

Clinical Study

# Minimally-invasive percutaneous treatments for low back pain and leg pain: a randomized controlled study of thermal disc decompression versus mechanical percutaneous disc decompression

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## Abstract

**BACKGROUND CONTEXT:** Minimally invasive techniques have recently been developed as alternative treatments to surgical interventions, especially for small or contained herniated disc.

**PURPOSE:** Aim of our study is to assess the efficacy of the mechanical percutaneous disc decompression (PDD) in comparison with the percutaneous radiofrequency targeted disc decompression (TDD).

**STUDY DESIGN:** We conducted a single-center noninferiority trial in which patients who had low back pain with radicular leg pain (RLP) from a contained herniated disc were randomly assigned in a 1:1 ratio to undergo either PDD or TDD.

**PATIENT SAMPLE:** From January 2016 to January 2017 a total of 327 patients were assessed for eligibility of whom 200 underwent randomization in the trial; 100 patients underwent the PDD and 100 underwent the TDD.

**OUTCOME MEASURES:** The primary outcome measure was the proportion of patients who reported >50% reduction in Numeric Rating Scale (NRS) leg pain score. Secondary outcome measure included the proportion of patients who reported >30% improvement in Oswestry Disability Index (ODI) score.

**METHODS:** Outcomes of this trial were measured with the use of patient-reported data obtained from validated questionnaires to assess the low back pain with RLP before intervention and at 6 and 12 months after interventions. MRI was performed before intervention and at 6 and 12 months after interventions. In addition to NRS and ODI scores, we collected the following data: age, gender, length of hospitalizations and return to work rate.

**RESULTS:** When using an intention to treat analysis with those lost to follow-up and requiring a second procedure counting as failures, there were no statistically significant difference between the two treatment groups in the primary and secondary outcomes at 6 months: >50% reduction in NRS leg pain (PDD vs. TDD)=67% versus 65%; >30% ODI improvement (PDD vs. TDD)=57% versus 55%. Similarly, there were no statistically significant differences between groups in outcomes at 12 months: >50% reduction in NRS leg pain (PDD vs. TDD)=51% (95% CI 41%–60%) versus 40% (95% CI: 30%–49%); >30% ODI improvement (PDD vs. TDD)=42% (95% CI 32%–51%) versus 30% (95% CI: 21%–39%). A nonintention to treat analysis which discounted those lost to follow-up showed the only statistically significant finding was the percentage of those reporting >30% ODI at the 12 month follow-up time, favoring the PDD group: (PDD vs. TDD)=58% (95% CI 46%–69%) versus 42% (95% CI: 22%–43%).

FDA device/drug status: Approved (DISKOM, Diskit II).

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**CONCLUSIONS:** PDD and TDD are comparable treatments for patients presenting with low back pain with RLP unresponsive to medical therapy caused by contained disc herniations. © 2021 Elsevier Inc. All rights reserved.

**Keywords:** Chronic low back pain; Intervertebral disc disease; Mechanical disc decompression; Thermal disc decompression

## Introduction

The lifetime prevalence of the lumbar radiculopathy associated with disc herniation ranges from 12.2% to 43% [1] and each year around 5 to 10 subjects per 1,000 inhabitants (0.5%–1%) suffer symptoms of sciatica, with poor quality of life implications [2].

Conservative treatments for spinal herniation generally provide a favorable clinical outcome, with a reduction of leg pain in most patients at 6 months and a complete recovery reported in a good proportion at 1 to 2 year follow up from therapy [3].

In cases of medical treatment failure, open surgical techniques may be indicated to remove the herniated disc [4]. However, these procedures may induce neural adhesion, spinal structural instability and other complications, with a rate ranging from 8% to 15.7% [5].

Minimally invasive techniques have recently been developed as alternative treatments to surgical interventions, especially for small or contained herniated disk (eg, percutaneous coblation nucleoplasty, decompression percutaneous discectomy, chemodiscolysis) [6].

These techniques often show lower rates of complications with similar results while potentially reducing costs related to hospitalization and morbidity [7].

Nowadays, the target of these techniques is to decompress the nerve root and many treatments are under evaluation [8].

The aim of our study was to assess the efficacy of mechanical percutaneous disc decompression (PDD) in

comparison with the percutaneous radiofrequency targeted disc decompression (TDD) Fig. 1 and Fig. 2.

