

Feasibility Study

Percutaneous Endoscope-assisted Visualized Implantation of Puncture Cylindrical Electrodes for Spinal Cord Stimulation: A Cadaveric Feasibility Study

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Background: Spinal cord stimulation is an established technique wherein diverse electrode types are strategically implanted within the spinal epidural space for neuromodulation. Traditional percutaneous puncture cylindrical electrodes (PEs) are predominantly implanted by interventionalists utilizing a percutaneous technique under the monitor of radiation, which is a nonvisualized procedure.

Objective: Our study aimed to assess the feasibility of percutaneous endoscope-assisted visualized implantation approach for PEs, delineating its specific merits and demerits compared to the traditional method.

Study Design: Laboratory study with Institutional Review Board Number B2023-056

Setting: Clinical Anatomy Research Center, Fudan University.

Methods: Eight freshly procured adult cadavers (4 women and 4 men) were operated on in this study. They were divided into either Group A or Group B, each encompassing 4 cadavers. Group A was subjected to endoscope-assisted PEs implantation, whereas Group B followed the conventional PEs implantation route.

In both groups the operative time of introducer needles placement (OTNP), total operative time (TOT), fluoroscopy time of introducer needles placement (FTNP), and total fluoroscopy time (TFT) were documented and analyzed. Furthermore, the precise positioning of the PEs and any ensuing complications were systematically examined.

Results: Both Group A and Group B successfully executed all predetermined surgical steps. A total of 16 PEs were implanted (dual electrodes in each cadaver): 8 using the percutaneous endoscope-assisted visualized approach (Group A) and 8 via the traditional methodology (Group B). Group A's mean \pm SD durations for OTNP, TOT, FTNP, and TFT were 10.25 \pm 1.03 minutes, 31.63 \pm 5.87 minutes, 4.58 \pm 1.35 seconds, and 43.73 \pm 14.46 seconds, respectively. In contrast, Group B exhibited mean \pm SD times of 11.55 \pm 2.81 minutes, 44.75 \pm 7.85 minutes, 23.53 \pm 4.16 seconds, and 66.30 \pm 6.35 seconds for the same metrics. No discernible statistical difference in OTNP and TOT emerged between the groups. However, Group A demonstrated reduced durations for both FTNP and TFT compared to Group B. The optimal position of the PEs was verified via fluoroscopy, with no recorded instances of dura rupture. These outcomes suggest that this endoscope-assisted technique neither increases surgical time nor compromises efficacy. Instead, it leads to a marked reduction in fluoroscopic duration relative to the traditional methodology.

Limitations: Anatomical study on a human cadaver, the quantity of cadavers, and the procedure's steep learning curve.

Conclusion: With the assistance of percutaneous spinal endoscopy, introducer needles can be punctured through the ligamentum flavum at the anticipated interlaminar window locus under direct visualization, improving the convenience of the puncture and reducing fluoroscopic

exposure. It is a viable alternative for surgeons from diverse training backgrounds to implant PEs, particularly benefiting those well-versed in endoscopic spine surgery techniques.

Key words: Percutaneous endoscopic, puncture cylindrical electrodes, spinal cord stimulation, anatomical study

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Spinal cord stimulation (SCS) is an established technique wherein diverse electrode types are strategically implanted within the spinal epidural space for neuromodulation. Over the past 5 decades, the SCS technology landscape has evolved remarkably, particularly since Shealy, et al's (1) groundbreaking implantation of an electrode in 1967. This technology evolution can be attributed to identifying novel neural targets, waveform innovations, advanced device intelligence, programming enhancements, and a deeper grasp of novel mechanisms of action (2-4).

Historically, indications for SCS predominantly encompassed failed back surgery syndrome (5,6) and complex regional pain syndrome (7). Presently, its therapeutic range has expanded to include peripheral vascular disease (8), refractory angina (9), phantom limb pain (10), and chronic head and neck pain, among others. Furthermore, global research endeavors continue to uncover novel applications (11,12).

Currently, there are 2 types of electrodes available commercially: surgical paddle electrodes (SEs) and percutaneous puncture cylindrical electrodes (PEs); each has advantages and limitations (13,14). Typically, SEs necessitate implantation via open surgery involving laminectomy performed by a surgeon. In contrast, PEs are implanted via a percutaneous method under radiological guidance, a procedure that is inherently nonvisual.

