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## REVIEW ARTICLE

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# Interventional Pain Management for Failed Back Surgery Syndrome

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■ **Abstract:** Patients who suffer from the condition known as failed back surgery syndrome (FBSS) present to the offices of physicians, surgeons, and pain specialists alike in overwhelming numbers. This condition has been defined as persistent back and/or leg pain despite having completed spinal surgery. As lumbar surgery continues to grow in prevalence, so will the number of patients suffering from FBSS. It is important for physicians treating this population to expand their knowledge of FBSS etiologies and appropriate diagnostic imaging modalities, combined with confirmatory diagnostic injections, and proper technique for interventional pain procedures. In doing so, the physician may adequately be prepared to manage these complex cases in the future, ideally with the support of stronger evidence. Management begins with a systematic evaluation of common FBSS etiologies such as new-onset stenosis, recurrent herniated nucleus pulposus (HNP), epidural fibrosis, pseudarthrosis, and others. History and physical may be supplemented by imaging including X-ray, magnetic resonance imaging, or computed tomography myelography. Certain diagnoses may be confirmed with diagnostic procedures such as intra-articular injections, medial branch blocks, or transforaminal nerve root

blocks. Once an etiology is determined, a multidisciplinary approach to treatment is most effective. This includes exercise or physical therapy, psychological counseling, medication, and interventional procedures. The most invasive treatment option, short of revision surgery, is spinal cord stimulation. This intervention has a number of studies demonstrating its efficacy and cost-effectiveness in this population. Finally, revision surgery may be used when indicated such as with progressive neurological impairment or with issues regarding previous surgical instrumentation. ■

**Key Words:** back pain, back pain with radiation, back pain without radiation, epidural analgesia, low back pain, neurosurgical procedures, pain, pain disorder, review

### INTRODUCTION

Patients who suffer from failed back surgery syndrome (FBSS) present to physicians' offices in overwhelming numbers. FBSS, inaccurately referred to as post-laminectomy syndrome by some practitioners, is diagnosed in patients who have persistent back pain despite having undergone spinal surgery of any type, including discectomy, laminectomy, or fusion.<sup>1</sup> A more comprehensive description has been presented by the International Association for the Study of Pain. Patients experience persistent low back pain at a given location despite operative interventions; alternatively, the pain could have a post-surgery onset. The back pain may also be associated with a referred or radiating pain.<sup>2</sup> Simply put, the surgery did not accomplish its intended purpose,

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whether it was to treat chronic axial back pain or radicular leg pain. The term *failed back surgery* would imply that it includes any level of the spine, but the available literature focuses primarily on the lumbosacral spine.

The number of lumbar spinal surgeries has increased over the past several decades (Table 1). An estimated 32,701 spinal fusions were performed in 1990. In 2001, there were a reported 356,638 hospitalizations for lumbar surgery.<sup>3</sup> Of those, 122,316 spinal fusions were for degenerative disease. That number is consistent with a 274% increase between 1990 and 2001. The prevalence of new laminectomies was estimated to be 250,000 each year as of 2002,<sup>1</sup> and 1,288,496 new posterior lumbar fusion operations were reported in the United States alone between 1998 and 2008.<sup>4</sup>

The rate of failure of such surgeries is notable. One study that investigated outcomes of discectomy for lumbar disc herniation at a follow-up of 10 to 22 years after surgery noted 74.6% of the patients had residual lower back pain and 12% of patients needed repeat surgery.<sup>5</sup> Another study by Javid et al.<sup>6</sup> evaluated the success of lumbar laminectomy surgery for 170 patients with spinal stenosis (central or lateral) with or without herniated nucleus pulposus (HNP). At 1-year follow-up, the surgery was considered unsuccessful for 30.4% of patients who had central stenosis, 22.8% of patients who had stenosis with HNP, and 34.8% of patients who had lateral stenosis. Given the accelerated rate of lumbar surgeries and the high failure rate, pain specialists will require a thorough understanding of FBSS as well as knowledge about conservative, non-surgical measures for managing these complicated cases.

