European Review for Medical and Pharmacological Sciences 2023; 27: 11303-11314

Assessment of efficacy of percutaneous epidural neuroplasty for lumbar stenosis and failed back surgery syndrome: effective and safe?

G. DAĞISTAN[1], I. ÖZDEMIR[2]

[1]Anesthesiology and Reanimation Department (Algology), Faculty of Medicine, Akdeniz University, Antalya, Turkey
[2]Anesthesiology and Reanimation Department (Algology), Faculty of Medicine, Koç University, İstanbul, Turkey

Abstract. – OBJECTIVE: Chronic, refractory low back and lower extremity pain is a common problem. There are many causes for persistent low back pain, including spinal stenosis (SS), disc herniation, facet disease, sacroiliac disease, adjacent segment disease, ligamentous disease, and failed back surgery syndrome (FBSS). FBSS and SS are common and often result in chronic, persistent pain and disability. After the failure of conservative treatments, percutaneous epidural neuroplasty (PEN) is often used in managing low back pain.

PATIENTS AND METHODS: **We retrospectively analyzed 117 patients who received PEN for FBSS and SS between January 2018 and January 2019. Clinical outcomes were assessed with the visual analogue scale (VAS) score and the Oswestry disability index (ODI). The follow-up period was 6 months. We aimed to evaluate the effectiveness of percutaneous epidural neuroplasty in managing chronic refractory low back and lower extremity pain secondary to FBSS and SS and to compare the differences between outcomes of SS and FBSS groups, before and after PEN.**

RESULTS: **Mean VAS scores were 6.15 ± 1.25 preoperatively, 2.97 ± 1.5 after 1 month, 3.18 ± 1.65 after 3 months, and 3.83 ± 1.64 after 6 months of follow-up. Mean ODI scores were 49.91 ± 13.87 preoperatively, 30.19 ± 12.01 after 1 month, 31.61 ± 12.46 after 3 months, 34.58 ± 12.52 after 6 months of follow-up.**

CONCLUSIONS: **Percutaneous epidural neuroplasty was shown to be a safe and effective treatment in managing refractory back/leg pain following FBSS and SS.**

Key Words:
Failed back surgery syndrome, Spinal stenosis, Percutaneous epidural neuroplasty.

Introduction

Chronic, refractory low back and lower extremity pain is a common issue affecting many people worldwide[1]. There are numerous factors contributing to persistent low back pain, including spinal stenosis (SS), disc herniation, facet disease, sacroiliac disease, adjacent segment disease, ligamentous disease, and failed back surgery syndrome (FBSS)[2-4].

SS is among the most prevalent causes of these conditions. While the exact prevalence of SS is not known, it has been reported that there are approximately 103 million patients with symptomatic lumbar SS worldwide. The symptoms in SS are believed to result from compression within the spinal canal due to the narrowing of structures within or pressure on the nerve roots. It is hypothesized that in the etiopathology, the compression of arterioles within the narrowed spinal canal leads to compromised nerve nourishment. Another theory suggests that the narrowed canal disrupts venous drainage, increasing venous pressure and leading to nerve root injury and the accumulation of toxic metabolites. Since it is generally associated with degenerative processes, it is more commonly encountered in the elderly population[5]. SS is the most frequent reason for lumbar spine surgery in adults over the age of 65[6,7]. Surgical decompression is considered the treatment, and the results of surgery have been documented in several publications[8-10]. However, a Cochrane review found insufficient evidence supporting the effectiveness of surgical decompression or fusion. Data from randomized trials[11] do not support the use of instrumented fusion for degenerative lumbar spondylosis in routine clinical practice.

Managing back and leg pain following spinal surgery can be very challenging. FBSS is identified by the International Association for the Study of Pain as persistent or recurrent low back pain of

Corresponding Author: Gözde Dağıstan, MD; e-mail: g_dagistan@hotmail.com

unknown cause in the same location, despite surgical intervention. FBSS can occur due to various preoperative, intraoperative, and postoperative factors[12]. Its etiology is not entirely clear, with many contributing factors[13].

Epidural adhesions following spinal surgery are thought to play a role in the etiology of epidural fibrosis[14-17]. There are numerous studies[18-25] demonstrating the effectiveness of percutaneous epidural neuroplasty (PEN) in patients with FBSS and SS. PEN is an effective treatment method for intractable back and leg pain that does not respond to conservative therapies, including epidural injections[26-28]. An advantage of PEN is that it allows the delivery of medications to the epidural space, which is not reached by medications given due to adhesions, through catheter assistance[27]. In this study, we aim to present the outcomes of our patients with SS and FBSS who underwent PEN.

Patients and Methods

Between January 2017 and January 2019, we conducted a review of the medical records of 117 patients diagnosed with lumbar SS and FBSS. This retrospective review series was conducted at a single center by examining the medical records of patients treated at our institution. All procedures were performed by the same physician, with appropriate monitoring, in an operating room. A single fluoroscopy C-arm system was used, and all injections followed a standardized protocol.

Inclusion criteria for this study encompassed patients experiencing back pain with or without radicular pain, those with SS (including patients graded as A or B according to the Schizas grading system), and individuals with FBSS (who had undergone one or more back surgeries). These conditions were confirmed through magnetic resonance imaging (MRI). Patients were required to have a visual analogue scale (VAS, 0-10) score of 4 or higher after undergoing conservative and invasive treatments for at least six months, which included medication, physiotherapy, and epidural injections. Exclusion criteria involved patients with instability, spondylolisthesis, traumatic injuries, as well as those with somatic, psychiatric disorders, or underlying systemic diseases. All patients received a caudal PEN.

Procedure

Patients were admitted to the operating room for caudal PEN. Their pulse rate, blood pressure, and pulse oximetry values were monitored. Intravenous access was established for the patients, and they were given intravenous fluids to maintain a volume of 500 cc throughout the procedure. All procedures were conducted under fluoroscopy guidance.

In lateral imaging, the sacral hiatus was identified. Using a 16-gauge epidural needle (RX Coudé®, Epimed Inc., NY, USA), the caudal epidural space was accessed just a few centimeters below the sacral hiatus. Confirmation of the needle's placement within the epidural space was achieved by injecting 1-2 cc of contrast material. Under fluoroscopy's anterior-posterior (AP) view, a 10 ml contrast material was injected to complete a lumbar epidurogram (Figure 1). The distribution of the contrast material was observed, and filling defects were identified.

Subsequently, the tip of the Racz catheter (Brevi-XL™, Epimed Inc., NY, USA) was advanced to the level and side of the filling defect in the anterolateral epidural space. An additional 1-2 cc of contrast material was injected to observe the spread of the contrast material in the epidural area with the filling defect and the nerve root (Figures 2 and 3). In lateral imaging, the catheter's tip position in the anterior epidural space and the spread of the contrast material in the anterior epidural space were confirmed (Figures 4 and 5).

