physical decompression procedure to ablate and vaporize the LF using a Ho:YAG laser. Epidural saline perfusion was then used to irrigate and clear the area visualized on the endoscopic video screen as well as to cool the ablation site. We thought that there was a limitation of visualization using a 1.2 mm Flexible Fiber Optic Endoscope; thus, we observed using a high-performance CMOS endoscope with 160 K pixel (Biomedica Healthcare, Tokyo, Japan) to obtain a better field of view in the same procedure (Fig. 3B).

In addition, after awakening from general anesthesia, the pig was observed for behavioral changes and neurological deficits for 1 month after the laser ablation procedure. This experiment was performed in triplicate.

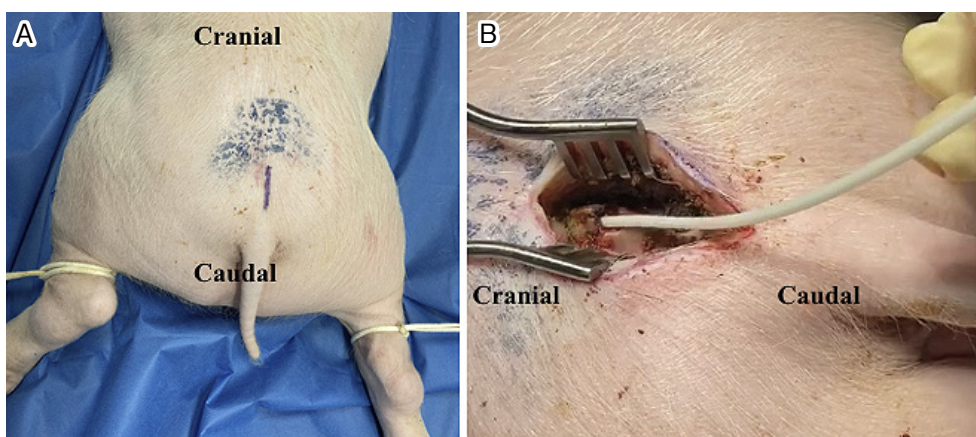


Figure 1. Photographs of the pig used in the experiments.

A: A small incision was made to expose the dorsal side of the sacrum.

B: A catheter was inserted into the caudal epidural space through the interlaminar space of the sacrum.

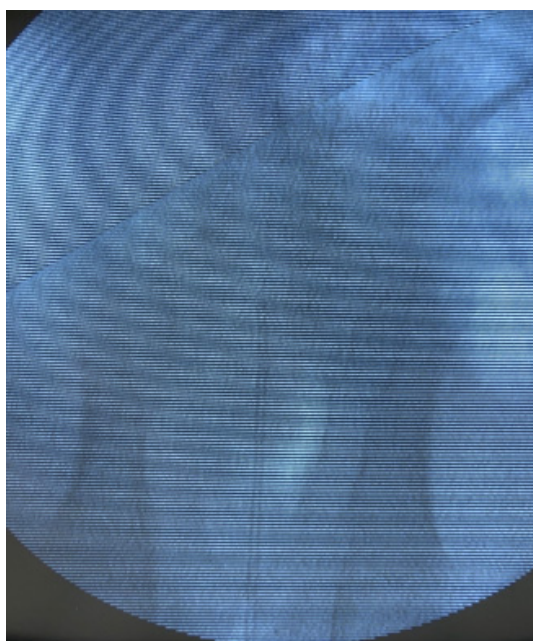


Figure 2. A catheter was advanced to the targeted lumbar region under fluoroscopic guidance.

Results

Through the epiduroscope, we could see the dura mater, nerve roots, epidural fat, ventral side of lamina, and LF (Fig. 4A, B). It was easy to see the dorsal side of the dura mater with the epiduroscope, but it was difficult to reach where we wanted to see in the small enclosed epidural space due to the problem of catheter tip maneuverability. In addition, epidural bleeding had made it difficult to maintain a good visual field. This problem could be solved to some extent by irrigation with saline; however, laser ablation in an unclear field of view is deemed dangerous, and the operation had to be interrupted. The Flexible Fiber Optic Endoscope we initially used did not provide a clear field of view due to problems with image quality and focal length, but by using the CMOS endoscope, we obtained a very clear field of view (Fig. 5A).

The LF could be ablated using a Ho:YAG laser under epiduroscopy. As the laser power increased, the LF was ablated deeply. However, when the laser power increased too much, the screen became cloudy due to vaporization, making it difficult to maintain a good field of view (Fig. 5A, B). No obvious dural tears occurred during the operation.