**Table 1. FBSS Statistics**

Slipman et al. <sup>1</sup>	250,000 estimated new laminectomies each year as of 2002
Pumberger et al. <sup>4</sup>	1,288,496 new posterior lumbar fusion operations in the United States between 1998 and 2008
Deyo et al. <sup>3</sup>	122,316 spinal fusions recorded in 2001, up from 32,701 in 1990; a 220% increase
Yorimitsu et al. <sup>5</sup>	74.6% residual LBP after back surgery and 12% reoperation rate after discectomy for LDH
Javid et al. <sup>6</sup>	At 1-year follow-up, lumbar laminectomy was considered unsuccessful for 30.4%, 22.8%, and 34.8% of patients with central stenosis, stenosis with HNP, and lateral stenosis respectively

FBSS, failed back surgery syndrome; LBP, low back pain; LDH, lumbar disc herniation; HNP, herniated nucleus pulposus.

## ETIOLOGY OF FBSS

The etiology of FBSS has been evaluated extensively. The major works identifying the etiology of FBSS are summarized in Table 2. The etiologies outlined in these projects can be divided into 3 broad categories: preoperative, intraoperative, and postoperative factors (Table 3). Identification of the etiology of FBSS will help guide patient care.

### Preoperative Factors

The preoperative factors are those that are modifiable by proper patient selection and communication. In regard to patient selection criteria, it has been shown that psychological risk factors<sup>10</sup> and matters of litigation, including workers' compensation, are predictors for poor surgical outcome.<sup>11</sup> Recognizing patients who match these profiles would help prevent unnecessary surgeries and lead physicians to continue with conservative treatment, thus saving the patient from traumatic insult and financial burden.

Physicians should communicate the goals of the surgical intervention and provide clear expectations to the patient. It is not uncommon for patients to expect a complete resolution of symptoms after invasive spinal surgery. Such expectations, however, are not realistic and impede satisfactory responses to surgery. It has been argued that a decrease in the Visual Analog Scale (VAS) of 1.8 units would be considered a satisfactory result, and a decrease in 3 units or more would be considered an extremely satisfactory result from surgery.<sup>12</sup>

### Intraoperative Factors

Intraoperative factors may include misdiagnosis or overlooking other spinal pathologies that are triggers of pain and radiculopathy. For instance, the surgeon may have diagnosed central stenosis secondary to disc herniation but neglect foraminal or lateral stenosis during the surgery. It is also possible for the surgeon to treat the wrong spinal level.<sup>13</sup> Inadequate decompression of stenosis, residual disc material, improper screw placement, or failed fusion that causes pseudarthrosis (non-union or abnormal motion at a fusion level)<sup>8</sup> may also contribute to the failure. One study provided a guide to the possible causes of post-surgical pain according to the time of onset. This study by Krishna et al.<sup>9</sup> found that if neuropathic pain is noted within

**Table 2. FBSS Etiologies**

Burton et al. <sup>7</sup>	Waguespack et al. <sup>8</sup>	Slipman et al. <sup>1</sup>	Krishna et al. <sup>9</sup>
Lateral spinal stenosis 58%	Foraminal stenosis 29%	Stenosis (all types) 21.5%	Misplaced screw
Adhesive arachnoiditis 16%	Painful discs 17%	IDD 21.5%	Loose spinous process
Recurrent HNP 12%	Pseudarthrosis 14%	Fibrosis 14.5%	Conjoint nerve root
Epidural fibrosis 8%	Neuropathic pain 9%	Recurrent HNP 12.4%	Bony fragments
Central stenosis 7%	Recurrent HNP 6%	DDD 9.1%	Nerve swelling
Others < 5% each	Others < 5%	Others < 6%	Graft subsidence

FBSS, failed back surgery syndrome; HNP, herniated nucleus pulposus; IDD, internal disc disruption; DDD, degenerative disc disease.