PEs have considerable appeal due to their minimally invasive nature and suitability for conscious sedation, which enables real-time communication between operator and patient during the procedure (15). However, as percutaneous electrodes are inserted through an introducer needle without direct visualization, there is a risk of causing injury to dura, blood vessels and the spinal cord itself by direct penetration and/or adjustment with the needle (16,17). Furthermore, in patients presenting with ligamentum flavum ossification or a narrow interlaminar window, achieving accurate introducer needle placement is challenging, even for adept professionals, often requiring repeated punctures and fluoroscopic guidance. Such scenarios elevate the traumatic injury risk to the dura and spinal cord (18). Additionally, many surgeons, due to their specific

training and operational tendencies, remain unfamiliar with epidural puncture techniques, prompting them to explore alternative methods. In view of these, PEs implantation in a visible state is very valuable and is applicable for surgeons of varied training backgrounds; it is particularly beneficial for a patient who has narrowing of the interlaminar window and calcification of the ligamentum flavum

The dramatic development of endoscopic spinal techniques offers promising prospects for the field of visualized implantation of PEs. In recent years, endoscopic spine surgery has been widely accepted due to its minimally invasive nature and high-definition visual field. The indications for endoscopic spine surgery have expanded with the rapid development of endoscopic armamentaria and technological innovations, from initial lumbar disc disease to other types of pathologies located throughout the spine (19-21). Our study aimed to describe the operative nuances of percutaneous endoscope-assisted visualized implantation of PEs for spinal cord stimulation (Figs. 1A, 1B) and validate the feasibility of the approach. To the best of our knowledge, this is the first study to place PEs using this endoscopic technique in a visible state.

METHODS

In our study, 8 fresh adult cadavers (4 women and 4 men) were utilized. They were divided into 2 groups: Group A and Group B, each containing 4 cadavers. Group A was subjected to endoscope-assisted PEs implantation, while Group B underwent the conventional method of PEs implantation. All surgical procedures were executed by Dr. Yu, an advanced neurosurgeon who has performed more than 800 endoscopic spine surgeries. Radiographic imaging was facilitated by the same radiologic technologist throughout the study employing a uniform C-arm.

In Group A, the operative time for introducer needles placement (OTNP) was the combined duration of both percutaneous endoscopic exposure of the ligamentum flavum and the subsequent introducer needle insertion under direct visualization. The fluoroscopy time for introducer needles placement (FTNP) was exclusively obtained from the C-arm system, denoting the

