

Cadaveric Study

Feasibility of Epidural Localization Using the EpiFaith® Syringe: A Cadaveric Study

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Disclaimer: There was no external
funding in the preparation of this
article.

Conflict of interest: Dr. Alaa Abd-
Elseyed serves as a consultant for
Flat Medical, the manufacturer
of the EpiFaith® syringe used in
this study.

Article received: 01-03-2025
Revised article received:
01-07-2025
Accepted for publication:
03-24-2025

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Background: Achieving accurate epidural access during surgery is challenging, with failure rates reported as high as 40%. The loss of resistance (LOR) technique remains the standard but relies heavily on the clinician's tactile sense, which can lead to inaccuracies. The EpiFaith® (Flat Medical) syringe, designed with a visual LOR cue, aims to enhance the accuracy of physicians' attempts to achieve epidural access.

Objective: This study aimed to evaluate the usability and accuracy of the EpiFaith® syringe for epidural access at the cervical, thoracic, and lumbar levels. The syringe was tested by 2 physicians—one with prior clinical experience using the device and one who would use it for the first time—on cadaver models.

Study Design: A cadaveric study was conducted by 2 providers who tested the EpiFaith® syringe across multiple spinal levels.

Setting: The study was carried out in medical facilities equipped with cadaveric simulation and fluoroscopic imaging.

Methods: Five fresh adult cadavers were used, with both providers performing epidural access procedures at spinal levels from C7 to S1. One provider had prior experience using the EpiFaith® syringe, while the other had none. Each procedure used 1 mL of normal saline for LOR detection, and successful epidural access was confirmed using contrast and fluoroscopy. Variables recorded included injection site, number of attempts, first-attempt success rates, device usage, and instances of false LOR.

Results: The experienced provider (Provider 1) performed procedures on 16 spinal levels across 4 cadavers, achieving a 100% first-attempt success rate with no false LOR events. The inexperienced provider (Provider 2) performed procedures on 7 spinal levels, achieving a 57.1% (4/7) first-attempt success rate, with 3 false LOR events (30%). Provider 2 accessed the epidural space successfully after adjusting the technique in response to false LOR signals.

Limitations: Cadaveric models lack normal physiological conditions, and the small sample size limits generalizability. Further studies in live settings are needed to validate the EpiFaith® syringe's clinical utility and learning curve.

Conclusion: The EpiFaith® syringe is an effective tool for achieving epidural access, particularly for experienced clinicians. Even inexperienced users can adapt to the device's feedback to access the epidural space successfully. Further clinical validation is necessary to confirm the syringe's potential to improve procedural accuracy and reduce false LOR events in real-world settings.

Key words: EpiFaith® syringe, loss of resistance (LOR), epidural access, cadaveric, cervical spine, thoracic spine, lumbar spine, spinal procedures, pain management, false loss of resistance (LOR), clinical training, fluoroscopy, cadaveric model

Pain Physician 2025; 28:E431-E435

Access to a patient's epidural space is essential for various analgesic interventions, including epidural catheterization, spinal cord stimulation, dorsal root ganglion stimulation lead placement, and epidural steroid injections (1). Incorrect access can result in suboptimal pain control and complications, such as dural puncture (2). Reported failure rates for epidural access can be as high as 40% (1).

The loss of resistance (LOR) technique is the current standard for accessing the epidural space (3). However, a significant drawback of this technique is its reliance on the provider's tactile sense to detect the pressure loss as the needle advances. To improve the accuracy of the LOR technique, several devices have been developed to provide clearer indications of when LOR occurs, either through visual or audio signals (4).

One such device is the EpiFaith® syringe (Flat Medical), which offers a visual cue upon successful entrance into the epidural space. The syringe employs an internal spring mechanism for continuous LOR detection. However, clinical data on the effectiveness of the EpiFaith® syringe remains limited. To date, only one clinical study has investigated its use for labor epidurals (5). In that study, no unintentional dural punctures or postural headaches were reported, and 3 out of 4 anesthesiologists preferred the EpiFaith® syringe over traditional syringes.

The objective of the present cadaveric study was to evaluate the usability and accuracy of the EpiFaith® syringe for epidural access at the cervical, thoracic, and lumbar levels. This syringe was tested by 2 physicians—one with prior experience using the device and one using it for the first time.

METHODS

Study Flow

This study was conducted using 5 fresh adult cadavers in an unfixed state to simulate live tissue conditions closely. The procedures were carried out at 2 medical facilities, each equipped with cadaveric simulation and fluoroscopic imaging setups.