**Table 3. Summary of Factors Leading to Failed Back Surgery Syndrome**

Preoperative Factors	Intra-operative Factors	Postoperative Factors
Improper selection criteria	Misdiagnosis	Stenosis (residual/new)
Premorbid psychological risk factors	Wrong spinal level	Epidural fibrosis
Litigation, including workers' compensation cases	Inadequate decompression	Herniated disc (residual/new)
Improper communication of goals	Residual disc material	Worsening degenerative disc
Unrealistic expectations of patient	Improper screw placement	
	Fusion instability	

48 hours after posterior lumbar interfusion surgery, it may be attributable to a misplaced screw, loose spinous process, conjoint nerve root, or bony fragments. If the pain is noted after 48 hours, then it may be attributable to nerve swelling or graft subsidence.

Surgical technique also plays a role in FBSS. The primary indication for initial lumbar spinal surgery is disc herniation causing radicular symptoms that have failed to respond to conservative treatments.<sup>14</sup> In the last decade, surgeons moved away from open microdiscectomy (common in the 1970s)<sup>15</sup> and began to use more minimally invasive techniques, such as microendoscopic discectomy.<sup>14</sup> Nucleoplasty—a percutaneous discectomy procedure—may also be performed for less severe disc protrusion in which annular integrity is maintained.<sup>16</sup> Although it may seem that such techniques would result in less pain and fewer complications, evidence has yet to prove these assumptions. Ryang et al.<sup>15</sup> compared participants who received standard open microdiscectomy to those who received minimal-access microsurgical discectomy. The authors did not find any statistical difference between the techniques in regard to surgical time, blood loss, complications, or pain improvement. Despite their findings, it is generally recommended that the most minimally invasive

technique be used, when applicable, to minimize pain related to tissue damage.<sup>16</sup>

### Postoperative Factors

Some of the most common causes of FBSS are postoperative and occur either as a direct result of the surgery or indirectly from structural changes that are inevitable. Spinal stenosis (foraminal and central), painful disc (residual and adjacent), and epidural fibrosis are consistently mentioned among the top causes of FBSS.<sup>1,7-9</sup>

A common cause of nerve irritation is stenosis of the spinal (central) and root (foraminal) canals due to degenerative changes.<sup>7</sup> This pain may be eliminated by surgery, only to return on the contralateral side. Residual disc material, worsening degenerative disc disease, new-onset HNP, internal disc disruption (IDD) of adjacent discs, or nerve root irritation by surgical hardware may also be focal sources of pain after fusions or discectomies.

Recently, researchers have taken an interest in epidural fibrosis as a cause of FBSS. Most spinal surgeries can cause epidural scarring and adhesions, which can irritate the surrounding nerves. The presence of fibrosis may not always result in pain, although it has been suggested to be the cause of FBSS in 8% to 14% of patients, according to different studies.<sup>1,7</sup>

### DIAGNOSIS

Modalities of diagnosis for FBSS have progressed substantially over the last decade (See Table 4). In particular, advancements in magnetic resonance imaging (MRI), discography, and computed tomography (CT) scans have enabled the cause for FBSS to be identified in as many as 94% to 95% of patients.<sup>1,8</sup> Differing availability of these modalities in different time periods may have contributed to discrepancies in the literature regarding FBSS etiologies. Indeed, the absence of discography, which was not readily available

**Table 4. Diagnostic Modalities for FBSS**

Modality	Comments
X-ray	Good for evaluating bony structures, alignment, and stability
MRI	Modality of choice; effective in diagnosing most etiologies; image quality limited due to artifact if surgical hardware present. Contrast-enhanced imaging may be required for those who have had previous surgery for HNP
CT myelogram	Alternative to MRI if surgical hardware causes artifact
CT with multiplanar reconstructions	Optimal in patients who have had previous fusion and/or pedicle screws
Discography	Interventional procedure to evaluate discogenic pain
Diagnostic injections (epidurals and medial branch blocks)	Useful for confirming etiology, particularly if the physical examination and imaging modalities do not match

FBSS, failed back surgery syndrome; MRI, magnetic resonance imaging; CT, computed tomography; HNP, herniated nucleus pulposus.

in the 1980s, may explain why Burton and colleagues<sup>7</sup> failed to cite IDD as a cause of FBSS, as IDD requires discography for diagnosis. Slipman et al.,<sup>1</sup> on the other hand, identified IDD as the second leading cause of FBSS in 2002.