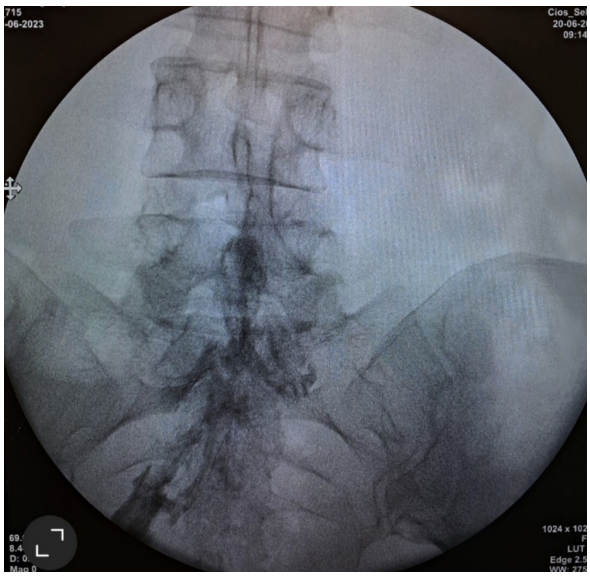

Figure 1. Epidurogram.

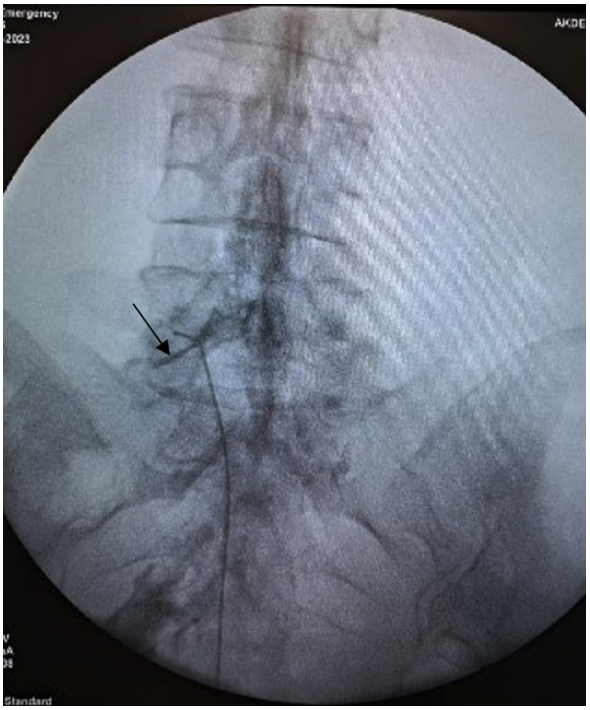

Figure 2. Antero-posterior view of catheter with flow of contrast (*arrow*) in patient who has spinal stenosis.

Following this, an injection of 1,500 units of hyaluronidase in 10 cc preservative-free saline was administered. A 3 mL test dose of a 10 mL local anesthetic/steroid solution, consisting of 2% lidocaine and 8 mg of dexamethasone (Dekort, Deva company, Kapaklı, Tekirdağ, Turkey) was given. If there were no signs of intrathecal or intravascular spread, the remaining 7 mL of the medication was administered. The catheter and needle were then removed together. Patients were transported to the recovery room if all parameters were satisfactory.

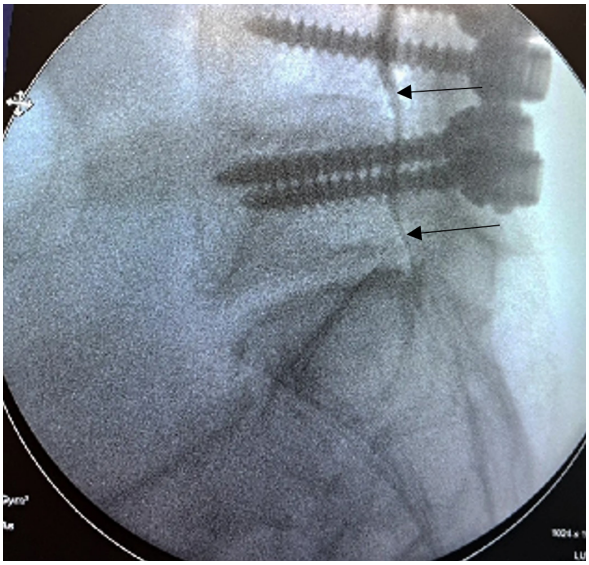

Figure 4. Lateral view of contrast spreading in the anterior epidural space *(arrows*).

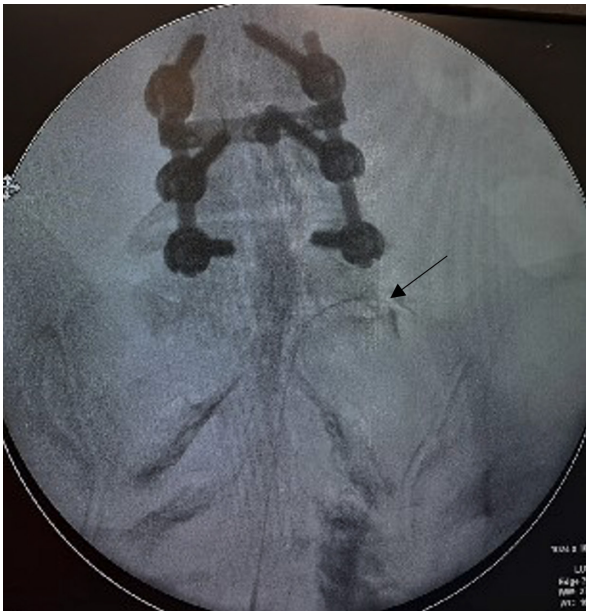

Figure 3. Antero-posterior view of a catheter with the flow of contrast (*arrow*) in a patient who has spinal surgery.

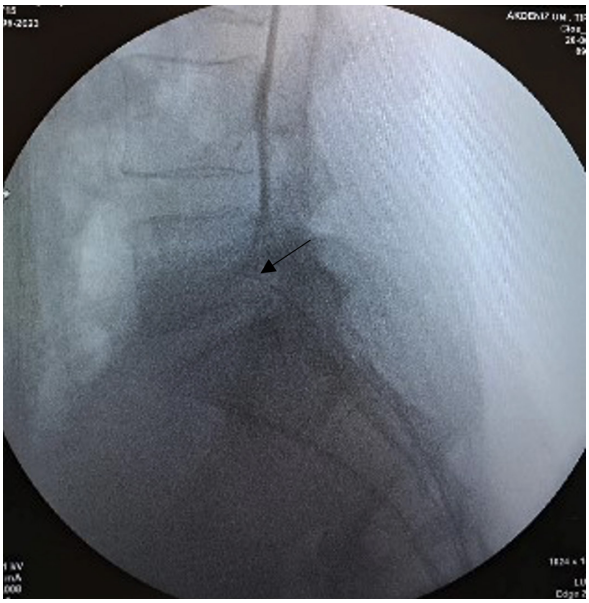

Figure 5. Lateral view of the catheter (*arrow*) and contrast spreading in the anterior epidural space.