## Methods

### Trial design

We conducted a single-center noninferiority trial in which patients who had low back pain with radicular leg pain (RLP) were randomly assigned, in a 1:1 ratio, to undergo either the mechanical Percutaneous Disc Decompression (group PDD) or the percutaneous radiofrequency Targeted Disc Decompression (group TDD).

We enrolled patients with more than 18 years of age who had a diagnosis of symptomatic contained disc herniation and who met the inclusion criteria (Table 1)(mmc1)(mmc2).

The diagnosis of symptomatic contained disc herniation was based on the presence of neurological signs and the findings on magnetic resonance imaging (MRI).

Patients were assessed for low back pain with RLP before being randomized.

According to the disc nomenclature, version 2.0 [9], contained lumbar disc herniation was defined as a focal displacement of disc material (<25% of the disc circumference) beyond the limits of the intervertebral disc space, covered by outer annulus fibrosus.

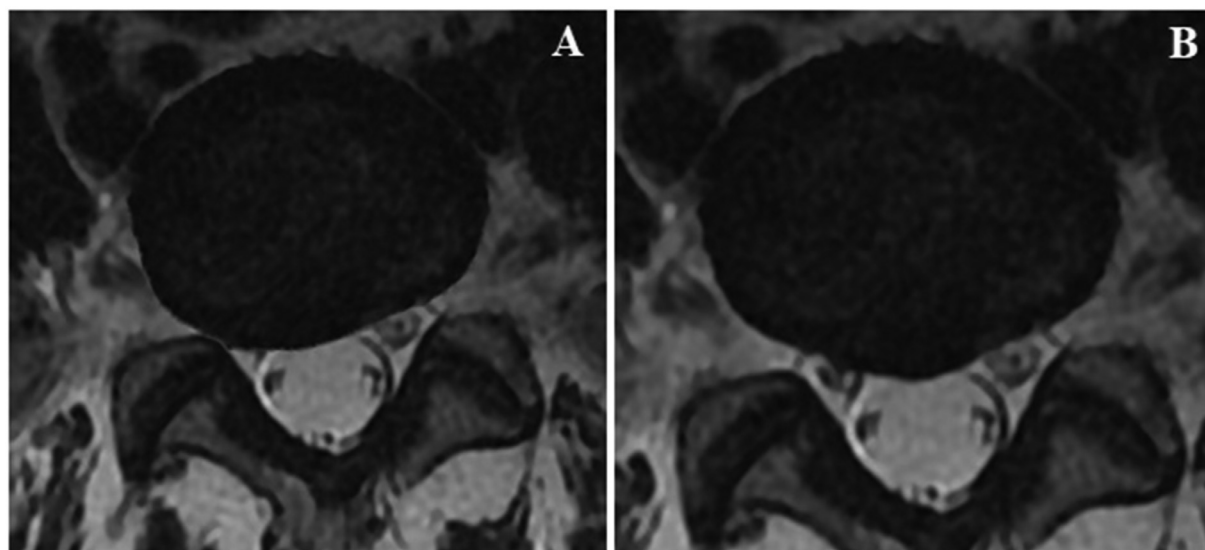


Fig. 1. Axial T2w MRI before (A) and after (B) PDD treatment.