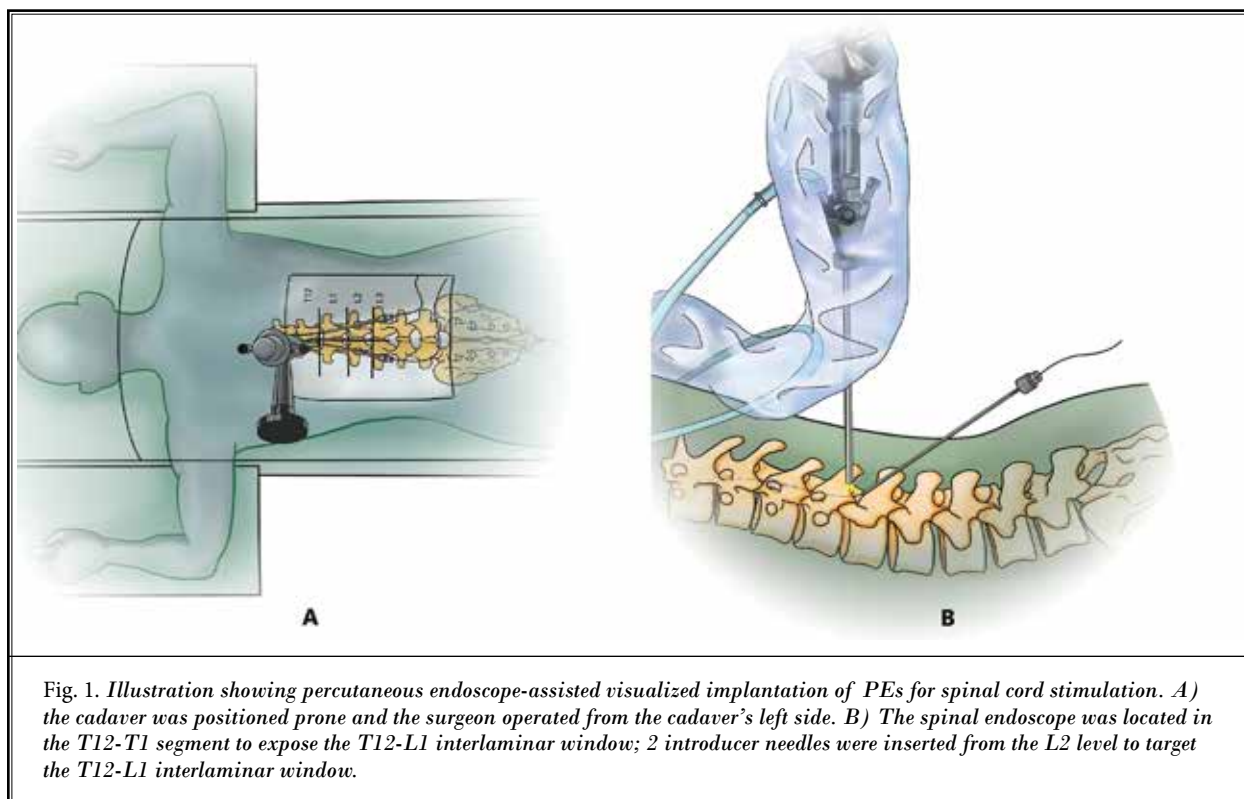


Fig. 1. Illustration showing percutaneous endoscope-assisted visualized implantation of PEs for spinal cord stimulation. A) the cadaver was positioned prone and the surgeon operated from the cadaver's left side. B) The spinal endoscope was located in the T12-T1 segment to expose the T12-L1 interlaminar window; 2 introducer needles were inserted from the L2 level to target the T12-L1 interlaminar window.

period required for the aforementioned processes. The total operative time (TOT) represented the total surgical duration, inclusive of both needle placement and dual PEs placement phases. Total fluoroscopy time (TFT) was the entire fluoroscopic duration documented in the C-arm system throughout the surgical intervention.

Conversely, for Group B, the OTNP was solely the duration required for introducer needles insertion facilitated by the C-arm. The remaining metrics (FTNP, TOT, and TFT) retain their interpretations as previously described. Data pertaining to OTNP, FTNP, TOT, and TFT for both groups were recorded and subsequently analyzed. Additionally, the terminal positioning of the PEs and any incidental complications were evaluated.

Our study's research protocol was subjected to review and subsequently granted approval by the Institutional Review Board (IRB) of Zhongshan Hospital, affiliated with Fudan University.

Endoscopic Instruments and the Puncture Cylindrical Electrodes

Surgical interventions were facilitated using the Delta endoscopic surgical system (Joimax GmbH) including an endoscope (15° angle), endoscopic sheaths, endoscopic punches, nucleus pulposus clamp, etc. The

radiofrequency probe (Trigger-FlexR Bipolar System, Eliquance LLC) was used to ablate soft tissue. In instances necessitating bone grinding, an endoscopic highspeed diamond burr (Primado P200-RA330, NSK-Nakanishi International, Co., Ltd.) was utilized. Throughout the surgical process, the operative site was continuously irrigated with an isotonic saline solution in order to maintain clarity. The puncture cylindrical electrodes (977A275, Intellis, Medtronic) were implanted within the thoracic segments of the 8 cadavers.

Percutaneous Endoscope-assisted Implantation of PEs (Group A)

1. Percutaneous endoscopic exposure of the ligamentum flavum

The cadavers were positioned prone on a radiolucent table. The surgeon operated from the cadaver's left side. The T12-T1 segment was designated for thoracic spinal cord electrode insertion, conforming to common clinical practices. A 10-mm skin incision was made, followed by introducing a pencil-like rod that made contact with the left T12-L1 facet joint. The paravertebral musculature and fascia were sequentially dilated.

Then the 10-mm Delta working cannula with oblique

mouth was inserted, which was verified with fluoroscopy both anteroposteriorly and laterally. Finally, the endoscopic surgical system with continuous irrigation was introduced. After the soft tissue was cleared using the radiofrequency probe, the left T12 lamina, L1 lamina, and ligamentum flavum between T12 and L1 could be identified under endoscopy (Fig. 2A). If the interlaminar space was narrow, a partial laminectomy (T12 lower part and L1 upper part) was performed utilizing a 3.5 mm endoscopic diamond burr and endoscopic Kerrison Rongeur.