### Imaging Modalities

Diagnosis may start with a basic standing X-ray with flexion and extension of the spine. These images are used to evaluate alignment, degeneration, and stability of the spine. With few exceptions, MRI is the mainstay for diagnosis. However, this modality does not accurately show the presence and severity of fibrosis. Thus, more advanced modalities have been suggested, such as epiduroscopy, which can be used to directly visualize and identify severe fibrosis in 91% of patients. In contrast, MRI can identify fibrosis in only 16.1% of patients.<sup>17</sup> It is important to evaluate lateral extraforaminal zones as well as levels above and below the suspected location. Contrast-enhanced imaging may be required to evaluate patients who have undergone surgery for HNP. Otherwise, non-enhanced MRI is sufficient to diagnose most other etiologies including stenosis, degenerative disc disease, facet joint arthropathy, adequate decompression of nerve roots, fibrosis, and arachnoiditis. Resolution and image quality should not be altered by titanium alloy instrumentation if the sequences are optimized for metal. Ferromagnetic metal alloy instrumentation, however, may cause enough artifact to obscure the spinal images. In such

circumstances, CT myelography with contrast medium is indicated. CT with multiplanar reconstruction is the optimal choice for assessing patients who have had fusion or pedicle screws.<sup>2,8,18,19</sup>

### Discography

Discogenic pain can be identified using provocative discography, wherein contrast is injected into the suspected disc to elicit pain. The clinician can repeat the process in an adjacent healthy disc to assess precision and severity of the pain response. Subsequently, contrast may be injected into the suspected disc and a CT scan performed so that the integrity of the disc can be observed; this process will enable the clinician to identify annular tears and HNP. Discography has become controversial for its high rate of false-positives and prevalence of post-procedural adverse outcomes, such as disc infections or intravertebral damage.<sup>20</sup> The clinician must therefore weigh the risks and benefits when considering this diagnostic modality.

### Diagnostic Injections

Etiologies such as facet joint arthropathy, sacroiliac joint (SIJ) pain, and foraminal and central stenosis can often be confirmed or localized using diagnostic injections such as intra-articular injections, medial branch blocks, and transforaminal or interlaminar epidural steroid injections. They can be especially useful because physical examination and MRI findings may not necessarily correlate with the actual pain generator.<sup>12</sup> For example, it is difficult to identify the SIJ as a source of pain by history and physical alone. If a patient complains of pain predominantly below the L5 vertebra while pointing directly to the posterior superior iliac spine, and tenderness to palpation is appreciated in the sacral sulcus, then the likelihood of SIJ pain is about 60%.<sup>21</sup> The diagnosis can be confirmed if pain is relieved with an anesthetic injection into the SIJ. Radicular symptoms have poor concordance to the spinal level associated with the dermatome in which they are located. Only 20% of pain found in a dermatome matches the respective spinal level.<sup>22</sup> For this reason, a selective transforaminal nerve root block can be used to confirm the spinal level that may be generating the pain. A combination of all of the modalities described above can guide the physician to an appropriate diagnosis and coordinated management plan.

## MANAGEMENT OF FBSS

The treatment of FBSS is similar to that of chronic back pain, as the options range from medication to physical therapy and ultimately to surgery. It is appropriate to start with conservative management of the residual pain by beginning with physical therapy and medication. When conservative measures are not effective in controlling the pain, more aggressive treatment may be warranted. In the absence of clear indications for surgical revision, minimally invasive interventional procedures are an effective option for treatment. A number of such procedures are available for the treatment of back pain in general and FBSS in particular. Each of these procedures has its own indications and efficacies. The ability to identify an etiology for the FBSS, as described above, will guide the physician toward the most appropriate procedure, thereby improving the response to treatment.

### Interventional Pain Procedures

Given the high failure rates of revision surgery,<sup>23</sup> minimally invasive interventional procedures (Table 5) should be considered for pain management after failed back surgery. The choice of procedure depends on the history (radicular vs. axial symptoms) and on the physical examination and diagnostic findings.