Demographics

A total of 117 caudal PEN procedures were performed in patients with lumbar SS and FBSS. The average age of the patients was 57.96 ± 12.28 years, with a gender distribution of 41% (n=48) being male. The duration of symptoms was at least 6 months. Among the 117 patients, 66 (56.4%) had SS, while 51 (43.6%) were diagnosed with FBSS. Out of the 51 patients with FBSS, 28 (54.9%) had instrumentation performed. Additionally, 37 (31.6%) patients had a history of one lumbar surgery, 10 (8.5%) had undergone two surgeries, 3 (2.6%) had three surgeries, and 1 (0.9%) had four previous lumbar surgeries. Patients in the study were stratified into two groups based on their history of previous lumbar surgeries: those with one surgery (31.6%; n=37) and those with two or more previous lumbar surgeries (12%; n=14). The demographic details of the patients are summarized in Table I.

Outcome Assessment

All patients completed a 6-month follow-up, which included a medical interview with a physician. The Oswestry disability index (ODI) and VAS scores were utilized to assess the clinical effectiveness of PEN in terms of pain reduction and functional improvement at baseline and at 1, 3, and 6 months after PEN.

Statistical Analysis

Data were analyzed using IBM SPSS version 23.0 (IBM Corp., Armonk, NY, USA). Continuous variables are presented as mean ± standard deviation, while categorical variables are expressed as numbers and percentages. The Kolmogorov-Smirnov test was employed to assess the normal distribution of the data. Parametric tests, including the independent *t*-test, were utilized for comparisons between independent groups when the assumptions for parametric tests were met. In cases where parametric test assumptions were not satisfied, the Mann-Whitney U test was used for independent group comparisons. In comparisons involving dependent groups, the Friedman Test (with post hoc Bonferroni-corrected Wilcoxon paired sample test) was employed. Differences between categorical variables were assessed using the Chi-square analysis. p-value <0.05 is considered significant.

Results

The mean VAS score at baseline was 6.15 ± 1.25. After one month of PEN, it decreased to 2.97 ± 1.5, followed by 3.18 ± 1.65 at three months, and 3.83 ± 1.64 at six months. The mean ODI score at the beginning was 49.91 ± 13.87. After one month of PEN, it improved to 30.19 ± 12.01, followed by 31.61 ± 12.46 at three months and 34.58 ± 12.52 at six months. Statistical analysis revealed significant differences in VAS and ODI values between the baseline and the 1st, 3rd, and 6th months (p: 0.0001). VAS and ODI values at 1st, 3rd, and 6th months were significantly lower compared to the baseline values. The VAS and ODI values at 6 months were significantly higher than those at 1st and 3rd months. These results are summarized in Table II.

For patients who had undergone one lumbar surgery, the mean VAS score at baseline was 6.27 ± 1.01. After one month of PEN, it decreased to 2.86 ± 1.47, followed by 3.19 ± 1.64 at three months, and 3.7 ± 1.59 at six months. In contrast, for patients who had undergone more than one surgical operation, the mean VAS score at baseline was 8.07 ± 0.91. After one month of PEN, it decreased to 4.43 ± 1.01, followed by 4.79 ± 1.42 at three months, and 5.50 ± 1.22 at six months. There was a significant difference in baseline VAS scores between the two groups. The group with more than one previous surgical operation had significantly higher baseline VAS scores compared to the group that had undergone one lumbar surgery and the group with lumbar SS. The VAS scores at 1st, 3rd, and 6th months for the group with more than one previous surgical op-

Table I. The demographic data of the patients.

	Age mean ± SD	Male	Female
Total (n = 117)	57.96 ± 12.28	48	69
SS (n = 66)	60.53 ± 11.21	21 (43.75%)	45 (65.22%)
FBSS (n = 51)	54.63 ± 12.89	27 (56.25%)	24 (34.78%)

Failed back surgery syndrome (FBSS), spinal stenosis (SS).

Table II. VAS (visual analogue scale) and ODI (Oswestry disability index) scores before and after procedures (p: 0.0001).

	VAS mean ± SD		ODI mean ± SD
Baseline	6.15 ± 1.25	Baseline	49.91 ± 13.87
1 month after	2.97 ± 1.5	1 month after	30.19 ± 12.01
3 months after	3.18 ± 1.65	3 months after	31.61 ± 12.46
6 months after	3.83 ± 1.64	6 months after	4.58 ± 12.52

eration were markedly higher than the mean VAS scores of the group with one lumbar surgery and the group with lumbar SS. The VAS scores at 1st, 3rd, and 6th months for the group with one lumbar surgery were significantly lower than the baseline VAS score. Similarly, the VAS scores at 1st, 3rd, and 6th months for the group with more than one previous surgical operation were significantly lower than the baseline VAS score. These results are summarized in Table III.

For patients who had undergone one lumbar surgery, the mean ODI scores at baseline were 51.03 ± 11.17. After one month of PEN, they improved to 29.89 ± 10.20, followed by 31.3 ± 10.67 at three months, and 33.95 ± 10.39 at six months. In contrast, for patients who had undergone more than one surgical operation, the mean ODI scores at baseline were 72.29 ± 12.93. After one month of PEN, they improved to 44 ± 11.94, followed by 44.86 ± 13.14 at three months, and 49.43 ± 13.41 at six months. There was a significant difference in ODI scores between the two groups. The group with more than one previous surgical operation had significantly higher ODI scores at 1st, 3rd, and 6th months compared to the group that had undergone one lumbar surgery. The ODI scores at 1st, 3rd, and 6th months for the group with one lumbar surgery were significantly lower than the baseline ODI score. Similarly, the ODI scores at 1st, 3rd, and 6th months for the group with more than one previous surgical operation were significantly lower than the baseline ODI score. These results are summarized in Table III.

For patients diagnosed with lumbar SS, the mean VAS scores at baseline were 5.68 ± 1.02. After one month of PEN, they improved to 2.71 ± 1.45, followed by 2.83 ± 1.52 at three months, and 3.55 ± 1.55 at six months. In contrast, for patients diagnosed with FBSS, the VAS scores at baseline were 6.76 ± 1.27. After one month of PEN, they improved to 3.29 ± 1.52, followed by 3.63 ± 1.73 at three months, and 4.20 ± 1.69 at six months. Although there was a significant difference in baseline VAS scores between the two groups, no significant differences were observed in VAS scores at other time points. In both groups, the VAS scores at 1st, 3rd, and 6th months were significantly lower compared to the baseline VAS scores. These results are summarized in Table IV.