2. Introducer needle puncture via endoscopic guidance and electrode insertion

After the ligamentum flavum between T12-L1 was fully exposed, an assistant held the endoscope in order to display its image on the screen. The surgeon then began to place the introducer needles (Fig. 3). The introducer needle's puncture began through the skin at the medial boundary of the L2 pedicle's projected skin interface. Upon reaching the intervertebral window between T12 and L1, the needle tip became visible.

Employing endoscopic guidance, the appropriate puncture location on the ligamentum flavum was determined while concurrently monitoring needle advancement depth, coupled with the "loss of resistance" technique (Fig. 2B). When the needle's position in the posterior epidural space was confirmed, the PEs were subsequently introduced into the epidural space via the introducer needle under live fluoroscopy (Fig. 4). A secondary introducer needle was employed for the dual PEs placement.

It is convenient to select a second suitable punc-

ture point on the other side of the ligamentum flavum. Under the monitoring of the endoscopic field of view (Fig. 2C), we can select the second puncture point on the ligamentum flavum conveniently for the second electrode, without interfering with the first placed electrode. The rest of the operation steps followed the steps previously described.

3. Spinal endoscope withdrawal

When the PEs were placed at their desired target, which was verified by anteroposterior and lateral fluoroscopic views (Fig. 5), the spinal endoscope was removed. A single stitch was employed to close the skin incision, followed by conventional subsequent procedures.

Traditional implantation of PEs (Group B)

In brief, the cadavers were placed prone on a fluoroscopy-compatible table. The introducer needle's skin entry point mirrored that of Group A at the medial border of the L2 pedicle projection. The needle's optimal orientation was maintained between 30° – 45°. The insertion aimed for the epidural space between the T12 and L1 laminae. Under fluoroscopic monitoring, the needles were advanced until they contacted the lamina just lateral to the spinous process of T12.

Once the lamina was contacted, the needle was slightly retracted and advanced superiorly and medially toward the center of the interlaminar space between T12 and L1. Then the C-arm was positioned laterally and the needle was advanced through the ligamentum flavum using the loss of resistance technique.

A lateral view confirmed needle positioning in the



Fig. 2. A) Endoscopic view of the ligamentum flavum between T12 and L1. B) Endoscopic view of inserting PEs through the ligamentum flavum. C) Endoscopic view of the left PEs that have been placed and the second introducer needle on the contralateral side.