Two physicians participated in the study: Provider 1, an experienced interventional pain physician with over 10 years of experience in epidural access and prior familiarity with the EpiFaith® syringe, and Provider 2, an interventional pain physician with no prior experience using the device. Both providers performed epidural access procedures at multiple spinal levels, rang-

ing from C7 to S1, using 1 mL of normal saline (NS) for LOR detection.

Device Description and Setup

The EpiFaith® syringe consists of 4 key components: a low-friction rubber stopper, an indicator with a color ring, a plunger, and a standard syringe barrel. The device also incorporates an internal spring mechanism for continuous LOR detection (Fig. 1). This mechanism converts tactile feedback into visual cues by adjusting the plunger to cover the indicator, allowing the device to sense pressure changes between 12-16 kPa. When the needle encounters tissue that cannot withstand the detected pressure, a visual signal is generated, mimicking the tactile sensation of LOR. For the procedures, the syringe was prefilled with one mL of normal saline.

Procedure

The cadavers were positioned prone on fluoroscopy tables to optimize imaging. After anatomical landmarks were palpated, an 18G epidural needle was inserted at the designated spinal levels, proximal to the ligamentum flavum. Following the insertion and removal of the stylet, the saline-filled EpiFaith® syringe was attached to the needle. The plunger was gradually depressed until the color indicator was fully covered, and the needle was advanced until the rubber stopper moved.

Successful epidural access was confirmed by injecting a contrast medium and visualizing its distribution under fluoroscopic guidance (Fig. 2). Successful access was defined as the visible spread of contrast within the epidural space, with no leakage or incorrect positioning.

Throughout the experiment, the following variables were recorded: cadaver number, injection site, number of attempts, first-attempt success rate, use of the device, and instances of false LOR. A false LOR was defined as the rubber stopper moving forward, leading the provider to use contrast for confirmation due to uncertainty regarding epidural space entry.

RESULTS

Provider 1, an experienced interventional pain physician, tested the EpiFaith® syringe on 4 cadavers across 16 spinal levels. Successful epidural access was achieved at all levels, including C7-T1, T1-2, T2-3, T6-7, T9-10, T10-11, T12-L1 (3 times), L1-2, L2-3, L3-4, L4-5, and L5-S1 (3 times). Provider 1 demonstrated a 100% first-attempt success rate (16/16), with no instances of false loss of resistance (LOR) recorded throughout the procedures (Table 1).

In contrast, Provider 2, an interventional pain

physician with no prior experience using the EpiFaith® syringe, tested the device on a single cadaver at 7 spinal levels. Successful epidural access was achieved at the C7-T1, T12-L1, L1-L2, and L4-5 levels. However, false LOR occurred at the T2-T3, T9-T10, and T11-12 levels. After adjusting for false LOR, Provider 2 accessed the epidural space successfully on the second attempt at these levels. The first-attempt success rate for Provider 2 was 57.1% (4/7), and the overall false LOR occurrence rate was 30% (3/10) (Table 2). On average, Provider 2 required 1.4 attempts per spinal level to achieve successful epidural localization.

DISCUSSION

The results of this cadaveric study demonstrate, across 2 providers and multiple spinal levels, a first-attempt success rate of 87% (20/23) when using the EpiFaith® syringe. These findings suggest that the EpiFaith® syringe facilitates accurate epidural access effectively, even in anatomically challenging regions. When categorized by spinal level, the success rates were 100% (2/2) at the cervical level, 75% (9/12) at the thoracic level, and 100% (9/9) at the lumbar level. That the success rates in the cervical and lumbar regions are higher than those in the thoracic region reflects the increased anatomical complexity of the thoracic spine. Notably, no false LOR events were recorded for Provider 1, underscoring the role of clinical experience in minimizing procedural errors. These results are consistent with those of a previous clinical study in which 4 anesthesiologists performed epidural catheterizations for labor anesthesia in 40 women. That study reported 4 instances of false LOR, but no unintentional dural punctures or postural headaches occurred (5). This consistency reinforces the potential of the EpiFaith® syringe to enhance the accuracy of epidural access.

A major observation in our study was that Provider 2, who had no prior experience using the EpiFaith® syringe,

encountered 3 instances of false LOR, necessitating a second attempt to achieve epidural access successfully. This finding is consistent with existing literature, emphasizing the importance of experience and training in improving the success rates of attempts to achieve epidural access (6). Despite encountering false LOR signals, Provider 2 successfully adjusted and accessed the epidural space at all levels, indicating that the EpiFaith® syringe provides sufficient feedback to allow users to modify their technique when initial signals are misleading.