After the first two experiments, the pig neither showed abnormal behavior nor any signs of pain or paresis. However, in the third experiment, the pig died during the operation.

On autopsy, the LF and lamina were deeply ablated as the laser power increased (Fig. 6A). There were no dural tears or nerve root injuries corresponding to the ablated site macroscopically (Fig. 6B). Histological slides of the ablated site in the axial sections showed that laser ablation formed oval cavities, round coagulations, and tissue charring on the LF and lamina (Fig. 6C-E). Furthermore, laser resection extended not only to the LF, but also to the cortical and cancellous bone of the lamina (Fig. 6E). However, there was no damage to the tissue around the ablated site beyond a depth

During autopsy, the lamina and LF were resected. We observed if there was any thermal or mechanical injury around the ablated site. Histological analysis was also performed to evaluate the amount of tissue ablation and damage to surrounding tissues. Immediately after resection of the lamina and LF at the ablated site, specimens were fixed in 10% neutral formalin. The specimens were paraffin-embedded and sectioned (10 μ m) perpendicular to each laser incision. The sections were subsequently stained with hematoxylin and eosin (H&E). The measurements of depth, width, and extent of resection from each laser ablation were performed using a light microscope (Olympus, AX73).

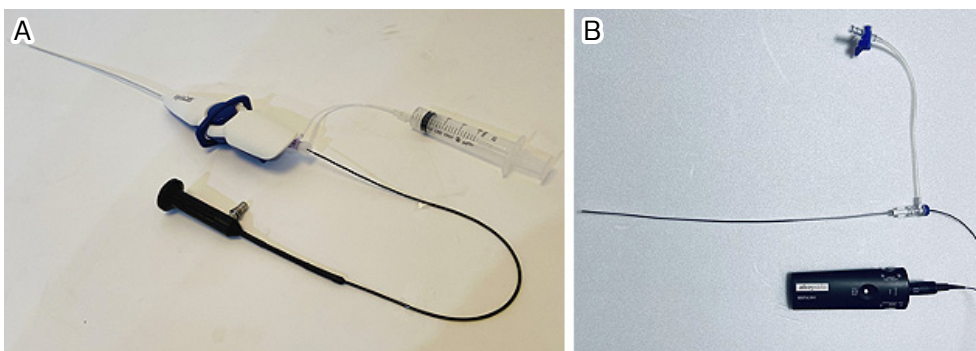


Figure 3. Photographs of the epiduroscopes.
A: 1.2 mm Flexible Fiber Optic Endoscope through the MyeloCath.
B: High-performance CMOS endoscope.

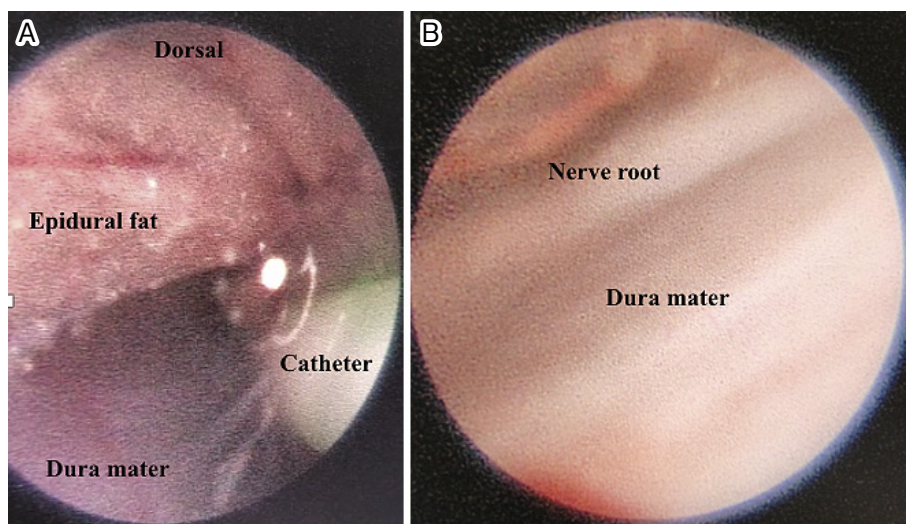


Figure 4. Epiduroscopy image obtained from the Flexible Fiber Optic Endoscope with 15K pixel.
A: Image showing the dura mater, epidural fat, and catheter tip.
B: Image showing the dura mater and nerve root.