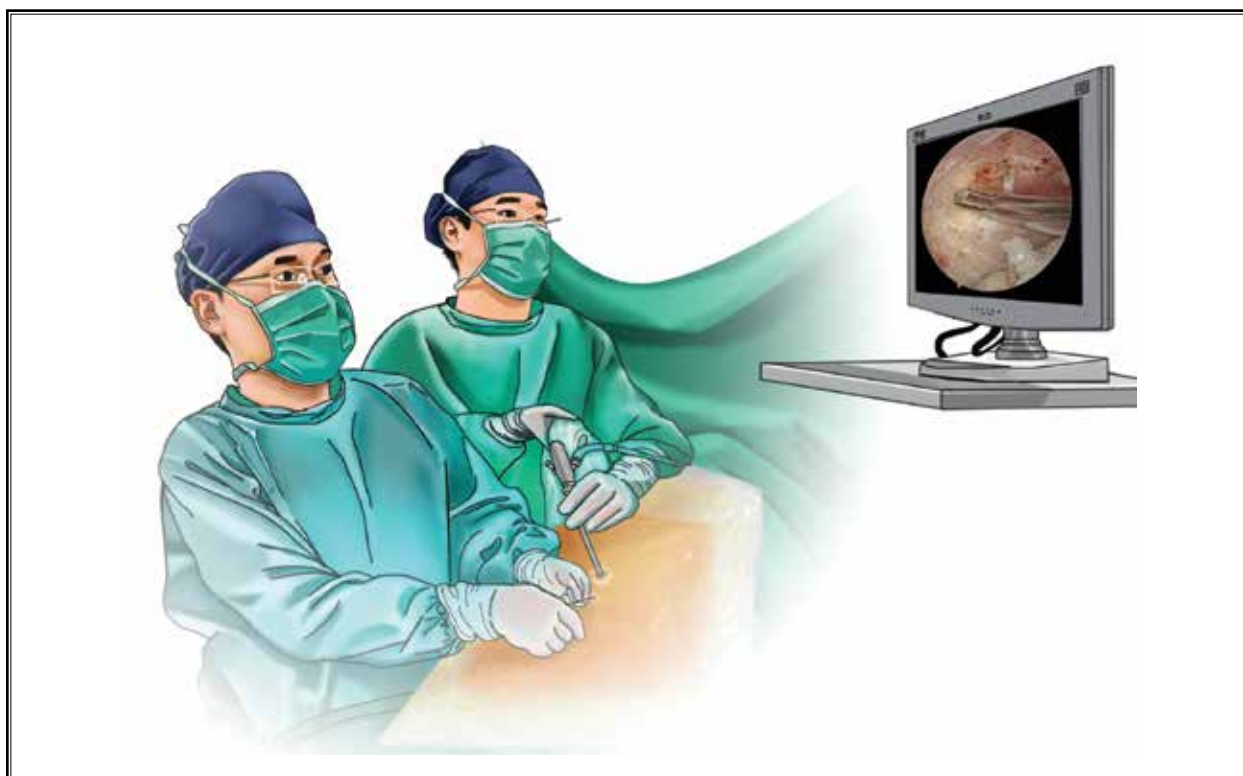


Fig. 3. Illustration showing the assistant holding the endoscope in order to display the ligamentum flavum image on the screen. The surgeon is placing the introducer needles.

posterior epidural space. The PEs was fed through the introducer needle into the epidural space under live fluoroscopy. Dual PEs placement was executed for every cadaver in Group B. Upon optimal PEs positioning and validation, the needle was gently retracted, followed by standard subsequent steps.

RESULTS

In both Group A and Group B, all predetermined surgical steps were successfully executed. In total, 8 PEs were implanted employing the percutaneous endoscope-assisted visualized implantation technique (Group A) while another set of 8 PEs were placed using the conventional method (Group B). Times, including OTNP, TOT, FTNP, and TFT for each procedure were recorded, as presented in Table 1.

For Group A, the mean \pm SD durations for OTNP, TOT, FTNP, and TFT were 10.25 ± 1.03 minutes, 31.63 ± 5.87 minutes, 4.58 ± 1.35 seconds, and 43.73 ± 14.46 seconds, respectively. In contrast, Group B's times for the same metrics were 11.55 ± 2.81 minutes, 44.75 ± 7.85 minutes, 23.53 ± 4.16 seconds, and 66.30 ± 6.35 seconds. There was no statistical difference in OTNP

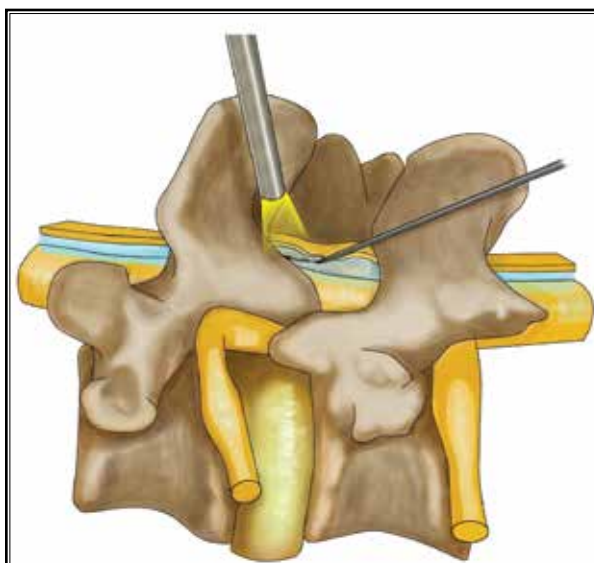


Fig. 4. Illustration showing that under endoscopic visualization, the appropriate puncture locus on the ligamentum flavum was determined and the needle advancement depth was monitored.

and TOT between Group A and Group B. However, both FTNP and TFT times were notably reduced in Group A in comparison to Group B, as detailed in Table 2. These findings underscore that percutaneous endoscope-assisted visualized implantation of PEs neither lengthens surgical duration nor compromises efficacy. Instead, it manifests a substantial reduction in fluoroscopy time relative to the traditional approach. Furthermore, the proper position of the PEs was verified via fluoroscopy. There was no rupture of the dura during the operation.