The false LOR events experienced by Provider 2

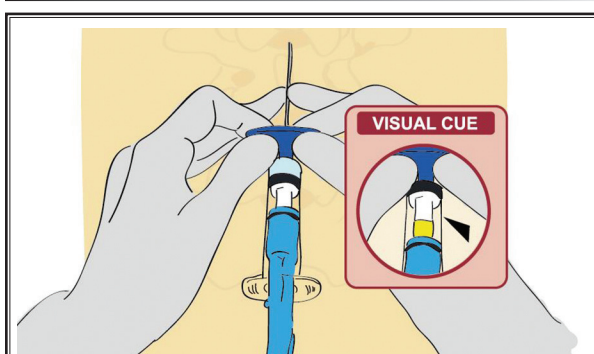


Fig. 1. The EpiFaith® syringe consists of a low-friction rubber stopper, a color-ring indicator, a plunger, and a syringe barrel. The device features an internal spring mechanism that provides continuous loss-of-resistance (LOR) detection, offering a visual cue when LOR occurs.

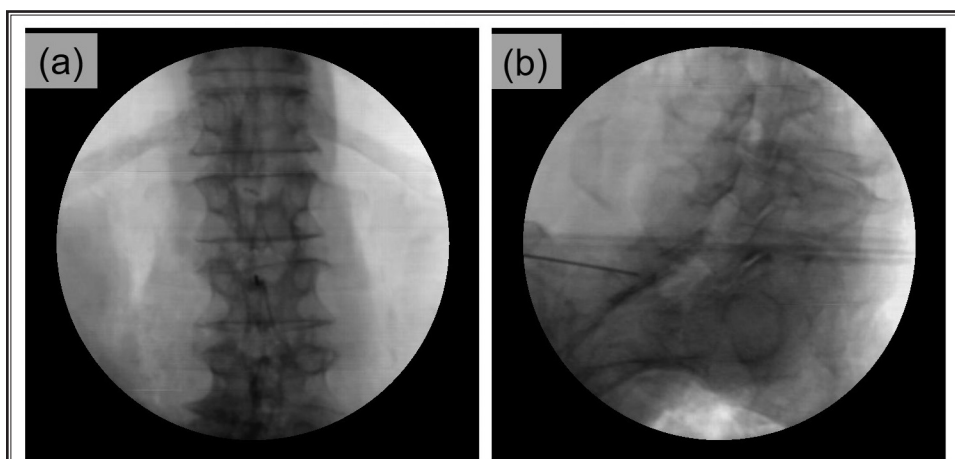


Fig. 2. A Tuohy needle was inserted into the interlaminar space under fluoroscopic guidance. An EpiFaith syringe was then used to access the epidural space, with the subsequent injection of iodinated contrast confirming the needle's position. (a) L1-L2 posteroanterior view (PA). (b) L4-L5 lateral view.

Table 1. Comparison of procedural success, first-attempt success, and false LOR rates between experienced and inexperienced providers using the EpiFaith® syringe.

	Provider 1 (n = 16)	Provider 2 (n = 7)
Procedure successful	100% (16/16)	100% (7/7)
Success rate of first attempts	100% (16/16)	57.1% (4/7)
False LOR occurrence	0% (0/16)	30% (3/10)
Number of attempts needed for success	1	1.4

Table 2. Study results.