For patients diagnosed with lumbar SS, the mean ODI scores at baseline were 44.55 ± 10.15. After one month of PEN, they improved to 27.42 ± 11.05, followed by 28.97 ± 11.6 at three months, and 31.79 ± 11.33 at six months. In contrast, for patients diagnosed with FBSS, the ODI scores at baseline were 56.86 ± 15. After one month of PEN, they improved to 33.76 ± 12.35, followed by 35.02 ± 12.82 at three months, and 38.20 ± 13.16 at six months. There were significant differences in ODI scores at baseline, 1st, 3rd, and 6th months between the

Table III. VAS (visual analogue scale) and ODI (Oswestry disability index) scores in patients who have one and multiple time operations before and after procedures.

	VAS operation = 1 mean ± SD n = 37	VAS operation > 1 mean ± SD n = 14	VAS p-value	ODI operation = 1 mean ± SD n = 37	ODI operation > 1 mean ± SD n = 14	ODI p-value
Baseline	6.27 ± 1.02	8.07 ± 0.91	.000	51.03 ± 11.17	72.29 ± 12.93	.000
1 month after	2.86 ± 1.47	4.43 ± 1.01	0.003	29.89 ± 10.20	44 ± 11.94	0.0001
3 months after	3.19 ± 1.64	4.79 ± 1.42	0.006	31.3 ± 10.67	44.86 ± 13.14	0.001
6 months after	3.7 ± 1.59	5.50 ± 1.22	0.001	33.95 ± 10.39	49.43 ± 13.41	0.0001

Table IV. VAS (visual analogue scale) and ODI (Oswestry disability index) scores before and after procedures.

	VAS SS mean ± SD n = 66	VAS FBSS mean ± SD n = 51	VAS *p*-value	ODI SS mean ± SD n = 66	ODI FBSS mean ± SD n = 51	ODI *p*-value
Baseline	5.68 ± 1.02	6.76 ± 1.27	.000	44.55 ± 10.15	56.86 ± 15	.000
1 month after	2.71 ± 1.45	3.29 ± 1.52	0.038	27.42 ± 11.05	33.76 ± 12.35	0.004
3 months after	2.83 ± 1.52	3.63 ± 1.73	0.01	28.97 ± 11.6	35.02 ± 12.82	0.009
6 months after	3.55 ± 1.55	4.20 ± 1.69	0.033	31.79 ± 11.33	38.20 ± 13.16	0.006

two groups. In both groups, the ODI scores at 1st, 3rd, and 6th months were significantly lower compared to the baseline ODI scores. Additionally, in both groups, the ODI scores at 6 months were significantly higher than those at 1st and 3rd months. These results are summarized in Table IV.

For patients who had undergone lumbar surgery with instrumentation, the mean VAS scores at baseline were 6.61 ± 1.08. After one month of PEN, they improved to 3.22 ± 1.57, followed by 3.52 ± 1.75 at three months, and 4.04 ± 1.66 at six months. For patients who had undergone lumbar surgery without instrumentation, the mean VAS scores at baseline were 6.29 ± 0.94. After one month of PEN, they improved to 2.89 ± 1.55, followed by 3.14 ± 1.86 at three months, and 3.71 ± 1.96 at six months. There were no significant differences in VAS scores between the two groups. In both groups, the VAS scores at 1st, 3rd, and 6th months were significantly lower compared to the baseline VAS scores. These results are summarized in Table V.

For patients who had undergone lumbar surgery with instrumentation, the mean ODI score at baseline was 55.71 ± 13.15. After one month of PEN, it improved to 34.07 ± 11.06, followed by 35.07 ± 12.15 at three months, and 38.36 ± 12.91 at six months. For patients who had undergone lumbar surgery without instrumentation, the mean ODI score at baseline was 58.26 ± 17.19. After one month of PEN, it improved to 33.39 ± 14, followed by 34.96 ± 13.86 at three months, and 38 ± 13.75 at six months. There were no significant differences in ODI scores between the two groups. In patients without instrumentation, the ODI scores at 1st, 3rd, and 6th months were significantly lower compared to the baseline ODI scores. These results are summarized in Table V.

Discussion

Many studies[18-25] have confirmed the effectiveness of PEN in managing refractory back and leg pain following FBSS and SS. In a randomized-controlled study, it was shown that the administration of a local anesthetic, steroid, and hypertonic sodium chloride during PEN was effective in relieving chronic pain that causes functional limitations[29].

The drugs used in PEN have various mechanisms of action. When hypertonic saline was first introduced, it was applied intrathecally as a

Table V. VAS (visual analogue scale) and ODI (Oswestry disability index) scores in patients who have enstrumentation and have not enstrumentation before and after procedures.

	VAS enstrumentation + mean ± SD n = 23	VAS enstrumentation - mean ± SD n = 28	VAS *p*-value	ODI enstrumentation + mean ± SD n = 23	ODI enstrumentation - mean ± SD n = 28	ODI *p*-value
Baseline	6.64 ± 1.19	6.91 ± 1.37	0.457	55.71 ± 13.15	58.26 ± 17.19	0.552
1 month after	3.14 ± 1.50	3.48 ± 1.56	0.441	34.07 ± 11.06	33.39 ± 14	0.847
3 months after	3.50 ± 1.81	3.78 ± 1.65	0.567	35.07 ± 12.15	34.96 ± 13.86	0.975
6 months after	4.11 ± 1.79	4.30 ± 1.60	0.457	38.36 ± 12.91	38 ± 13.75	0.924

neurolytic agent[30]. When administered epidurally during PEN, it reduces edema around inflamed nerve roots[31,32]. It provides blockade with a local anesthetic effect on both myelinated and unmyelinated fibers[33,34]. Hypertonic saline at concentrations of 4% and higher is cytotoxic to fibroblasts[35]. The use of normal saline during PEN has also been found to be effective. However, patients who received 10% saline required less additional interventional treatment[36,37].

As widely known, steroids have anti-inflammatory properties and reduce fibroblast formation[38]. Triamcinolone has been confirmed to retard fibroblast proliferation[35]. Local anesthetics also have various effects, and in clinical and experimental settings, they have shown long-term improvement or an equal response to steroids[39]. Among the mechanisms of action of local anesthetics are the suppression of nociceptive discharge, sympathetic blockade, anti-inflammatory effects, and blockade of axonal transport of nerves[25].