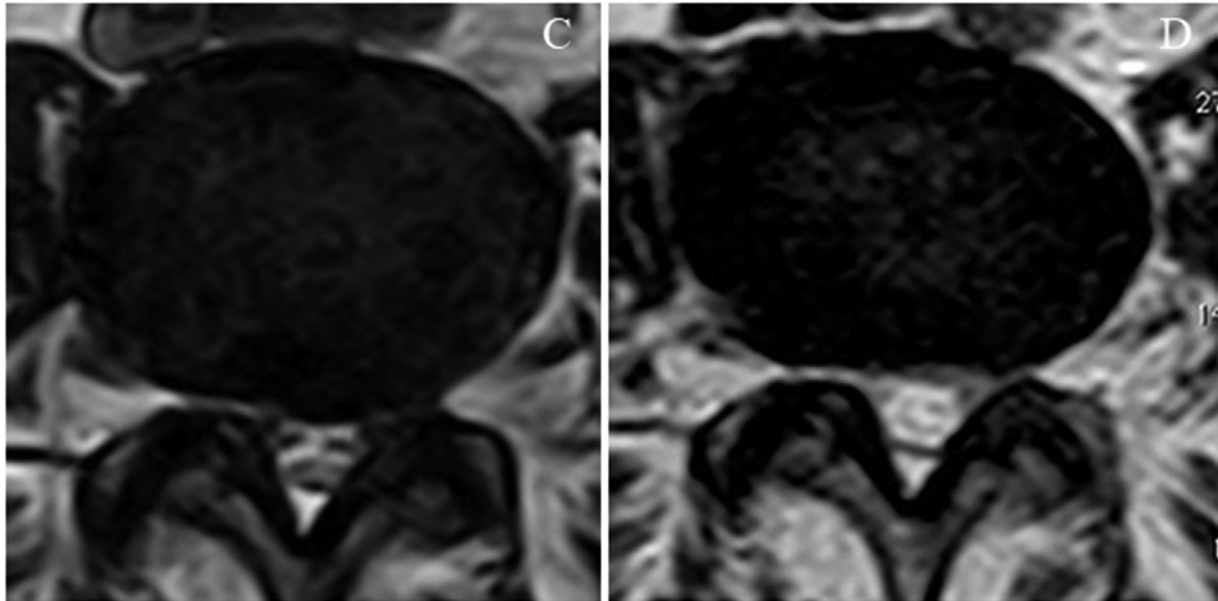


Fig. 2. Axial T2w MRI before (C) and after (D) TDD treatment.

Simple randomization was performed with the use of a web-based system that enabled computer-generated random treatment assignment.

Randomization was stratified according to the presence or absence of contained disc herniation.

When an apparent clinical benefit was not obtained in the first month, patients underwent a second treatment between 45 and 60 days from intervention and remained included in the study groups according to an intention-to-treat analysis.

All the interventional neuroradiologists that performed the procedures were highly experienced in performing the two trial interventions.

#### *Data collection and outcomes*

Outcomes of this trial were measured with the use of patient-reported data obtained from validated questionnaires such as Numeric rating Scale (NRS) and Oswestry Disability Index (ODI) to assess the low back pain [10,11]. We confirmed that the patients answered the questionnaires before intervention and at 6 and 12 months after interventions. The questionnaires were presented to the patients at their first clinical assessment for low back pain with RLP and next hospital visits during follow-up and were completed without the assistance of any person involved in the trial.

If a patient did not present to a follow-up appointment, phone calls were placed to home, work, and mobile phone numbers identified by current electronic medical record search (at least three calls at different times of day). If this means of contact was unsuccessful, the individual was considered “lost to follow-up.”

The primary outcome measure was the proportion of patients who reported >50% reduction in NRS leg pain score. Categorical data were used given that studies on interventions for spine pathology may result in responders and nonresponders, thus negating the ability to use mean or average data [12,13]. Additionally, this approach for assessing spine pain has been recommended by the National Institutes of Health [14]. Secondary outcome measures included the proportion of patients who reported >30% improvement in ODI score, median change in NRS leg pain score, median change in ODI score, opioid discontinuation, and change in work status at 6-month and 12-month follow-up

The ODI ranges from 0 to 100, with higher scores indicating greater disability [15].

The NRS ranges from 0 to 10, with higher scores indicating greater pain intensity [16].

A >30% improvement in ODI score represents a robust measure of improvement in disability [17].

MRI was performed before intervention and at 6 and 12 months after interventions. Imaging was evaluated by senior radiologists highly experienced in neuroradiology.

In addition, we collected the following data: age, gender, length of hospitalizations and return to work rate.

#### *Procedure techniques*

Prophylactic antibiotics were administered prior to the procedure, oral antibiotics were prescribed in advance and started a day before. All patients had intravenous access.

The patient was placed in a prone position using cylindrical rolls at the level of the iliac crests, to better display the intervertebral spaces.