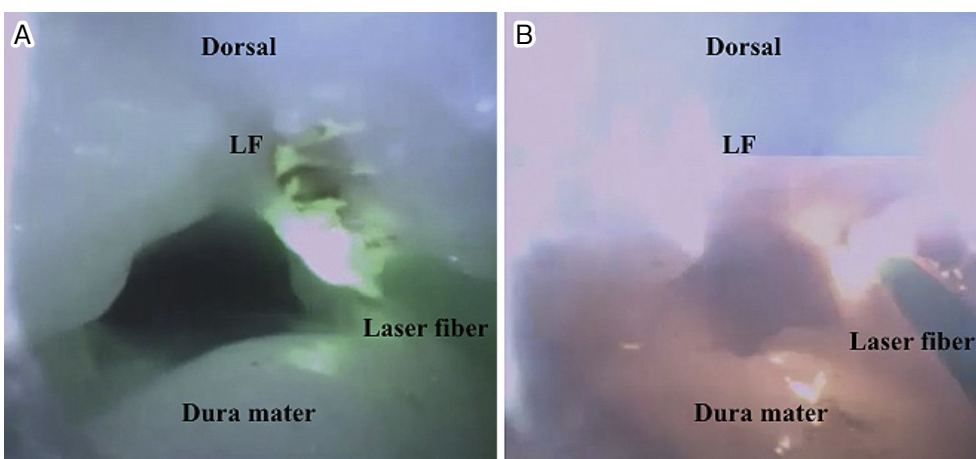


Figure 5. Epiduroscopy image obtained from the CMOS endoscope with 160K pixel.
A: Image showing ablation of the LF using a Ho:YAG laser. A very clear field of view was then obtained.
B: When the laser power increased too much, the screen became cloudy due to vaporization, making it difficult to maintain a good field of view.