Hyaluronidase is another drug used during PEN. Hyaluronidase breaks down hyaluronic acid in connective tissue, thereby increasing the distribution and absorption of subsequently injected drugs. Hyaluronidase reduces inflammation by reducing neutrophil infiltration, thus achieving more successful results in epidural steroid injections[40-42]. Hyaluronidase has also been shown to prevent the formation of scar tissue. Using hyaluronidase in conjunction with steroids appears to be more effective than using steroids alone[43]. In our clinic, all patients who underwent PEN received a local anesthetic, steroid, hyaluronidase, and hypertonic sodium chloride.

Several studies[18-22] have demonstrated the effectiveness of PEN in patients with SS. In a study by Manchikanti et al[19], which compared caudal epidural injection to PEN in patients with chronic low back pain due to SS, at the end of the first year, significant pain relief was found in only 4% of the caudal epidural steroid group, while this rate was 76% in the PEN group.

Manchikanti et al[21] followed up on the above study, expanding the group of patients with SS who received PEN, including 70 patients in a larger patient group. After 1 year of follow-up, PEN demonstrated significant pain relief effectiveness.

In our clinic, we applied PEN to 66 patients with SS. We observed significant reductions in VAS and ODI scores at 1, 3, and 6 months (Table III).

Recent high-quality randomized controlled studies and observational studies have been analyzed in a review and meta-analysis[22] demonstrating the effectiveness of PEN in patients with SS, providing moderate (level II) evidence for the short- and long-term effectiveness of the procedure.

In this review, patients followed up for more than 6 months were taken into consideration to determine the long-term efficacy of PEN[22]. Since our study followed patients for 6 months, we can conclude that our study found PEN to be successful in terms of short-term efficacy.

In patients with SS, surgical decompression is often recommended and has been reported to yield good outcomes[8-10]. However, there is insufficient evidence supporting the effectiveness of surgical decompression or surgical fusion. Data from randomized trials[11] do not support the routine use of instrumented fusion for degenerative lumbar spondylosis in clinical practice.

In one study[44], the reoperation rate for patients with SS who had been operated on for more than 10 years was reported as 17%, while in another study[45], this rate was reported as 14% at the 5-year follow-up, with an estimated increase to 20% at the 10-year mark. Therefore, a careful evaluation is necessary before making a surgical decision for patients with SS. It is crucial to understand the nature of SS in the treatment decision. In the literature, no significant worsening was observed at the one-year follow-up in patients who underwent symptomatic and non-operative treatment. Sudden deterioration in symptoms and neurological function is presumed to be unlikely, and prophylactic treatment is not associated with definitive benefits[2]. Conservative treatments are recommended to be tried before deciding on surgery[7]. Ultimately, when satisfactory results are not achieved after conservative treatments, surgical intervention can be considered. Helm and Knezevic[18] also recommend applying PEN before surgery for patients with back pain and/or leg pain refractory to conservative treatment.

Failed Back Surgery Syndrome (FBSS) is defined as persistent and/or recurrent pain following lumbar spinal surgery. It is observed in 10-40% of patients who have undergone spinal surgery[46-48]. Even if the surgical procedure is anatomically and technically successful, FBSS can occur for various reasons[44]. These reasons include foraminal stenosis, recurrent disc herni-

ation, iatrogenic instability, problems related to facet joints, sacroiliac joint dysfunction, and epidural scar tissue formation that compresses nerve roots after surgery[47-51].

In the case of pain following FBSS, it is believed that epidural fibrosis plays a role. Peridural fibrosis is considered a normal biological process following spinal surgery. However, it is believed that the fibrous tissue formed after surgery compresses the dura, compresses the nerve root, inhibits the mobility of the nerve root, and causes low back pain and radiating pain to the lower extremity[52]. Besides the mechanical compression of fibrous tissue on the nerve root, it is also thought to play a role in pain pathophysiology by causing disturbances in nerve blood flow, irritation of the dorsal root ganglion, and other neurophysiological changes[25].

The relationship between epidural scar tissue and pain has been described by multiple studies[17,51,53]. Kuslich et al[51] were among the first to describe this relationship. They used local anesthetics during a laminectomy to identify pain-sensitive structures in the spinal canal, mostly in nerve roots compressed by scar tissue. Ross et al[17] in a randomized controlled study, found that recurrent radicular pain was 3.2 times more likely to occur in patients with more peridural scar in the epidural region following lumbar surgery. Additionally, Jou et al[52] provided electrophysiological evidence in rats showing neurophysiological changes caused by peridural fibrosis following post-laminotomy.

Patients with pain related to FBSS have reported more severe pain and poorer quality of life compared to patients with common conditions like rheumatoid arthritis, osteoarthritis, and fibromyalgia[45,46]. FBSS patients often become resistant to medical treatments and require more effective interventions[47,54].

In our study, the group of patients with FBSS had higher initial pain scores and ODI scores compared to the SS group. These scores were even higher in those who had undergone multiple lumbar surgeries. Many studies[18,23-25] have demonstrated the efficiency of PEN in managing refractory back and leg pain following FBSS. When looking at the results of a 2-year follow-up study comparing caudal epidural steroid injection and PEN in FBSS patients, the PEN group showed superior pain relief and functional improvement[25]. Epidural fibrous tissue prevents the drugs from reaching the pathological epidural space and compressed nerve roots. The drugs administered to the epidural space always follow the path of least resistance, which means they do not spread to the epidural area with fibrous tissue. The main advantage of PEN is the ability to mechanically open adhesive fibrotic areas in the epidural space with a catheter, chemically with hyaluronidase, and using opacifying agents hydrostatically. In the study mentioned above, the possible reason for the failure of caudal epidural steroid injection compared to PEN was considered to be the inability of the drugs to reach the target area due to epidural fibrosis[25].

In our study, 44% of patients who underwent PEN had FBSS. We observed a significant reduction in VAS and ODI scores in patients with FBSS. Among these patients, 55% had instrumentation, while 45% did not. When patients with and without instrumentation were compared, no significant difference was observed in VAS and ODI scores. In both groups, significant reductions were observed in VAS and ODI scores at months 1, 3, and 6 (Table V). When we compared patients who had undergone lumbar surgery once with those who had undergone multiple surgeries in the FBSS group, the VAS and ODI scores of the group with multiple surgeries were higher. The reduction in VAS and ODI scores after the procedure was less (Figures 6 and 7, Table III).

The decision for repeat spinal surgery should be well-considered. In one study, in the 5-year follow-up of reoperated patients, reoperation was successful in only 34% of cases[46]. In another study[55], it was shown that the success rate of the first spinal surgery was over 50%, but after the second surgery, this rate dropped to 30%, after the third surgery to 15%, and after the fourth surgery to 5%. Additionally, many patients become resistant to conventional treatments after repeated surgeries[46,56,57].