**Epidural Injections.** One mechanism proposed to underlie radicular pain is an inflammatory process elicited by phospholipase A2, which is found in herniated disc material.<sup>24</sup> Epidural injections, often with a solution of local anesthetic and steroid, are the most commonly used procedures to treat radicular pain. The injected steroids inhibit the inflammation.<sup>25</sup> Three main approaches to epidural steroid injection include the interlaminar (midline and paramedian) and transforaminal approaches at the lumbar, cervical, and thoracic levels. For sacral nerve involvement, the caudal approach is used (see Figure 1).

The efficacy of epidural steroid injections for treating chronic back pain is controversial.<sup>26</sup> In a systematic review of interlaminar and transforaminal approaches, Abdi et al.<sup>27</sup> concluded that there was moderate evidence of long-term relief for interlaminar injections at the cervical level and limited evidence at the lumbar level, whereas moderate evidence supported transforaminal injections at both levels. The transforaminal and interlaminar approaches have also been reviewed by

Benny et al.<sup>28</sup> and Parr et al.,<sup>29</sup> respectively. The former reviewed 10 randomized controlled trials and found strong evidence that transforaminal injections could provide short-term and long-term relief from lumbosacral radicular pain. Parr et al.<sup>29</sup> concluded that there was level II (medium) evidence for short-term relief and level III (weak) evidence for long-term relief after interlaminar epidural injections. How these outcomes relate to patients with FBSS is unclear. One may postulate that these procedures were initially ineffective at providing pain relief because the patients eventually required surgery. How much more effective would these procedures be after surgery? Different outcome measures may be useful for assessing the efficacy of epidural injections. For example, transforaminal epidural injections have been shown to prevent the need for repeat surgery.<sup>30</sup>

Not unlike the efficacy of epidural injections in patients without previous surgery, strong evidence is lacking to support the use of these treatments in patients with FBSS. The weakness of the current literature may be attributed to varying study methods, including selection criteria, treatment dosing, controls, and outcome measures. In patients with FBSS, the efficacy of epidural injections is complicated by instrumentation, anatomical changes, and scar tissue, which make accurate needle placement difficult. Furthermore, evidence suggests that blind epidural injections in patients who have had previous surgery have a high rate of dural puncture; though, use of fluoroscopic guidance may prevent this complication.<sup>31</sup>

The apparent lack of strong evidence in favor of epidural injections, combined with increased procedural complexity and risk of complication, may steer physicians away from this treatment method. However, some promising studies are making epidural injections a potential treatment option. A recent study by Manchikankti et al.<sup>32</sup> evaluated the efficacy of caudal epidural injections with and without steroid as indicated for patients who had persistent back and/or leg pain (more than 6 months post-surgery) with no evidence of facet pain and who had not responded to conservative treatment, including bed rest, medications, physical therapy, exercise, or chiropractic manipulation. The randomized, double-blinded study showed 60% to 70% of patients achieved significant pain relief (> 50%) over a period of 1 year with no significant difference between the steroid and non-steroid group. In addition, 40% to 55% of patients exhibited significant functional improvement. A 1-year follow-up of this group showed

