Feasibility Study

Novel Injectable Nerve Stimulation Electrode Placed on the Dorsal Root Ganglion Using an Extravertebral Approach: A Feasibility Study in Cadavers

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Background: Dorsal root ganglion stimulation (DRGS) is an established method for treating persistent and severe pain conditions. However, performing DRGS has significant challenges. Current DRGS systems are expensive, hindering accessibility for many patients and health care systems. Additionally, placing DRGS devices requires specialized training in epidural techniques and lead anchoring methods. Technical and financial requirements also limit the clinical applicability and availability of DRGS.

Objectives: This study evaluated the feasibility of a new method for rapidly delivering near-DRG stimulation in human cadavers. The method involves a fluoroscopy-guided transforaminal approach using a fully implantable, injectable electrode, and its associated delivery system.

Study Design: A human cadaver feasibility study.

Setting: A cadaver laboratory.

Methods: In this study, 3 anesthesiologist pain physicians received training on the injectable electrode device and delivery system using spine phantom models. They then applied the device's associated implantation techniques to 2 adult male cadavers. In the first cadaver, a single injectable electrode was placed near the left L2 lumbar DRG. In the second cadaver, injectable electrodes were placed near the left L1 and L2 DRG levels, and a benchmark DRGS device was installed at the left L1 level using fluoroscopic guidance. A careful anatomical dissection was then performed for each implanted device.

Results: The stimulating contacts of the injectable electrodes were accurately positioned within one mm of the DRG at the lumbar L1 and L2 levels in both cadavers. The distances of both the injectable lead and benchmark DRGS device at the L1 level were measured as one mm from the posterior aspect of the DRG.

Limitations: The findings of this study are based on anatomical examinations of a limited number of human cadavers and may not fully represent living human anatomy.

Conclusions: To our knowledge, this feasibility cadaver study is the first of its kind to examine the accuracy and efficiency of a fluoroscopy-guided transforaminal approach to place injectable electrodes near the DRG. These promising results suggest that this method could be a viable alternative to existing DRGS techniques, warranting further investigation into its clinical potential.

Key words: Cadaveric study, technical report, anatomical feasibility, dorsal root ganglion stimulation, peripheral nerve stimulation, chronic pain, neuropathic pain, injectable electrode

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Persistent and debilitating chronic pain affects up to 20% of the global population (1). A significant proportion of patients with chronic pain remain refractory to conventional treatment methods (2). Neuromodulation techniques, including spinal cord stimulation and dorsal root ganglion stimulation (DRGS), are established interventions for managing various chronic and intractable pain syndromes (3-8). Notably, DRGS has gained attention for offering effective focal dermatome-specific analgesia, even in cases where conventional dorsal column spinal cord stimulation therapies have proven inadequate (3,9). The US Food and Drug Administration has approved DRGS for lower extremity complex regional pain syndrome types I and II; DRGS has also shown promise in managing pain etiologies such as pelvic pain, phantom limb pain, and painful diabetic neuropathy (8).

Under x-ray fluoroscopy, the preferred DRG electrode implantation approach is to target the DRG from the interlaminar space to the neuroforamen via the percutaneous insertion of a thin cylindrical lead with an array of small stimulating contacts into and through the spinal epidural space (10,11). This central to peripheral strategy generally ensures stable intraforaminal electrode placement.

The clinical dissemination of DRGS is constrained by factors such as high implementation costs, the need for advanced procedural training in percutaneous placement, and lead anchoring. Technical hurdles arising from device adverse events include electrode dislocation or fracture or situations where spinal epidural access is challenging or impossible due to neuroforaminal stenosis or the presence of spinal hardware (11). To expand the clinical accessibility of DRGS, new minimally invasive approaches are needed that deliver effective stimulation near the DRG while minimizing the burden associated with prescribing, placing, and managing the existing electrode technologies.