All procedures were performed under fluoroscopic guidance in the angiographic suite, with an ipsilateral approach

Table 1  
Inclusion and exclusion criteria

<b>Inclusion criteria</b>
Low back pain with Radicular Leg Pain unresponsive to medical and/or PT common treatments (NSAIDs, Corticosteroid drugs, myorelaxants etc.)
Contained disc herniation unresponsive to epidural injection and/or PT
Unilateral single level disc herniation
Duration of symptoms >3 mo
Age >18 y old
Other common sources of low back pain ruled out*
Written informed consent
<b>Exclusion criteria</b>
MRI findings of extruded hernia
Facet joint arthropathy syndrome
Black disc (Pfirrmann grade IV and V)
Dallas grade 5 annular tear in discogram for index disc
Intersomatic disc height reduction >50%
Spondylolysis at index level
Spondylolisthesis at index level >grade 1
Degenerative lumbar scoliosis (Cobb angle >20°)
Those receiving remuneration for their pain treatment (eg, disability, worker's compensation)
Those involved in active litigation relevant to their pain
Incarceration
BMI >35
Addictive behavior, severe clinical depression, or psychotic features
Possible pregnancy or other reason that precludes the use of fluoroscopy
Active bacterial infection or treatment of infection with antibiotics within the past 4 wk
Unexplained neurologic deficits, progressive motor deficit, or clinical signs of myelopathy
Medical conditions causing significant functional disability (eg, stroke, COPD)
Any other medical condition precluding safe disc access
Allergy preventing the use of any medication or injectate
Chronic widespread pain or somatoform disorder (eg, fibromyalgia)

\* Lumbar z-joint pain ruled out through fluoroscopically-guided medial branch blocks. Sacroiliac joint (SIJ) pain ruled out (if pain location is below L5) through image-guided diagnostic SIJ intra-articular injections.

to the disc herniation. We treated only a single level, intraforaminal, unilateral herniation disc.

The target intervertebral disc was identified obtaining anterior-posterior and latero-lateral projections. To approach the disc, the fluoroscope was positioned in the oblique position so that the superior articular process of the inferior lumbar vertebral body was bisecting the disc endplate at its midportion.

Local anesthesia (2 cc of 2% mepivacaine) was used to anesthetize the skin and soft tissues.

#### *The mechanical PDD technique*

We used the DISKOM Percutaneous discectomy probe (BiopsyBell, Mirandola, Italy).

After local anesthesia, a 17-gauge introducer cannula with stylet was advanced ventro-laterally to the superior

articular process in the “safe zone” described by Kapoor et al. [18] and placed intradiscally. The stylet was removed, the discectomy probe inserted and locked through the luer-lock connection to the access cannula.

The device was switched on and continuously moved in antero-posterior direction inside the disc for 3 minutes. During this procedure, about 2 cc of nucleus pulposus are directly removed and collected in the probe chamber. Finally, the probe and the introducer cannula were withdrawn sequentially.

#### *The percutaneous radiofrequency TDD technique*

After local anesthesia, a Diskit II needle (20 G, 15-cm length, 20-mm active tip, with radiopaque marker active tip; NeuroTherm, Wilmington, MA, USA) was advanced ventro-laterally to the superior articular process in the “safe zone” and placed intradiscally.

First, we performed an electro-stimulation at 2 V at 2 and 50 Hz to confirm that the needle was correctly positioned far away from the segmental nerve.

Then, we applied intradiscal pulsed radiofrequency TDD at a frequency of 5 Hz, pulse width of 5 ms, amplitude of 60 V, and a maximum temperature of 40°C, for a duration of 12 minutes, with the NT1100 generator (NeuroTherm).

Immediately following PDD/TDD, a transforaminal epidural steroid block with 1% lidocaine and methylprednisolone 40 mg/mL (total volume: 2 mL) was performed at the affected nerve root level.

At the end of the procedure, patients were observed for approximately 4 hours prior to discharge.

Each patient underwent the following clinical and therapeutic protocols for 40 days after the procedure: rest for 4 days avoiding movements that overload the rachis (such as lifting of loads and push and pull of carts or heavy object), antibiotic therapy for 5 days (amoxicillin/clavulanic acid), medical therapy in case of pain (paracetamol: 1,000 mg BID; analgesic drugs as needed) and then they got 2 sessions (1 hour each) per week for 4 weeks of physical therapy (PT) with traditional techniques and proper exercise programs [19,20].

#### *Trial oversight*

The study was approved by the local ethics committee and all patients provided written informed consent before being enrolled.

The authors designed the trial, analyzed the data, wrote the manuscript (with the first draft written by the first author), made the decision to submit the manuscript for publication, and vouch for the completeness and accuracy of the data and analysis and for the fidelity of this report to the trial protocol.