DISCUSSION

SCS is well established as a safe, effective, reversible, and minimally invasive method for treating chronic neuropathic pain syndromes originating from a diverse range of etiologies (2-12). Currently, SEs and PEs are 2 mainstream types of electrodes available commercially. Each electrode type has distinct advantages and limitations, which will not be elaborated here as they are not the focus of this paper.

The current literature lacks consensus on the superiority of one electrode type over the other. The

choice predominantly hinges upon patient-specific factors, the surgeon's training background, technical preferences, and accrued experience (13,14). PEs are usually placed under conscious sedation with the aid of fluoroscopic guidance in many centers worldwide, which is not a "direct vision" procedure. A patient is able to give timely feedback to the stimulation, thus confirming the correct electrode coverage (15). However, the indirect visual nature of percutaneous introducer needles placement also has disadvantages: 1) adjustments to the introducer needle's position within the ligamentum flavum often necessitate repeated fluoroscopy, especially for the secondary needle; 2) the needle's penetration through the ligamentum flavum and subsequent entry into the epidural space relies heavily on tactile feedback, introducing potential risks of inadvertently injuring the dura mater and spinal cord (16,17); 3) the technique is often unfamiliar territory for many surgeons, prompting a preference for open surgical implantation instead (13); 4) in some patients who present with a narrowed interlaminar window or a calcified ligamentum flavum, even expert hands may

grapple with achieving an accurate puncture into the planned epidural space, thus frequently resorting to repetitive punctures and fluoroscopic checks. In certain instances, unintended dura and/or spinal cord injuries may occur (18).

The methodology of percutaneous endoscope-assisted visualized implantation of PEs is emerging as a viable solution to the above challenges. Primarily, the technique of percutaneously exposing the ligamentum flavum through the interlaminar window, a genuinely minimally invasive procedure, can be executed under conscious sedation (22,23). This approach aligns with the anesthesia modalities of traditional PEs implantation, ensuring immediate feedback from patients upon stimulation. Moreover, under the high-definition visual field of endoscopy, the an introducer needle tip can be monitored and the ligamentum flavum's puncture entry point can be selected and adjusted easily, which is better than just depending on the fluoroscopic image guidance. Additionally, the needle tip depth entering the ligamentum flavum can also be observed, complement-

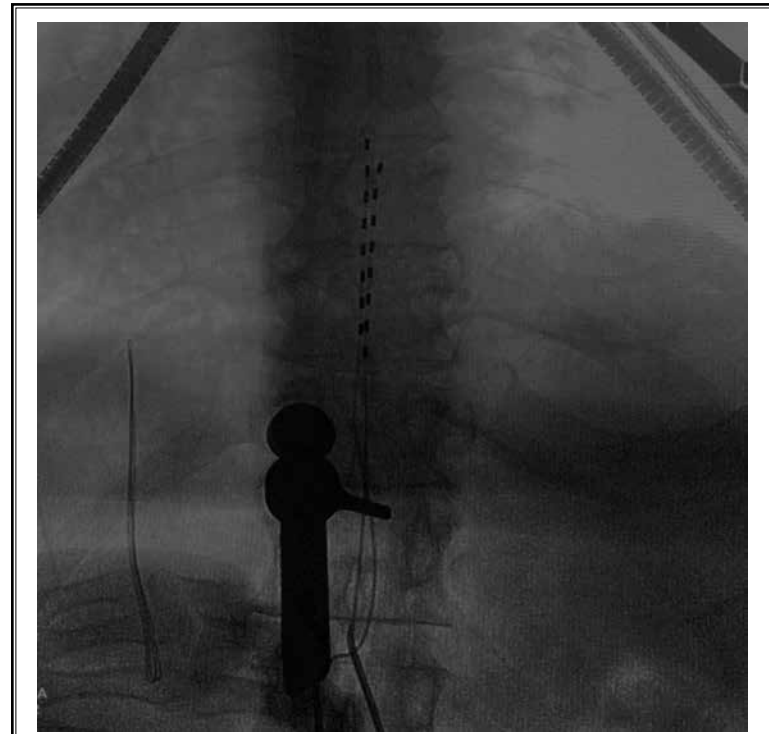


Fig. 5. The final position of the dual PEs in midline at T9-T10 verified by fluoroscopy. The working cannula of endoscope and the 2 introducer needles can be seen in the image.

Table 1. OTNP, TOT, FTNP, and TFT values.