In this study, a high initial pain score before the procedure was associated with negative outcomes after the procedure. We also obtained worse outcomes in patients who had undergone multiple surgeries compared to those who did not undergo reoperation. We did not observe any serious complications during the procedures and follow-up periods.

Conclusions

In conclusion, PEN is an effective and safe treatment method for patients with both SS and

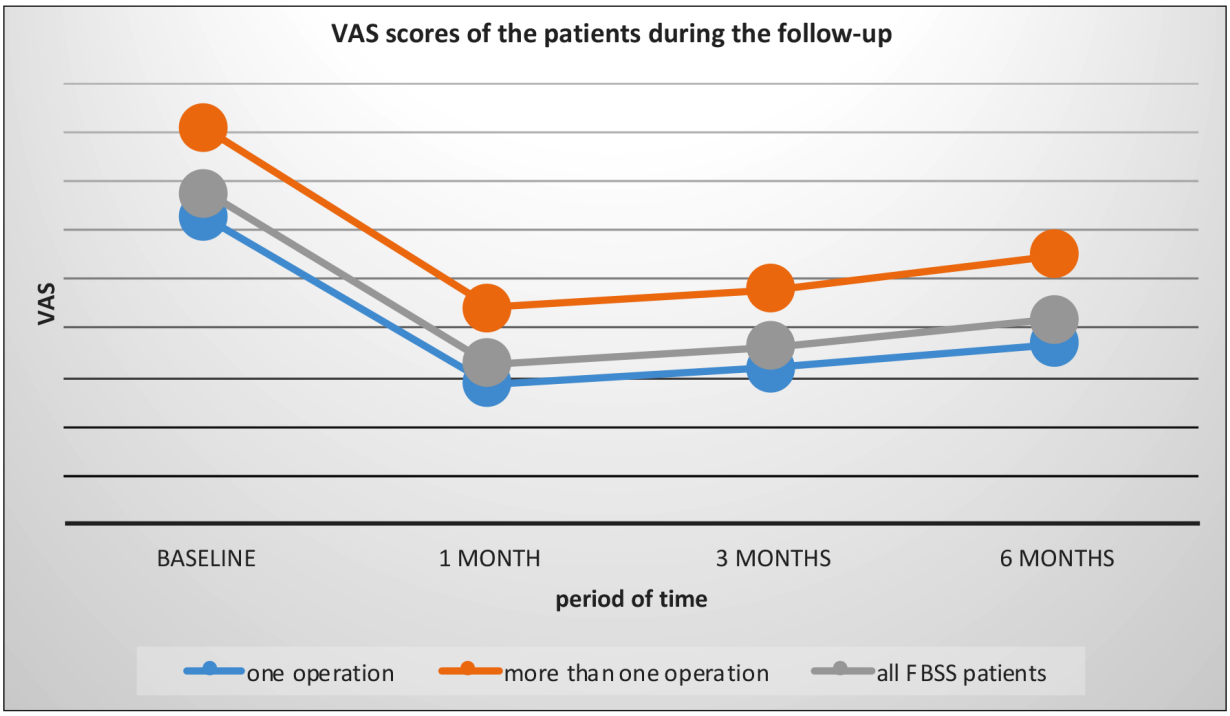

Figure 6. Pain relief in patients who have one or more than one operation.

FBSS. Repeated surgeries negatively affect the effectiveness of PEN. We recommend applying PEN before surgical treatment, provided there is no progressive neurological deficit, contraindication, or red flags suggesting fracture, malignancy, infection, or other systemic diseases.

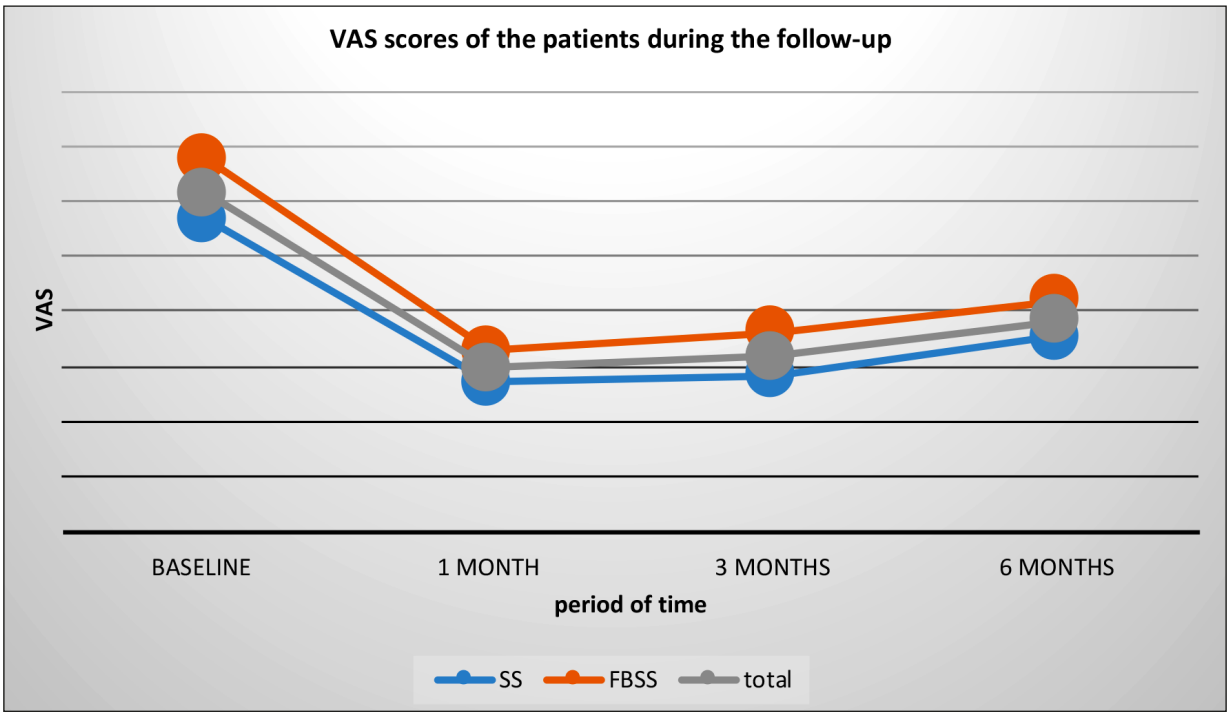

Figure 7. Pain relief in patients who have SS and FBSS.

Conflict of Interest
The authors declare that they have no conflict of interests.

Informed Consent
Informed consent was obtained from all individual participants included in the study.

Ethics Approval
The study was approved by the Research Ethics Committee (REC) at Akdeniz University with number KAEK-601.