The recent development of injectable electrodes stems from the clinical need for more affordable, simple-to-deploy neuromodulation therapies for peripheral nerve stimulation and DRGS. The Injectrode® (Neuronoff Inc.) is a device designed to be administered near the DRG through a small diameter needle injection and a peripheral approach comparable to that applied in delivering transforaminal epidural steroid injections (TFESIs) (12,13). Injectable electrodes that are designed to be delivered using techniques familiar to interventionalists would allow a wider range of clinicians to implement neuromodulation treatments earlier in the spectrum of treatments for chronic pain, benefitting patients who would otherwise not have access to DRGS therapy.

In our feasibility study, we aimed to assess the efficiency and anatomical precision of placing an Injectrode via a transforaminal, peripheral approach toward the DRG in the lumbar spine. We used a conventional cylindrical lead developed by Abbott Neuromodulation as a benchmark for assessing the placement accuracy and time required to implant a conventional DRGS device.

Methods

This feasibility study was carried out in 2 locations: The Department of Anatomy at Case Western Reserve University in the US and the Institute of Clinical and Functional Anatomy at the Medical University of Innsbruck in Austria. Case Western Reserve University provided an un-embalmed male cadaver for this study. The Medical University of Innsbruck provided one preserved male cadaver for scientific and educational use. In both the US and Austria, ethical approval for this type of study is not legally mandated. The cadaver donated by The Medical University of Innsbruck was preserved by arterial injection of an ethanol-glycerol solution and subsequent immersion in phenolic acid for 3 months. Another dissection study, not yet published, about ultrasound-guided application of Injectrodes on peripheral cutaneous nerves was carried out simultaneously in the same cadaver.

Before starting our study, both cadavers were thoroughly evaluated for anatomical abnormalities and previous spinal surgeries that could potentially interfere with placing neuromodulation devices. Of note, one cadaver had a prior medical history of multilevel spinal fusion surgery, which left metal instrumentation, including rods and screws, at the L3 level extending to the L5 level. However, this instrumentation and prior surgery were determined to have no significant effect on placing either the Injectrode or the DRGS benchmark device at the L1 and L2 lumbar levels.

The Injectrode F1

The version of the Injectrode (version F1) used in our study was made from a continuous 25 µm platinum-iridium (90%/10%) wire, twisted with a partial insulative coating and wound to form a 100-strand helical coil, one mm in diameter (Fig. 1). In our study, we used Injectrodes 100 mm long in order to reach deeper nerve targets. The stimulating end of the device was a 5

mm segment (single contact) of the exposed microwire-structured coil. The antenna at the proximal end of the device, called the subcutaneous collector, was a 20 mm segment of the exposed microwire-structured coil that was deployed fully subcutaneously, with no aspect of the device crossing the skin barrier.

In its proposed clinical use, the Injectrode directs stimulation from an external pulse generator placed over the subcutaneous collector, toward the target nerve. The Injectrode kit includes a 5-component delivery system consisting of 1) an 18G (outer diameter 1.27 mm) blunt delivery needle, 2) a sharp penetrating trocar, 3) a blunt stimulating trocar, 4) a transfer cannula containing the Injectrode, and 5) a delivery pin.

The Abbott SlimTip

Commercially available Abbott DRG therapy (Proclaim™ DRG Neurostimulation System) includes a slim cylindrical-tip lead which is 1.0 mm in diameter and is available in 50 (short) or 90 (long) cm lengths, both of which were available for use in our study. The distal 2.0 cm of each Abbott DRG lead consists of 4 1.25 mm stimulating contacts spaced 5 mm apart. The Abbott DRG system used as the benchmark in our study includes the SlimTip lead and its associated trial implant kit, and is intended for use as a percutaneous trial lead. The conventional DRGS full-system implantation procedure that involves placing an implanted pulse generator and the use of a "permanent" implant tunneling kit and extensions, was not a part of our study.