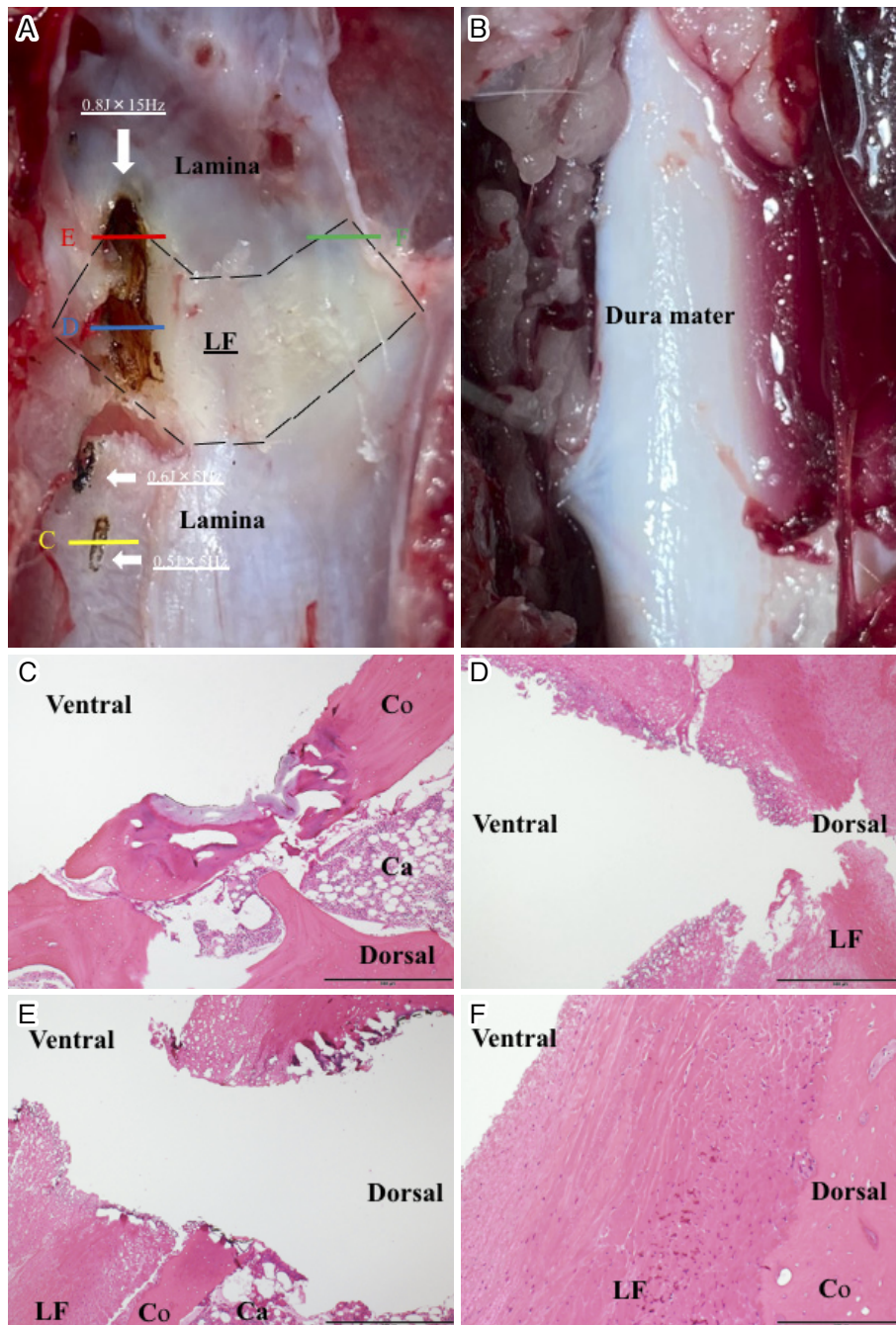


Figure 6. Autopsy photographs after the experiments and histological analyses of the ablated LF and lamina.

A: Photograph showing the ablated LF and lamina. The dashed black lines indicate outlines of the LF. As the laser power increased, the LF and lamina became deeply ablated (the yellow, blue, red, and green lines show the cross sections of the slides in Figs. 5. C, D, E, and F respectively).

B: Photograph showing the lack of a dural tear or nerve root injury corresponding to the ablated site.

C, D, and E: Axial sections of each ablated site in Fig. 5A on H&E staining showing that laser ablation formed oval cavities, round coagulations, and tissue charring on the LF and lamina. Furthermore, laser resection extended not only to the LF, but also to the cortical and cancellous bone of the lamina. However, no damage was noted to the tissue around the ablated lesion beyond a depth of 500 μ m.

F: Axial section of the normal LF and lamina on H&E staining.

Scale bars (C, D, and E): 500 μ m, Scale bar (F): 200 μ m

Co, cortical bone; Ca, cancellous bone

of 500 μm .

Discussion

In this study, although it was possible to partially ablate the LF using the Ho:YAG laser under epiduroscopy, it was difficult to maintain a clear field of view and freely decompress the target lesion. There was no thermal or mechanical injury around the ablated site, including the dura mater and nerve root. Furthermore, histological analysis showed that there was no damage to the tissue around the ablated site beyond a depth of 500 μm . These results suggest that the Ho:YAG laser can ablate the ligamentum and bone tissues with pinpoint accuracy without causing damage to the surrounding tissues. Based on the findings obtained in this experiment, we discussed the problems and countermeasures for epiduroscopy, irrigation, bleeding, laser decompression, and complications.

First, the biggest problem with epiduroscopy is the maneuverability of the catheter tip. MyeloCath has linear mobility to the right and left, but a catheter with more delicate movement is required to freely reach the desired location in the small enclosed epidural space. We have also found that using a CMOS endoscope with better image quality gave us a better field of view; however, a fiberscope that could adjust the focal length to match the point of view would be necessary.

The second issue is irrigation. An irrigation solution is essential for adequate epiduroscopic views. Although it was possible to inject as much saline as we wanted into the epidural space, it was difficult to drain. We hypothesized that the cause of death during the operation in the third experiment was increased intracranial pressure due to excessive saline perfusion into the epidural space. Park et al.³³⁾ have reported that some patients complained of headaches during the epiduroscopic laser decompression procedures, and increased intracranial pressure due to the high irrigation volume or speed might be the cause of the headache. Our study suggests that excessive saline injection into the epidural space may cause death in the worst case due to increased intracranial pressure. Although it is important to limit the volume and speed of irrigation, it is also necessary to consider drainage methods such as elevating the head or draining from another portal on the cranial side of the decompression level. For clinical application, epiduroscopy may be dangerous to perform under general anesthesia and should thus be performed under local anesthesia while checking for symptoms of intracranial hypertension, such as headache, vomiting, elevated blood pressure, and bradycardia.