Data Availability
The data that support the findings of this study are available from the corresponding author, [GD], upon reasonable request.

Authors' Contribution
All the authors equally contributed, read, and approved the final manuscript. Both authors confirm responsibility for the following: study conception and design, data collection, analysis and interpretation of results, and manuscript preparation.

Funding
The research was not financially supported.

ORCID ID
GD: 0000-0002-1777-3507
IO: 0000-0002-7751-3758

References

1) Mu X, Wei X, Chen S, Ou Y, Wei M, Wei J. Intradiscal steroid injection for the treatment of chronic non-specific low back pain. Eur Rev Med Pharmacol Sci 2023; 27: 3372-3382.
2) Schofferman J, Reynolds J, Herzog R, Covington E, Dreyfuss P, O'Neill C. Failed back surgery: etiology and diagnostic evaluation. Spine J 2003; 3: 400-403.
3) Katz JN, Harris MB. Clinical practice. Lumbar spinal stenosis. N Engl J Med 2008; 35: 818-825.
4) Golob AL, Wipf JE. Low Back Pain. Med Clin North Am 2014; 98: 405-428.
5) Katz JN, Zimmerman ZE, Mass H, Makhni MC. Diagnosis and Management of Lumbar Spinal Stenosis: A Review. JAMA 2022; 327: 1688-1699.
6) Deyo RA, Ciol MA, Cherkin DC, Loeser JD, Bigos SJ. Lumbar spinal fusion: a cohort study of complications, reoperations, and resource use in the medicare population. Spine (Phila Pa 1976) 1993; 18: 1463-1470.
7) Weinstein JN, Tosteson TD, Lurie JD, Tosteson AN, Blood E, Hanscom B, Herkowitz H, Cammisa F, Albert T, Boden SD, Hilibrand A, Goldberg H, Berven S, An H. Surgical versus nonsurgical therapy for lumbar spinal stenosis. N Engl J Med 2008; 358: 794-810.
8) Amundsen T, Weber H, Nordal HJ, Magnaes B, Abdelnoor M, Lilleâs F. Lumbar spinal stenosis: conservative or surgical management?: A prospective 10-year study. Spine (Phila Pa 1976) 2000; 25: 1424-1436.
9) Johnsson KE, Uden A, Rosen I. The effect of decompression on the natural course of spinal stenosis: A comparison of surgically treated and untreated patients. Spine 1991; 16: 615-619.
10) Atlas SJ, Keller RB, Robson D, Deyo RA, Singer DE. Surgical and nonsurgical management of lumbar spinal stenosis: four-year outcomes from the maine lumbar spine study. Spine (Phila Pa 1976) 2000; 25: 556-562.
11) Gibson JN, Waddell G. Surgery for degenerative lumbar spondylosis. Cochrane Database Syst Rev 2005; 4: CD001352.
12) Baber Z, Erdek MA. Failed back surgery syndrome: current perspectives. J Pain Res 2016; 9: 979-987.
13) Chan CW, Peng P. Failed back surgery syndrome. Pain Med 2011; 12: 577-606.
14) Brzezicki G, Jankowski R, Blok T, Klimczak A, Szymas J, Huber J, Szukala A, Siemionow M, Nowake S. Postlaminectomy osteopontin expression and associated neurophysiological findings in rat peridural scar model. Spine (Phila Pa 1976) 2011; 36: 378-385.
15) Ronnberg K, Lind B, Zoega B, Halldin K, Gellerstedt M, Brisbyet H. Peridural scar and its relation to clinical outcome: a randomised study on surgically treated lumbar disc herniation patients. Eur Spine J 2008; 17: 1714-1720.
16) Almeida DB, Prandini MN, Awamura Y, Vitola ML, Simião MP, Milano JP, Bordignon KC, Ache MP, Raminaet R. Outcome following lumbar disc surgery: the role of fibrosis. Acta Neurochir (Wien) 2008; 150: 1167-1176.
17) Ross JS, Robertson JT, Frederickson RC, Petrie JL, Obuchowski N, Modic MT, Triboletet ND. ADCON-L European Study Group. Association between peridural scar and recurrent radicular pain after lumbar discectomy: magnetic resonance evaluation. Neurosurgery 1996; 38: 855-861.
18) Helm S, Knezevic NN. A review of the role of epidural percutaneous neuroplasty. PainManag 2019; 9: 53-62.
19) Manchikanti L, Cash KA, McManus CD, Pampati V, Singh V, Benyamin R. The preliminary results of a comparative effectiveness evaluation of adhesiolysis and caudal epidural injections in managing chronic low back pain secondary to spinal stenosis: a randomized, equivalence controlled trial. Pain Physician 2009; 12: 341-354.

20) Manchikanti L, Pampati V, Fellows B, Beyer CD, Damron KS, Cash KA. Effectiveness of percutaneous adhesiolysis with hypertonic saline neurolysis in refractory spinal stenosis. Pain Physician 2001; 4: 366-373.

21) Manchikanti L, Cash KA, McManus CD, Pampati V. Assessment of effectiveness of percutaneous adhesiolysis in managing chronic low back pain secondary tolumbar central spinal canal stenosis. Int J Med Sci 2013; 10: 50-59.

22) Manchikanti L, Knezevic NN, Sanapati MR, Boswell MV, Kaye AD, Hirsch JA. Effectiveness of Percutaneous Adhesiolysis in Managing Chronic Central Lumbar Spinal Stenosis: A Systematic Review and Meta-Analysis. Pain Physician 2019; 22: 523-550.

23) Yousef AA, As EL-D, Al-Deeb AE. The role of adding hyaluronidase to fluoroscopically guided caudal steroid and hypertonic saline injection in patients with failed back surgery syndrome: a prospective, double-blinded, randomized study. Pain Pract 2010; 10: 548-553.

24) Helm S, Racz GB, Gerdesmeyer L, Justiz R, Hayek SM, Kaplan ED, El Terany MA, Knezevic NN. Percutaneous and endoscopic adhesiolysis in managing low back and lower extremity pain: a systematic review and meta-analysis. Pain Physician 2016; 19: 245-281.

25) Manchikanti L, Singh V, Cash KA, Pampati V. Assessment of effectiveness of percutaneous adhesiolysis and caudal epidural injections in managing post lumbar surgery syndrome: 2-year follow-up of a randomized, controlled trial. J Pain Res 2012; 5: 597-608.

26) Racz GB, Heavner JE, Smith JP, Noe CE, Al-Kaisy A, Matsumoto T, Lee SC, Nagy L. Pain and Treatment. InTech, 2014.

27) Racz GB, Heavner JE, Trescot A. Percutaneous lysis of epidural adhesions evidence for safety and efficacy. Pain Pract 2008; 8: 277-286.