Prestudy Experience and Training

In our study, the methodology for device placement training was demonstrated and evaluated using a fluoroscopy-guided peripheral needle approach to the DRG. Training included practice on phantoms, which consisted of spinal columns embedded in clear gelatin, and a male cadaver. This allowed for the refining of techniques necessary to accurately place Injectrodes near the DRG using a TFESI-compliant peripheral approach. Each Injectrode implanter was a novice for this application. They carried out the Injectrode placements after actively participating in a 30-minute training session (Fig. 2). Notably, a conventional SlimTip DRGS lead from Abbott Laboratories was successfully placed in these models by a pain physician experienced in conventional DRGS techniques in order to establish a benchmark for placing the Injectrodes.

Procedure for Near-DRG Injectrode Placement in a Cadaver

The first step in our Injectrode placement in a cadaver was to identify the neural targets of interest using a combination of fluoroscopy and ultrasound. A fluoroscope (Siemens Arcadis Varic; Siemens Healthcare GmbH) was used in the context of DRGS. From the information gathered using imaging, a device of appropriate length was selected, an intended site of anticipated stimulation was determined, and a needle trajectory was planned.

The traditional needle target for lumbar TFESI is

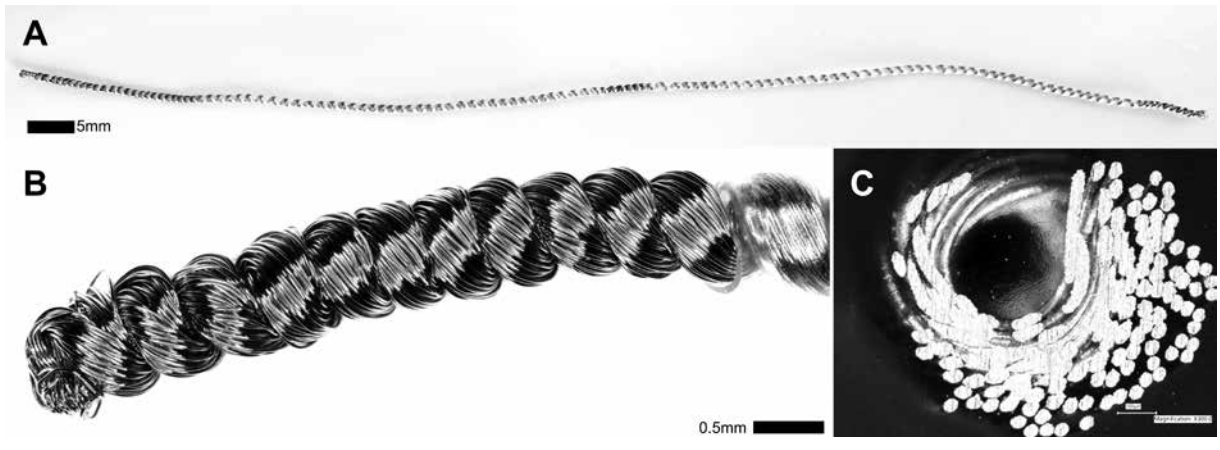

Fig. 1. *(A) The 100 mm Injectrode is made to target nerves at a depth of 4–7 cm from the skin surface. (B) The device has a helical wire structure manufactured with a platinum iridium (90% / 10%) microwire and polyolefin coating. (C) The Injectrode microwire form is a coil with 100 parallel microwire strands.*

the epidural space caudal to the inferior margin of the pedicle and immediately superior, lateral, and anterior to the targeted exiting nerve. On oblique fluoroscopic images, the target area forms a triangle bordered by the inferior margin of the pedicle, the nerve root exit, and a line drawn inferiorly from the anterior margin of the pedicle. This approach, described as a path for transforaminal drug injection that minimizes the risk of direct nerve injury and vascular injection, was selected for testing the Injectrode based on the same safety and efficacy rationale as a traditional TFESI (13).

To initiate device placement, a sharp trocar was first inserted into the delivery needle and secured in position by a Luer lock connection. Next, the delivery needle was then inserted through the skin at the site of future external stimulation to create a small subcutaneous pocket, which was then advanced toward the desired target. After removing the trocar, a transfer cannula containing the Injectrode was connected to the delivery needle via a Luer lock connection. The combined transfer cannula and delivery needle apparatus was primed with saline and the delivery pin was fully inserted into the transfer cannula in order to move the Injectrode into the delivery needle.