	Group A-Endoscope-assisted				Group B-Traditional			
	OTNP (min)	TOT (min)	FTNP (sec)	TFT (sec)	OTNP (min)	TOT (min)	FTNP (sec)	TFT (sec)
1	9.500	25.000	4.300	32.800	9.000	36.000	23.800	60.300
2	12.000	40.500	6.800	68.300	14.500	56.000	20.500	70.200
3	10.000	28.000	4.000	40.100	8.500	48.000	19.600	74.700
4	9.500	33.000	3.200	33.700	14.200	39.000	30.200	60.000
Mean value	10.250	31.625	4.575	43.725	11.550	44.750	23.525	66.300

OTNP, operative time for introducer needles placement; TOT, total operative time; FTNP, fluoroscopy time for introducer needles placement; TFT, total fluoroscopy time

ing the “loss of resistance” technique and offering a more intuitive grasp than mere tactile sensation. The introducer needles placement is the key step for PEs implantation. The visualization during introducer needle placement aligns more cohesively with typical surgical practices.

Our cadaveric study revealed negligible statistical difference in OTNP and TOT between Group A and Group B. This suggests that while the percutaneous endoscope-assisted visualized implantation of PEs introduced an additional procedure—exposing the ligamentum flavum—it didn’t prolong the operation duration. Conversely, both FTNP and TFT in Group A were notably reduced in comparison to Group B ($P < 0.05$). Evidently, endoscopic visualization during needle placement can streamline the technical aspects and reduce fluoroscopy duration, addressing growing concerns related to radiation exposure during SCS procedures (24,25).

Given the burgeoning adoption of endoscopic spinal surgery procedures and the subsequent proliferation of training courses for residents and spine fellowships, an increasing number of spine surgeons now have foundational expertise in endoscopic procedures (26,27). The technique introduced in this paper adapts spinal endoscopy for PEs placement, offering a novel avenue for these surgeons.

Limitations

The present cadaveric study has several limitations that merit attention: 1) sample size constraints—the sample size is limited due to experimental conditions, potentially influencing the robustness of the study’s conclusions. 2) Dissimilarity to live surgery: a cadaver study doesn’t entirely simulate the intricacies of surgical procedures on live patients. Some other influencing factors, such as intraoperative bleeding control and patient cooperation during surgery need to be further

Table 2. Comparison of OTNP, TOT, FTNP, and TFT in the 2 groups.

	Group A Endoscope-assisted	Group B Traditional	P
OTNP (min)	10.250	11.550	0.48002 ($P > 0.05$)
TOT (min)	31.625	44.750	0.05954 ($P > 0.05$)
FTNP (sec)	4.575	23.525	0.00029 ($P < 0.05$)
TFT (sec)	43.725	66.300	0.04813 ($P < 0.05$)

OTNP, operative time for introducer needles placement; TOT, total operative time; FTNP, fluoroscopy time for introducer needles placement; TFT, total fluoroscopy time

evaluated in real-world clinical settings. 3) Operator expertise bias: the operator is a neurosurgeon with sufficient experience in endoscopic spinal surgery, not an interventional specialist traditionally versed in fluoroscope-guided PE placements. This operator selection introduces an inherent bias, making the study’s findings particularly pertinent to surgical practitioners. 4) Cost considerations: the addition of an endoscopic procedure in the introduced method comes with an associated increase in medical costs. It is essential to scientifically evaluate the benefits through a cost-effectiveness analysis, expressed as the incremental cost-effectiveness ratio.

In future research, it is imperative to conduct prospective controlled studies with the participation of intervention experts, comparing the surgical time, fluoroscopy time, surgical complications, surgical outcomes, and other related parameters of real patients under traditional and endoscopic assisted approaches. Future studies should also incorporate cost-effectiveness analyses to comprehensively assess the economic implications. It is crucial to emphasize that the introduction of the

percutaneous endoscopic assisted implantation of PEs in this paper does not advocate for the replacement of established techniques. Instead, we seek to enrich the surgical arsenal by offering an alternative modality, catering to surgeons spanning diverse training backgrounds.

CONCLUSION

With the assistance of percutaneous spinal endoscopy, introducer needles can be strategically punctured

through the ligamentum flavum at the anticipated interlaminar window locus under direct visualization. This approach not only enhances the precision and ease of the puncture but also mitigates reliance on fluoroscopy. Consequently, this method offers a viable alternative for surgeons from diverse training backgrounds to implant PEs, particularly benefiting those already well-versed in endoscopic spine surgery techniques.

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