28) Viesca C, Racz G, Day M. Spinal techniques in pain management: Lysis of adhesions. Anesthesiol Clin North America 2003; 21: 745-766.

29) Manchikanti L, Pampati V, Fellows B, Beyer CD, Damron KS, Cash KA. Effectiveness of percutaneous adhesiolysis with hypertonic saline neurolysis in refractory spinal stenosis. Pain Physician 2001; 4: 366-373.

30) Racz G, Heavner JE, Singleton W, Carline M. Hypertonic saline and corticosteroid injected epidurally for pain control. In: Techniques of Neurolysis: Current Management of Pain. Racz GB (Ed.). Springer Boston, MA, USA, 73-86 (1989).

31) Jewett DL, King JS. Conduction block of monkey dorsal rootlets by water and hypertonic saline solutions. Exp Neurol 1971; 33: 225-237.

32) Rojiani AM, Cho ES, Sharer L, Prineas JW. Electrolyte-induced demyelination in rats. 2. ultrastructural evolution. Acta Neuropathol 1994; 88: 293-299.

33) King JS, Jewett DL, Sundberg HR. Differential blockade of cat dorsal root C fibers by various chloride solutions. J Neurosurg 1972; 36: 569-583.

34) Kukita F, Yamagishi S. Excitation of squid giant axons in hypotonic and hypertonic solutions. Jpn J Physiol 1979; 29: 669-681.

35) Birkenmaier C, Redeker J, Sievers B, Melcher C, Jansson V, Mayer-Wagner S. An evaluation of medications commonly used for epidural neurolysis procedures in a human fibroblast cell culture model. Reg Anesth Pain Med 2011; 36: 140-144.

36) Heavner JE, Racz GB, Raj P. Percutaneous epidural neuroplasty: prospective evaluation of 0.9% NaCl versus 10% NaCl with or without hyaluronidase. Reg Anesth Pain Med 1999; 24: 202-207.

37) Manchikanti L, Rivera JJ, Pampati V, Damron KS, McManus CD, Brandon DE, Wilson SR. One day lumbar epidural adhesiolysis and hypertonic saline neurolysis in treatment of chronic low back pain: a randomized, double-blind trial. Pain Physician 2004; 7: 177-186.

38) Baqai A, Bal R. The mechanism of action and side effects of epidural steroids. Tech Reg Anesth Pain Manag 2009; 13: 205-211.

39) Manchikanti L, Singh V, Cash KA, Pampati V, Falco FJ. A randomized, double-blind, active-control trial of the effectiveness of lumbar interlaminar epidural injections in disc herniation. Pain Physician 2014; 17: 61-74.

40) Fronza M, Muhr C, Calheiros Da Silveira DS, Sorgi CA, Rodrigues SFP, Farsky SHP, Paula-Silva FWG, Merfort I, Faccioli LH. Hyaluronidase decreases neutrophils infiltration to the inflammatory site. Inflamm. Res 2016; 65: 533-542.

41) Kim SB, Lee KW, Lee JH, Kim MA, Kim BH. The additional effect of hyaluronidase in lumbar interlaminar epidural injection. Ann Rrehabil Med 2011; 35: 405-411.

42) Yousef AA, As EL-D, Al-Deeb AE. The role of adding hyaluronidase to fluoroscopically guided caudal steroid and hypertonic saline injection in patients with failed back surgery syndrome: a prospective, double-blinded, randomized study. Pain Pract 2010; 10: 548-553.

43) Kim SB, Lee KW, Lee JH, Kim MA, An BW. The effect of hyaluronidase in interlaminar lumbar epidural injection for failed back surgery syndrome. Ann Rehabil Med 2012; 36: 466-473.

44) Martin BI, Mirza SK, Comstock BA, Gray DT, Kreuter W, Deyo RA. Reoperation rates following lumbar spine surgery and the influence of spinal fusion procedures. Spine 2007; 32: 382-387.

45) Kim CH, Chung CK, Park CS, Choi B, Hahn S, Kim MJ, Lee KS, Park BJ. Reoperation rate after surgery for lumbar spinal stenosis without spondylolisthesis: a nationwide cohort study. Spine J 2013; 13: 1230-1237.

46) North RB, Campbell J, James CS, Conover-Walker MK, Wang H, Piantadosi S, Rybock JD, Longet

DM. Failed back surgery syndrome: 5-year follow-up in 102 patients undergoing repeated operation. Neurosurgery 1991; 28: 685-691.

47) Thomson S, Jacques L. Demographic characteristics of patients with severe neuropathic pain secondary to failed back surgery syndrome. Pain Practice 2009; 9: 206-215.

48) Chan CW, Peng P. Failed back surgery syndrome. Pain Med 2011; 12: 577-606.

49) Leveque JC, Villavicencio AT, Rubin L, Bulsara K, Gorecki JP. Spinal cord stimulation for failed back surgery syndrome. Neuromodulation 2001; 4: 1-9.

50) Çakıt BD, Genç H, Balaban Ö, Nacır B, Erdem HR. Sakroiliac joint dysfunction in patients with failed back surgery syndrome. J PMR Sci 2010; 13: 25-30.

51) Kuslich SD, Ulstrom CL, Michael CJ. The tissue origin of low back pain and sciatica: a report of pain response to tissue stimulation during operations on the lumbar spine using local anesthesia. Orthop Clin North Am 1991; 22: 181-187.

52) Jou IM, Tai TW, Tsai CL, Tsai TM, Yung WS, Jung YC. Spinal somatosensory evoked potential to evaluate neurophysiologic changes associated with postlaminotomy fibrosis: an experimental study. Spine (Phila Pa 1976) 2007; 32: 2111-2118.

53) Lee JY, Stenzel W, Ebel H, et al. Mitomycin C in preventing spinal epidural fibrosis in a laminectomy model in rats. J Neurosurg 2004; 100: 52-55.

54) Harden RN, Weinland SR, Remble TA, Houle TT, Colio S, Steedman S, Kee WG. Medication quantification classes and revised detriment weights by survey of American pain society physicians. J Pain 2005; 6: 364-371.

55) Nachemson AL. Evaluation of results in lumbar spine surgery. Acta Orthop Scand Suppl 1993; 251: 130-133.

56) North RB, Kidd DH, Farrohki F, Piantoadosi SA. Spinal cord stimulation versus repeated lumbosacral spine surgery for chronic pain: a randomized, controlled trial. Neurosurgery 2005; 56: 98-107.

57) Hsu E, Atanelov L, Plunkett AR, Chai N, Chen Y, Cohen SP. Epidural lysis of adhesions for failed back surgery and spinal stenosis: factors associated with treatment outcome. Anesth Analg 2014; 118: 215-224.