A fully placed Injectrode system consists of 3 sections, each deployed using a delivery pin and needle. The sections include a stimulating anchor deployed adjacent to the target nerve, a central anchor at mid-trajectory, and a collector placed subcutaneously in order to facilitate transcutaneous coupling with external pulse generators placed directly on the collectors. In order to maximize transcutaneous power coupling, the distance of the subcutaneous collector from the skin surface is minimized by forming a shallow collector pocket. This pocket's depth is traceable using either ultrasound or fluoroscopy and is recommended to be less than one cm for viable transcutaneous coupling (14). The delivery instruments contain markings to appropriately place each Injectrode section (Fig. 3).

In our study, 2 Injectrode devices were placed near the left L1 and L2 dorsal root ganglia in the male cadaver using the TFESI-compliant, peripheral delivery approach to the DRG. The sharp trocar was first installed in an 18G delivery needle using a Luer lock and was inserted 2 cm into the skin. The sharp trocar was then tilted parallel to the skin and swept back and forth to create a subcutaneous pocket before being tilted upward and under fluoroscopy further inserted toward the target lumbar foramen (Fig. 3A).

The topmost visible marking on the Injectrode delivery needle was used to confirm that a 10 cm, "medium-length" device was the appropriate size for the target. When the delivery needle was positioned above the foramen opening, confirmed by anteroposterior and lateral fluoroscopy, the sharp trocar was removed and the 10 cm Injectrode was loaded from a transfer cannula

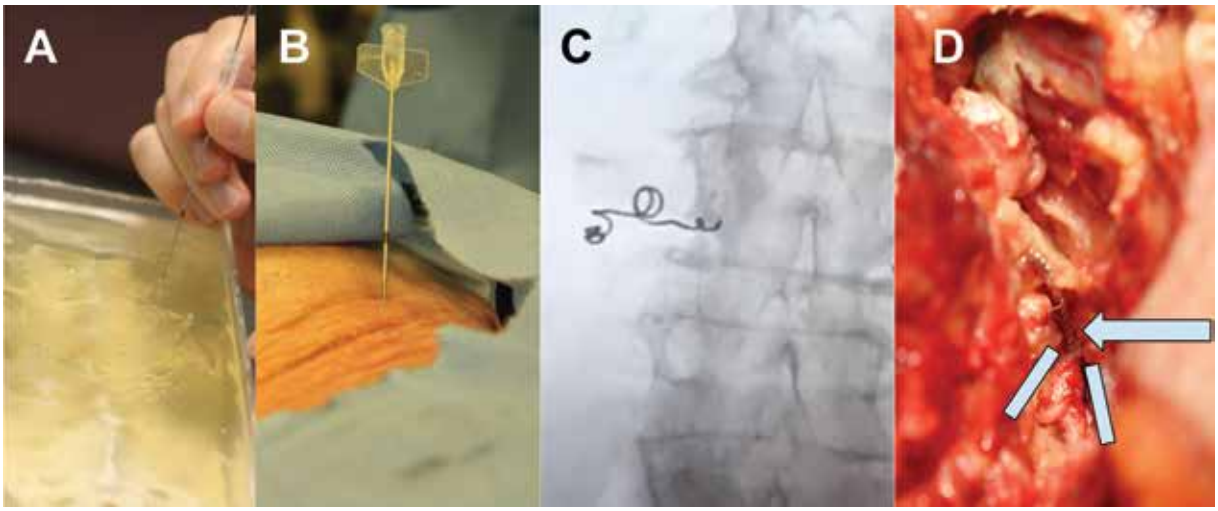

Fig. 2. *(A) Spine embedded in transparent gelatin used for injectable lead placement training. (B) Injectrode delivery needle using a transforaminal approach to terminate near the L2 DRG. (C) Anteroposterior fluoroscopy showing a fully deployed Injectrode system. (D) Injectrode (arrow) terminating near the posterior division of the left lumbar L2 DRG (lines).*

into the empty delivery needle. This was done by attaching the transfer cannula to the delivery needle, lubricating the transfer cannula with a saline syringe, and fully inserting the delivery pin into the transfer cannula. The transfer cannula was then removed from the delivery needle (Fig. 3B).