Provider	Spinal Level	Cadaver	Procedure successful	Number of Attempts	First Attempt Success	False LOR Occurrence
Provider 1	L4-5	Cadaver 1	Yes	1	Yes	No
Provider 1	L5-S1	Cadaver 1	Yes	1	Yes	No
Provider 1	C7-T1	Cadaver 2	Yes	1	Yes	No
Provider 1	T2-3	Cadaver 2	Yes	1	Yes	No
Provider 1	T6-7	Cadaver 2	Yes	1	Yes	No
Provider 1	T9-T10	Cadaver 2	Yes	1	Yes	No
Provider 1	T12-L1	Cadaver 2	Yes	1	Yes	No
Provider 1	L3-4	Cadaver 2	Yes	1	Yes	No
Provider 1	L5-S1	Cadaver 2	Yes	1	Yes	No
Provider 1	T10-11	Cadaver 3	Yes	1	Yes	No
Provider 1	T12-L1	Cadaver 3	Yes	1	Yes	No
Provider 1	L1-2	Cadaver 3	Yes	1	Yes	No
Provider 1	L5-S1	Cadaver 3	Yes	1	Yes	No
Provider 1	T1-2	Cadaver 4	Yes	1	Yes	No
Provider 1	T12-L1	Cadaver 4	Yes	1	Yes	No
Provider 1	L2-3	Cadaver 4	Yes	1	Yes	No
Provider 2	C7-T1	Cadaver 5	Yes	1	Yes	No
Provider 2	T2-3	Cadaver 5	Yes	2	No	Yes
Provider 2	T9-10	Cadaver 5	Yes	2	No	Yes
Provider 2	T11-12	Cadaver 5	Yes	2	No	Yes
Provider 2	T12-L1	Cadaver 5	Yes	1	Yes	Yes
Provider 2	L1-2	Cadaver 5	Yes	1	Yes	Yes
Provider 2	L4-5	Cadaver 5	Yes	1	Yes	Yes

may be attributable to anatomical variations, particularly in the thoracic region. Ligamentum flavum gaps have reported to exist along the midline in the cervical, T1-3, T9-12, and lumbar spine (7). Additionally, false LOR may occur if the clinician deviates from the midline, causing the needle to enter paravertebral muscles or tissues, which lack the rigidity needed to withstand the sensing pressure of the syringe. Interspinous cysts are another possible cause of false LOR events (7). Previous studies have shown that subcutaneous tissue

can tolerate pressures ranging from 110 to 401 cmH₂O (10.78 to 39.3 kPa) (8). Meanwhile, the EpiFaith® syringe generates a sensing pressure of approximately 12 kPa. If the needle enters subcutaneous tissue, its lower resistance compared to the ligamentum flavum could trigger premature movement of the rubber stopper, generating a false LOR signal. In such cases, the device's visual feedback may mislead the clinician into believing the needle has entered the epidural space successfully before it has reached the intended location.

Limitations

This study has several limitations that should be considered when interpreting the findings. Firstly, the use of cadaveric models inherently limits the replication of normal physiological conditions. Cadavers do not exhibit cerebrospinal fluid pressure, venous circulation, active tissue responses, or other physiological factors that influence the behavior of the epidural space during procedures. Additionally, because the models in this study were cadavers, there were no clinical outcomes to assess, such as patient feedback on post-procedural pain, the occurrence of dural puncture, or other complications. The absence of these real-world factors may affect the generalizability of our findings to live clinical settings.

Secondly, the sample size was relatively small, comprising 5 cadavers and 2 providers. While this quantity allowed for a focused study, a larger sample size with more providers would be beneficial by allowing for the obtaining of more comprehensive data. Such expansion could increase the generalizability of the results to broader clinical practice.

Finally, the study featured 2 providers with different levels of experience using the EpiFaith® syringe. Although this decision offers valuable insight into

the device's usability across experience levels, it also limits the understanding of the learning curve associated with the syringe. Further studies involving a wider range of providers, with varying expertise, would provide deeper insight into how quickly clinicians can adapt to the device and how effective it can be in a real-world clinical setting.

CONCLUSION

Our study demonstrates that the EpiFaith® syringe is an effective tool for achieving epidural access. Although false LOR events were observed by the less experienced provider, that provider was able to adjust the technique used and gained access to the epidural space successfully. Further exploration is needed to understand the clinical significance of the signals generated by the EpiFaith® syringe. By converting tactile feedback into visual cues, the device provides valuable insight into pressure changes at the needle tip. Understanding how these signals correlate with anatomical landmarks and tissue resistance could enhance precision, helping clinicians interpret subtle shifts in plunger movement—whether indicating subcutaneous tissue,

ligamentum flavum, or epidural space entry—and refine clinical decision-making.

Additionally, investigating the learning curve associated with the device could inform training programs aimed at reducing false LOR and optimizing its use. After further validation in clinical settings, the EpiFaith® syringe could become a valuable addition to routine epidural procedures, offering reliable feedback and improving the accuracy of epidural localization. As clinicians gain more experience in interpreting the device's visual cues, first-attempt success rates may improve, and complications could be minimized.

Data Availability Statement

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Author Contributions

AA methodology, planning protocol, performing study, data collection and analysis, manuscript writing.

JZ study performance, manuscript writing.

AS manuscript writing and planning.

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