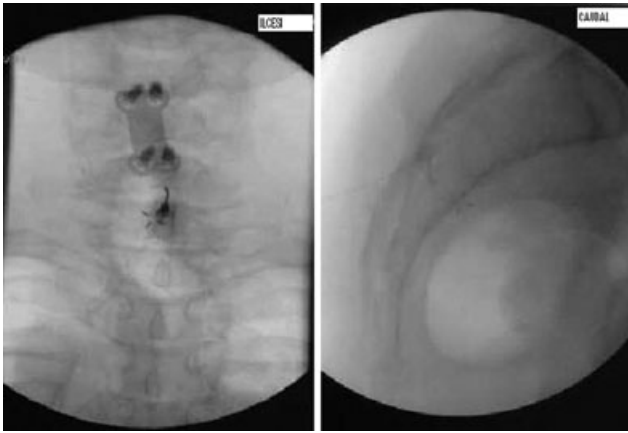
**Table 5. Interventional Procedures**

Study	Conclusions
<b>Epidural Injections</b>	
Davulder et al. <sup>35</sup>	Local anesthetic, hyaluronidase, and corticosteroid injected into the fibrotic nerve root sleeve is a potential therapy to treat FBSS pain
Davulder et al. <sup>36</sup>	No difference in efficacy for treating FBSS with nerve root injection using any of the following 3 solutions: 1 mL bupivacaine 0.5% + 1,500 units hyaluronidase + 1 mL saline, 1 mL bupivacaine 0.5% + 40 mg methylprednisolone, or 1 mL bupivacaine 0.5% + 1,500 units hyaluronidase + 40 mg methylprednisolone
Abdi et al. <sup>27</sup>	Moderate evidence for interlaminar epidural injections in the cervical spine and limited evidence for injections in the lumbar spine for long-term pain relief
Manchikanti et al. <sup>32</sup>	Moderate evidence for cervical and lumbar transforaminal epidural injections for long-term nerve root pain Moderate evidence for caudal epidural injections for long-term nerve root and chronic low back pain relief Over 55% of pts showed improvement in functional status and 60% to 70% experienced significant pain relief after caudal epidural injections for chronic function-limiting low back pain in FBSS population without facet joint pain
Parr et al. <sup>29</sup>	Evidence for blind interlaminar epidural injections in managing pain of all types is limited except for short-term relief of pain secondary to disc herniation and radiculitis This evidence does not represent contemporary interventional pain management practices and also may not be extrapolated to fluoroscopically guided lumbar injections
Manchikanti et al. <sup>33</sup>	Caudal epidural injection may provide functional improvement and pain relief in a significant proportion of patients with chronic function-limiting low back pain and post-surgery syndrome without facet joint pain
Yousef et al. <sup>34</sup>	The addition of hyaluronidase to fluoroscopically guided injection of caudal epidural steroid and hypertonic saline improved long-term pain relief in patients with FBSS
Benny et al. <sup>28</sup>	This systemic review included prospective, retrospective and randomized clinical trials showing strong evidence for transforaminal injections in the treatment of lumbosacral radicular pain for both short-term and long-term relief
Gharibo et al. <sup>37</sup>	Transforaminal injections provide more subjective relief than interlaminar injections in patients suffering from lumbar radicular pain
<b>Radiofrequency neurotomy/ablation</b>	
Van Kleef et al. <sup>39</sup>	Radiofrequency lumbar zygapophysial joint denervation results in significant alleviation of pain and functional disability in a select group of patients with chronic low back pain, both on a short-term and a long-term basis
Leclaire et al. <sup>40</sup>	Radiofrequency facet joint denervation may provide some short-term improvement in functional disability among patients with chronic low back pain, but the efficacy of pain relief was not established
Schofferman et al. <sup>44</sup>	Repeated radiofrequency neurotomies are an effective long-term palliative management of lumbar facet pain. Each radiofrequency neurotomy had a mean duration of relief of 10.5 months and was successful more than 85% of the time
Van Wljk et al. <sup>41</sup>	The combined outcome measure and VAS showed no difference between radiofrequency and sham, though in both groups, significant VAS improvement occurred. The global perceived effect was in favor of radiofrequency. In selected patients, radiofrequency facet joint denervation appears to be more effective than sham treatment
Cohen et al. <sup>45</sup>	The only factor associated with a successful outcome was paraspinal tenderness. Variables that correlated with treatment failure were "facet loading," long duration of pain, and previous back surgery
Gofeld et al. <sup>43</sup>	Previous lumbar surgery was not a predictor for outcome of radiofrequency denervation This large, prospective clinical audit indicates that proper patient selection and anatomically correct radiofrequency denervation of the lumbar zygapophysial joints provide long-term pain relief in a routine clinical setting
Nath et al. <sup>42</sup>	Radiofrequency facet denervation is not a placebo and could be used in the treatment of carefully selected patients with chronic low back pain
<b>Adhesiolysis</b>	
Manchikanti et al. <sup>46</sup>	Endoscopic or non-endoscopic epidural adhesiolysis + corticosteroid + saline is a safe and cost-effective procedure for relieving chronic intractable pain in post-lumbar laminectomy patients
Manchikanti et al. <sup>47</sup>	Non-endoscopic epidural adhesiolysis was more cost effective than endoscopic adhesiolysis Of the patients with chronic low back pain who received epidural adhesiolysis and hypertonic saline neurolysis, 97% had > 50% relief at 3 months, 93% at 6 months, and 47% at 1 year
Manchikanti et al. <sup>48</sup>	Also showed that this is a cost-effective treatment, with cost for 1-year improvement of quality of life at \$2,693 57% of patients with chronic low back pain who did not receive pain relief from conservative management, including epidural steroid injections, experienced significant long-term relief from spinal endoscopy with adhesiolysis combined with steroid and local anesthetic
Manchikanti et al. <sup>49</sup>	The adhesiolysis group had more significant relief than the non-adhesiolysis group In patients with FBSS, 72% showed significant relief of pain at 6 months and 52% at 12 months with non-endoscopic adhesiolysis; 40% showed significant relief of pain at 6 months and 22% at 12 months with endoscopy