To begin placing the Injectrode, the delivery pin was inserted up to its first marking to place the Injectrode stimulating tip and stimulating tip anchor near the left L2 DRG. The delivery needle was then gently retracted toward the skin surface as the clinician continued to dispense the Injectrode's central anchors (Fig. 3C). Finally, upon seeing the delivery needle's subcutaneous delivery marking, the delivery needle was tilted into the subcutaneous space and the delivery pin was fully inserted into the delivery needle in order to eject the full collector into the previously defined subcutaneous pocket (Fig. 3D).

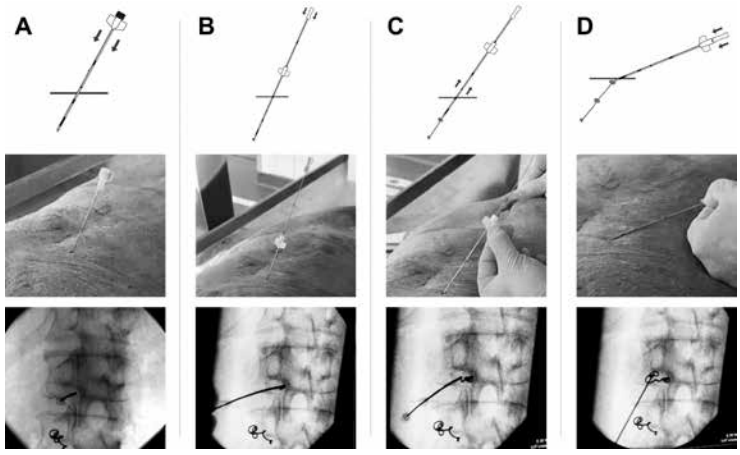

Fig. 3. *(A) The first column shows, under fluoroscopy, the delivery needle advanced to the left L1 DRG using a sharp trocar attachment. (B) The second column shows insertion of the delivery pin to begin placing the Injectrode F1 from the delivery needle. (C) The third column shows retraction of the delivery needle toward the skin to string the Injectrode F1 toward the subcutaneous space. (D) The fourth column shows tilting of the delivery needle parallel to the skin to deliver the collector/receiver into the defined subcutaneous pocket.*

Procedure for DRGS Abbott SlimTip Placement in a Cadaver

An Abbott SlimTip lead was then placed at the left L1 DRG in the male cadaver using the contralateral approach prescribed by Abbott Neuromodulation (15).

Outcomes

Cadaveric device evaluations typically include carefully evaluating placement using imaging and dissection performed by experts (16-19). The caliper modality of an ultrasound system (Sonosite PX, Fujifilm SonoSite) was used to assess the end depth of the Injectrode's subcutaneous collector component from the skin surface after full device deployment and the distance from the point of the delivery needle insertion (injection point) to the target nerve. Careful dissection of the lead locations was performed by experienced anatomists in order to assess the distance between the tips of the Abbott and Neuronoff leads from their nerve targets, measured in millimeters (Fig. 4). Finally, the time taken to place each device was measured in seconds. For the Injectrode, this included the time for device preparation, target localization under fluoroscopy, and complete device placement, terminating after the full deployment of the subcutaneous collector. For the Abbott lead, this included the time for device preparation, target localization under fluoroscopy, lead positioning, and interlaminar anchor ("S" tension loop) formation but did not include the time required for skin anchoring or full closure after placement.

Statistics

Neither descriptive nor test statistics were applicable in this feasibility study.