Table 2  
Baseline characteristics of the patients

Characteristics	PDD	TDD
Age - y (mean±SD; range)	58,7±11,7; 33–87	56,7±12,1; 33–82
Female sex - no. (%)	47	49
Duration of pain at presentation (mo)	4	4
NRS leg pain score (mean)	8	8
ODI score (mean±SD)	26,2±4,9	25,9±4,8
<i>Percutaneous Lumbar Disk Decompression Level</i>		
L2–L3	1	1
L3–L4	4	3
L4–L5	54	56
L5–S1	41	40

*Statistical analysis*

Considering disease symptoms incidence and our annual ambulatory admissions, we calculated a sample size of 200, with 95% confidence interval [2].

We performed a standard analysis assessing primary and secondary outcomes without including patients lost to follow-up and we also performed an intention to treat analysis in which every patient lost to follow-up or receiving a second treatment was considered a “treatment failure.”

Comparison between treatment groups was made using the Student’s *t* test.

A two-sided *p* value <.05 was considered to indicate statistical significance. Analyses were performed using SPSS version 23.0 (IBM, Armonk, New York).

**Results**

*Participants*

From January 2016 to January 2017 a total of 327 patients were assessed for eligibility of whom 200 underwent randomization in the trial. A total of 100 patients underwent the PDD and 100 underwent the TDD.

There were no differences between the two groups in any of the baseline characteristics of the patients, as reported in Table 2.

Eight patients in the PDD group underwent a second PDD treatment due to persistent low back pain with RLP and nine in the TDD group underwent a second TDD.

Twenty patients for each group were lost to the 12-month follow-up. Therefore, the standard analysis included 143 patients (72 in the PDD group and 71 in the TDD group).

*Outcomes at follow-up*

The 6-month and 12-month outcomes of the procedure are shown in Table 3.

*Outcomes at 6-month follow-up*

The patients who were not lost at 6 months follow-up with standard analysis reported: >50% reduction in NRS leg pain (PDD vs. TDD)=73,62% (95% CI 63%–81%) instead of 72,22% (95% CI 62%–80%). They also reported >30% ODI improvement (PDD vs. TDD) with 62,63% (95% CI 57%–71%) instead of 61,11% (95% CI 50%–70%).

With intention to treat analysis we observed: >50% reduction in NRS leg pain (PDD vs. TDD) with 67% (95% CI 57%–75%) instead of 65% (95% CI 55%–73%); >30% ODI improvement (PDD vs. TDD) was 57% (95% CI 47%–66%) instead of 55% (45%–64%).

There were no statistically significant differences in the primary and secondary outcome between the two treatment groups at 6-month follow-up (Table 3).

We also reported that at the control MRI after 12 months, although it was not a primary aim of the study, the hernia size reduction were respectively for the PDD Group in the range between 20% and 30% and for the TDD Group 40% to 50% per radiologist read.

All those patients who were working preoperatively returned to work. The mean time to return to work was 16.5 days (10–60 days).

Table 3  
Standard analysis and intention-to-treat analysis 6-month and 12-month follow-up

	Proportion of subjects with >50% reduction in NRS leg pain score	95% CI	Proportion of subjects with >30% ODI improvement	95% CI
Standard analysis - 6 mo from PDD (n=91)	73.62%	[0.63, 0.81]	62.63%	[0.57, 0.71]
Standard analysis - 6 m from TDD (n=90)	72.22%	[0.62, 0.80]	61.11%	[0.50, 0.70]
Intention-to-treat analysis - 6 mo from PDD (n=100)	67.00%	[0.57, 0.75]	57.00%	[0.47, 0.66]
Intention-to-treat analysis - 6 mo from TDD (n=100)	65.00%	[0.55, 0.73]	55.00%	[0.45, 0.64]
Standard analysis - 12 mo from PDD (n=72)	70.80%	[0.59, 0.80]	58.33%	[0.46, 0.69]
Standard analysis - 12 mo from TDD (n=71)	56.33%	[0.44, 0.67]	42.25%	[0.22, 0.43]
Intention-to-treat analysis - 12 mo from PDD (n=100)	51.00%	[0.41, 0.60]	42.00%	[0.32, 0.51]
Intention-to-treat analysis - 12 mo from TDD (n=100)	40.00%	[0.30, 0.49]	30.00%	[0.21, 0.39]

### Outcomes at 12-month follow-up

The percentage of patients who were not lost to follow-up at 12 months reported in the standard analysis showed the following results: >50% reduction in NRS leg pain (PDD vs. TDD) was 70,8% (95% CI 59%–80%) of cases instead of 56,33% (95% CI 44%–67%). They also reported >30% ODI improvement (PDD vs. TDD) with 58,33% (95% CI 46%–69%) instead of 42,25% (95% CI 22%–43%).