VAS, Visual Analog Scale; FBSS, failed back surgery syndrome.

76% of patients who received only lidocaine experienced some improvement in pain, with 56% having significant relief (> 50%), while 67% of patients who

received steroid (celestone) had relief and 61% reported significant relief. The study was limited, however, in that it lacked a placebo group for comparison.<sup>33</sup>



**Figure 1.** Fluoroscopic images of interlaminar cervical epidural injection (left) and caudal epidural injection (right). The interlaminar approach involves central insertion of the needle between the laminae as identified by this fluoroscopic image. The caudal approach involves insertion of the needle into the sacral hiatus as identified by this lateral fluoroscopic image.

Some have considered the addition of hyaluronidase to traditional injectate solutions. Hyaluronidase is proposed to work by disrupting the proteoglycan ground substance of epidural adhesions, thereby preventing additional scarring. Yousef et al.<sup>34</sup> evaluated the addition of hyaluronidase to injectate by dividing patients into 2 groups. One group received a solution of steroid, anesthetic, and hypertonic solution. The second group received the same solution plus hyaluronidase. Outcome measurements included the verbal pain score (0 to 4), lumbar spine range of motion, and opioid usage. They found no significant difference between the 2 groups in any measure between 3 weeks and 6 months after treatment. Significant improvements were noted, however, only in the hyaluronidase group 6 months to 1 year after treatment.

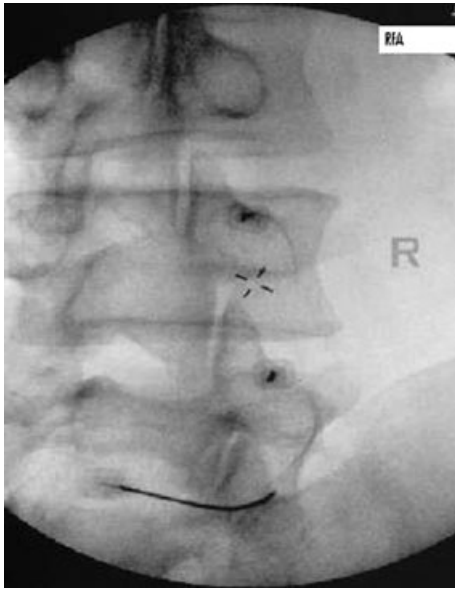
When focused mononeuropathy is suspected, selective nerve root treatment via transforaminal injection may be indicated. Two randomized studies sought to evaluate the efficacy of nerve root injections. The first of these was conducted by Devulder et al.<sup>35</sup> After achieving poor results with the caudal approach, the authors opted to focus treatment on the nerve root level. They found that 2 transforaminal injections of steroid, anesthetic, and hyaluronidase administered 1 week apart improved pain 1 and 3 months after treatment. Another study that evaluated 3 different injectate solutions (Group A, bupivacaine and hyaluronidase; Group B, bupivacaine and methylprednisolone; Group C, bupivacaine, methylprednisolone, and hyaluronidase) showed no significant difference between the groups