Results

Two Injectrodes were placed near the target DRG at the left L1 and L2 lumbar levels in the male cadaver. A single Abbott SlimTip lead was placed on the left L1 DRG of the same cadaver. A medium length, 10 cm Injectrode device was placed near the left L2 DRG. The total time to completely place the Injectrode device, from target identification under fluoroscopy, to delivery of the subcutaneous collector, was 390 seconds. The depth of the target DRG was 7.0 cm, which was within the ability of the delivery system to reach. The final distance from the point of the delivery needle insertion (injection point) to the target nerve was 7.50 cm. The depth of the Injectrode subcutaneous collector after placement, as identified and measured under ultrasound, was 0.52 cm, within the 1.0 cm depth recommended by the manufacturer.

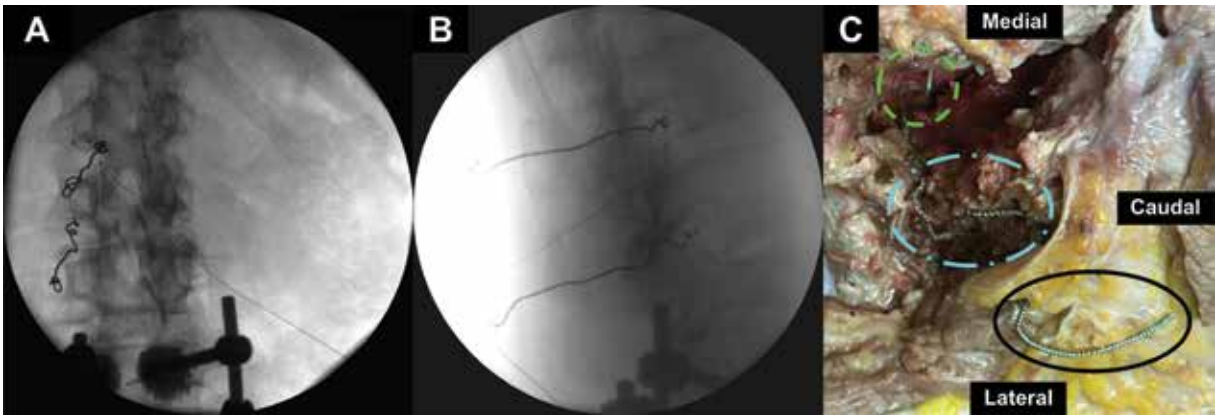

Fig. 4. *(A) Oblique and (B) lateral fluoroscopy showing positional overlap of the injectable electrode and the conventional DRGS lead after placement. (C) Cadaveric dissection shows the Injectrode collector in subcutaneous tissue (black oval), Injectrode anchors traversing the paraspinal musculature (blue alternating dot-dash oval), and the Injectrode stimulating tip directly adjacent to the emerging benchmark device lead (green dashed circle).*

Similarly, a medium length, 10 cm Injectrode device was placed near the left L1 DRG. The total time required to complete placing the Injectrode was 204 seconds. The depth of the target DRG was 8.0 cm, which required a more medial insertion point to achieve the stimulator terminating near the target DRG. The final distance from the injection point to the target DRG using this medial entry point was 6.50 cm. The ending depth of the Injectrode subcutaneous collector was measured under ultrasound as 0.66 cm. Finally, an Abbott SlimTip lead was placed on the left L1 root. The total time to place the SlimTip DRG lead from target identification under fluoroscopy to percutaneous externalization of the lead was 569 seconds.

Careful dissection of the left L1 DRG was performed with the electrodes left positionally intact, as confirmed by fluoroscopy (Fig. 5). The dissection revealed that the Abbott SlimTip lead emerged from the left L1 vertebral foramen, laid 1.0 mm atop the left L1 DRG. The left L1 Injectrode, placed using the lateral transforaminal approach, was seen to overlap with the placement location of the Abbott SlimTip lead that had been placed using the conventional epidural approach (Fig. 4). The dissection confirmed the location of the tip of the left L1 Injectrode within 1.0 mm of the target spinal nerve, extending from the DRG. Careful dissection of the left L2 DRG was also performed, and the tip of the Injectrode was again determined to be within 1.0 mm of the spinal nerve, extending from the L2 DRG.