The third issue is the management of bleeding. Epidural bleeding makes it difficult to maintain a good visual field. This problem could be solved to some extent by irrigation with saline, but excessive saline perfusion is a risk factor for increased intracranial pressure and should be avoided, as mentioned above. In addition, bleeding can lead to neuro-

logical complications due to epidural hematoma³⁴⁾. The achievement of effective hemostasis and clear visualization is important to reduce the risk of vascular injury and epidural hematoma. We believe that gentle manipulation, intraoperative blood pressure control, and the addition of epinephrine to the irrigation solution might be useful in preventing bleeding. It may also be important to develop a small bipolar hemostatic device with good tip handling that can be used in the epidural space.

The fourth issue is the safety of Ho:YAG laser decompression. Johnson et al.³⁰⁾ have demonstrated that in an ex vivo study of porcine spines, Ho:YAG laser ablated the LF and produced carbonization around the rim of the laser hole. They also showed that constant flushing with room-temperature saline drastically reduced the surface temperature during exposure to Ho:YAG laser, and charring was reduced by shortening the laser pulse width. Lee et al.³⁵⁾ have reported that in a cadaveric study on temperature distributions of the lumbar intervertebral disc during laser annuloplasty, the temperature would rise upon irradiation and fall slowly with the cessation of irradiation, and the most distinctive elevation of the temperature was observed from probes located 3 mm away from the laser fiber tip, both in depth and lateral positions. Li et al.²⁸⁾ reported that 2 out of 220 patients experienced a burning sensation in the ipsilateral lower limb during the thermal procedure using Ho:YAG laser, which disappeared when the Ho:YAG laser ablation stopped. This sensation was possibly related to the high temperature generated by vaporization of the Ho:YAG laser. These results indicate that a sufficient distance between the laser tip and the neural structures of no less than 3 mm and constant flushing with saline may prevent thermal damage to surrounding tissues such as the dura mater and nerve roots. However, in patients with severe spinal canal stenosis, there is little free space in the epidural space; thus, this technique requires caution in its clinical application.

Dural tear is a well-known complication of spinal surgery. Kim et al.³⁴⁾ have reported that a dural tear was identified in 1 case (0.8%) of 127 patients who underwent SELD for lumbar disk herniations, and tearing occurred during the insertion of the epiduroscope into the thecal sac. They state that the possibility of dural tear is extremely low because SELD does not use a knife or Kerrison rongeur. Moreover, as the diameter of the epiduroscope is small, tearing tends to be small and often present without overt symptoms. However, Jo et al.³²⁾ have demonstrated that even with low power and short duration, Ho:YAG laser can destroy tissue if laser energy is applied directly to the dura and nerve root. Therefore, surgeons should pay close attention to the operation of the epiduroscope and laser, and be prepared to convert to open surgery for repair if uncontrolled cerebrospinal fluid leakage due to major dural tear is observed.

Subchondral osteonecrosis is also a complication associated with laser surgery^{34,36)}. Tonami et al.³⁶⁾ have already reported four cases of subchondral osteonecrosis of the vertebral body in 183 patients (2.2%) who underwent percutane-

ous laser discectomy. Subchondral osteonecrosis is defined as an abnormal signal intensity on magnetic resonance imaging identified in bone located directly adjacent to the region of the intervertebral disc treated with laser energy. Although the clinical significance of subchondral osteonecrosis has not yet been examined, possible causative mechanisms include thermal injury and photoacoustic shock. In this study, bone resorption was also observed in the lamina at the ablated site. This suggests that osteophyte resection of the medial facet joint, which causes nerve compression, may be possible through the epidural space. However, we need to consider appropriate laser power to prevent excessive bone ablation.

This study has several limitations. First, the epidural space in a pig is not exactly the same as that in humans. Second, a pig without LF hypertrophy does not reflect the actual LSCS model. Third, the catheter was inserted into the epidural space through the interlaminar space of the sacrum rather than the sacral hiatus, which may be more difficult to operate. Despite these limitations, we believe that this study has unique strengths and provides a foundation for further studies.

In conclusion, although it was possible to partially ablate the LF using Ho:YAG laser under epiduroscopy without causing damage to the surrounding tissues, it was difficult to maintain a clear field of view and freely decompress the target lesion. This method is a potentially highly invasive procedure that requires caution in its clinical application and needs further improvement in terms of the instruments and techniques used.

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Ethical Approval: The experimental animal ethics committee in our university approved this study (approval number: 2020272).

Informed Consent: None. This study was not included in any clinical trials.

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