With intention to treat analysis we observed that in >50% NRS leg pain (PDD vs. TDD): 51% (95% CI 41%–60%) instead of 40% (95% CI: 30%–49%); the patients that reported >30% ODI improvement (PDD vs. TDD) were 42% (95% CI 32%–51%) instead of 30% (95% CI: 21%–39%).

A nonintention to treat analysis which discounted those lost to follow-up, showed the only statistically significant finding in this study which was the percentage of those reporting >30% ODI only at the 12 months follow-up time favored the PDD group.

### Complications

Other than transient adverse events (ie, vasovagal reactions), we report one case of spondylodiscitis that occurred in a patient treated with the TDD that was already debilitated by advanced diabetes.

### Discussion

In this randomized controlled study, we report our experience with PDD and TDD, comparing treatment outcomes in 200 patients.

The outcome analysis at the 6-month follow-up shows equivalence among groups as regard to NRS and ODI. We found that there is a slight trend favoring PDD according to the ODI score, but only at the 12-month follow up and it is not demonstrated on the intention to treat analysis.

The better results obtained with the PDD after 12 months may be explained by technical differences among devices. Indeed, the PDD allows to directly remove about 2cc of nucleus pulposus through aspiration, obtaining a higher intradiscal vacuum as compared with the TDD technique. This effect could provide a greater nerve root decompression, resulting in a longer reduction of leg pain at the 12-month follow up and, in the nonintention to treat analysis, a >30% ODI at the 12 month follow-up time, favoring the PDD group.

Even if there were no statistically significant differences between the two groups and anytime, we can also confirm the feasibility of minimally-invasive percutaneous treatments for contained, nonextruded disc-protrusions as reported in previous studies [21,22].

In a small percentage of patients, a second treatment of disc decompression with or without medical therapy was necessary to obtain the reduction of pain symptoms. On MRI, we found different herniation dimensions and,

according to MRI findings, this adverse event can be explained by larger contained herniations for patients retreated as compared to the others that underwent just a single procedure. We conclude that the herniation dimension is crucial to decide to plan 2<sup>nd</sup> procedure at the outset. Moreover, the percentage of patients who needed the double treatment was equivalent in both groups (Table 3), excluding the procedural techniques from the possible causes.

We obtained also satisfactory results at follow-up as regard to complications, according to previous reports [23,24]. Indeed, we reported just one case of spondylodiscitis, that occurred in a patient treated with the TDD that was already debilitated by advanced diabetes mellitus.

There are some limitations to this study. First, 20 patients per group were lost to the 12-month follow-up, reducing the power of the analysis. If on the one hand this may reflect positive results if patients refused to come back because returned to their normal life, on the contrary it could reflect their dissatisfaction due to bad results. Therefore, we preferred to consider them as “treatment failure” in the intention to treat analysis.

Moreover, the aim of the trial was to evaluate clinical outcome of PDD and TDD at 12-month follow-up and we did not compare devices with different disc herniation sites. Despite this we did not report differences in clinical outcomes at 6-month follow-up as well as retreatment rate, in our experience the location of disc herniation should still be taken into account in presurgical planning. Indeed, in cases of small foraminal protrusions, the smaller size of the TDD device allowed to obtain an easier and faster access with good clinical outcome at 6-month follow-up. Therefore, further study may be warranted to understand if treatments tailored to herniated disc sites could be related with better outcomes.

Finally, despite our best effort, the long-term outcomes of the two procedures could be biased by confounders such as degree of disc herniation, history of duration before treatment and osteoarthritis.

### Conclusions

PDD and TDD are safe and comparable treatments for patients presenting with low back pain with RLP unresponsive to medical therapy caused by contained disc herniations. In this randomized controlled study, we found that there were no statistically significant differences between groups at any time points.

### Declarations of Competing Interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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## Supplementary materials

Supplementary material associated with this article can be found in the online version at <https://doi.org/10.1016/j.spinee.2021.12.008>.

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