Discussion

The Abbott Neuromodulation Proclaim System currently stands as the only DRGS system approved by the US Food and Drug Administration to treat complex regional pain syndrome types I and II. The anterograde or transgrade intraspinal approach for placing the SlimTip lead is the most widely studied approach for implementing DRGS.

Case series exist involving the Proclaim System's use in a transforaminal approach targeting lumbar DRG (20,21). One series involved the "outside-in" placement of the Proclaim DRGS lead in 4 patients who had a prior medical history of lumbar decompressive surgery and subsequent Failed Back Surgery Syndrome with inaccessible epidural spaces. The 4 patients reported Visual Analog Scale pain scores and functional improvements up to 26 months post permanent device implantation. While these results are promising, the limited scope of this case series highlights the need for additional investigations of the transforaminal approach to DRG stimulator placement. Currently, there are no devices on the market that are designed to optimize the transforaminal targeting of the lumbar DRG and postganglionic spinal nerves.

Our cadaveric study is a preliminary assessment of the feasibility of placing an injectable electrode on the lumbar DRG using a peripheral TFESI-compliant approach with respect to procedural time and placement accuracy. A conventional epidural approach with an Abbott SlimTip lead was used as the reference standard for DRGS. Our study revealed that both the Injectrode

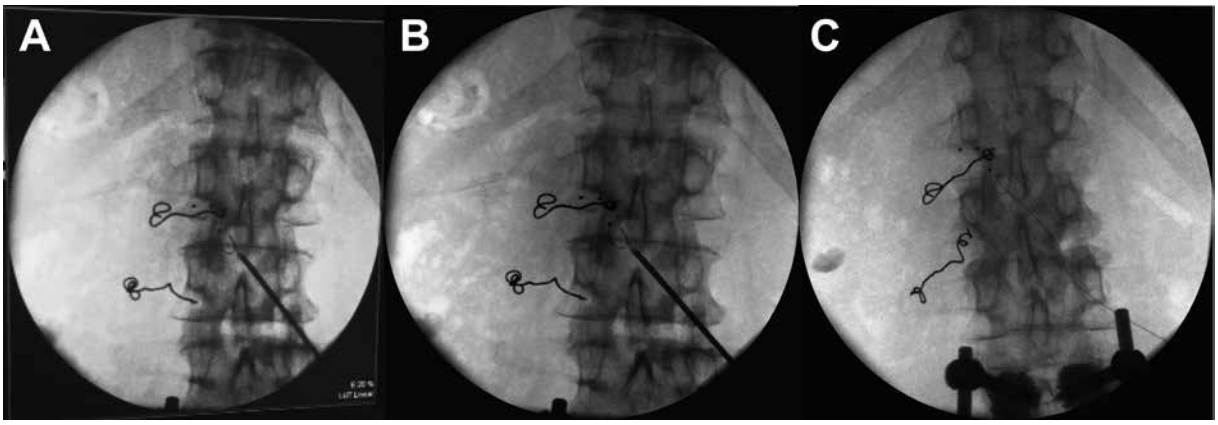

Fig. 5. *(A) The conventional DRGS lead passed into the target L1 left foramen using a contralateral approach. (B) Strain/ tension relief loops formed in the epidural space. (C). Benchmark device after percutaneous insertion before fascial anchoring.*

and SlimTip lead achieved high accuracy in anatomical placement, a finding corroborated by fluoroscopy, ultrasound, and dissection methods.

The epidural approach required for placing the SlimTip lead was approximately 2 times longer than the time required for peripheral placement of the Injectrode system, even when placed by a practitioner unfamiliar with the TFESI electrode deployment technique. This discrepancy was observed even without considering the eventual time required for anchoring the SlimTip lead to the fascia. Furthermore, our study offers an initial look at the Injectrode's potential in scenarios where traditional placement approaches may be hindered by factors such as existing spinal hardware or anatomical limitations such as spinal stenosis, wherein placement using conventional epidural access approaches could risk nerve damage (7,11,21).

Prior to our cadaveric study, Injectrode implantation methods were demonstrated and practiced using transparent spine models in an interactive half-hour training session, conducted only one hour before its application in human cadavers. Despite the limited training duration and quick transition to practical application, the Injectrode's placement quality was high. Given that TFESIs are the mainline therapy applied early in the treatment of lumbar radicular pain (13,22), the peripheral approach detailed here for electrode deployment is readily accessible to a broad range of interventional clinicians already skilled in using needle-based therapies. Thus, adapting TFESI techniques for placing the Injectrode could provide a new avenue for introducing neuromodulation earlier in the chronic pain treatment continuum.

Limitations

Our study's findings are derived from procedures performed on only 2 cadavers, which may not represent the full spectrum of anatomical variability encountered in a patient population. While the results are promising, the anatomical precision and ease of electrode placement observed might differ in clinical settings due to variations in anatomy, presence of pathological conditions, or previous surgical modifications not represented in the cadavers used.

Our feasibility study was conducted without the capability to assess stimulation efficacy and sensory feedback, which are critical components in determining the optimal placement of neuromodulation devices in patients. In clinical practice, real-time feedback from patients during stimulation helps fine-tune electrode placement for maximum efficacy, a process that was not replicable in this cadaveric model (18). Therefore, the translation of these positioning accuracies and procedural efficiencies into effective clinical outcomes remains hypothetical until validated in clinical trials involving live subjects.

Our study did not address the long-term stability of the implanted devices, including potential risks of migration or mechanical failure over time, which are significant considerations for permanent implants (11). The interaction of the device with biological tissues during activities and muscle movements, which could affect the device's position and functional integrity, was also not explored. Additionally, the effect of inflammatory responses or fibrotic tissue development around the implant site, which could influence the

device's long-term functionality and safety, remains unexamined. However, the safety considerations for the paraforaminal approach are likely close to those applied in TFESIs, including the risk of injury to the nerve and segmental/radicular arteries (23).

The DRG typically lies within the superior aspect of the foramen, hugging the pedicle before extending distally to the location where the dorsal roots mix with the ventral roots to form the spinal nerve. Each nerve root is supplied by a radicular artery that lies ventral to the DRG. To avoid injury to the anatomy near the DRG, the proposed Injectrode delivery needle approach toward the dorsal and caudal aspects of the foramen was performed using a blunt trocar and carefully advanced using bony anatomical landmarks and imaging guidance. We anticipate that a blunt approach utilizing intraoperative stimulation or neuromonitoring will maximize procedural safety both before and during electrode placement.

Conclusions

In conclusion, our study provides preliminary non-clinical confirmation of the feasibility of placing an injectable electrode (Injectrode) on the lumbar DRG by assessing the procedure time and placement accuracy relative to a benchmark DRGS device. Future research should focus on validating these findings in clinical settings, especially to determine the long-term safety, stability, and efficacy of the transforaminal peripheral near-DRG approach using the Injectrode device.

Author Contributions

Conceptualization: BB, TB, CJ, BM, SN, and AS. Methodology: BB, TB, CJ, BM, SN, and AS. Software: CJ and DL. Validation: BM, AA, and AS. Formal analysis: D L and CJ. Investigation: BB, TB, CJ, BM, SN and DL. Resources: SN, DL, and BB. Data curation: TB, D L, and CJ. Writing – original draft preparation: BB, TB, DL, ES, and SN. Writing – review and editing: BB, TB, CJ, BM, DL, ES, SN, AA, and AS. Visualization: DL. Supervision: BB and TB. Project administration: BB. Funding acquisition: BB and SN.

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Conflict of Interest

DL, ES, and SN are employees of Neuronoff, Inc. DL, ES, SN, AA, and AS hold shares or options in Neuronoff Inc. BB reports consultancy and travel fees received from Abbott Laboratories, Saluda Medical, Medtronic, Nevro, and Salvia Bioelectronics. All other authors certify that he or she, or a member of his or her immediate family, have no commercial association (i.e., consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted article.

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