after 3 and 6 months.<sup>36</sup> Transforaminal injections are commonly believed to be more effective when administered at the lumbar spinal level than when administered between the laminae. This premise is supported by a prospective, blinded, randomized trial published by Gharibo et al.<sup>37</sup> The authors reported that the 2 approaches had similar short-term (10 to 15 days) results based on the Oswestry Disability Index, depression scale, and walking tolerance measurements. However, the transforaminal approach provided more significant relief of pain on the Numeric Rating Scale.

**Facet joint procedures—*intra-articular joint steroid injection, medial branch block, and radiofrequency ablation.*** When the complaint of pain is primarily axial, the suspicion for facet joint pathology is increased. When facetogenic pain is confirmed by physical examination and imaging, there are 2 potential techniques for treatment: intra-articular and medial branch nerve ligation. The efficacy of intra-articular injections has not been proven convincingly in the literature.<sup>38</sup> In regard to medial branch denervation, standard practice is to perform a diagnostic block—or 2 separate blocks as discussed below—with an anesthetic solution to confirm temporary relief of pain. Once the level is confirmed, the physician may proceed to radiofrequency ablation (RFA) of the nerve (Figure 2) with a sustained elevated temperature.

Some studies have shown that RFA is not efficacious for facetogenic pain.<sup>39–41</sup> However, Nath et al.<sup>42</sup> and Gofeld et al.<sup>43</sup> showed strong evidence for long-term improvements with RFA for patients who had a positive response to double diagnostic blocks. Furthermore, repetition of the procedure in 10.5-month intervals provided long-term relief in 83% of patients, according to a study by Schofferman et al.<sup>44</sup> The results of these studies may be applicable to patients who have had previous surgery, as Cohen et al.<sup>45</sup> found that previous surgery had no negative or positive influence on RFA treatment outcomes.

**Adhesiolysis.** As stated earlier, FBSS can be attributed to epidural fibrosis in 8% to 14% of patients. The extent of fibrosis can be related to severity of radicular symptoms after surgery. Ross et al.<sup>50</sup> conducted a randomized, double-blinded, prospective study with 149 patients who underwent discectomy for HNP and were evaluated 6 months after surgery. An MRI was obtained to screen for evident fibrosis, and the patients' pain was measured on a VAS from 0 to 10. The extent of



**Figure 2.** Fluoroscopic image of lumbar medial branch radiofrequency ablation (RFA). In this oblique view, the needle is seen at the junction of the superior articular process and the transverse process where the medial branch nerve traverses. The needle placement is the same for medial branch block and RFA.

fibrosis was then correlated with the level of pain. They discovered that patients with more extensive scarring were 3.2 times more likely than patients without scarring to develop recurrent radicular pain after discectomy. This phenomenon may be attributable to nerve compression, restriction of nerve movement through nerve sleeves, or decreased flexibility of nerves due to tethering.<sup>51</sup> Consequently, several studies have used a variety of perioperative treatments, including lidocaine 1%,<sup>52</sup> pimecrolimus,<sup>53</sup> cepea-extract heparin, allantoin mixtures,<sup>54</sup> and others<sup>55</sup> to determine how to prevent extensive scar formation after this type of surgery.

For those with existing adhesions and fibrosis, interventional adhesiolysis is an effective procedure for reducing associated pain<sup>47-49,56</sup> and has been shown to be more effective than caudal epidural steroid injections for reducing pain and improving disability.<sup>49</sup> Manchikanti et al.<sup>49</sup> found that 73% of patients who underwent targeted percutaneous adhesiolysis with lidocaine, 10% hypertonic saline, and non-particulate betamethasone had significant pain relief (> 50%) and functional status improvement (> 40% reduction of Oswestry Disability Index 2.0) compared with only 12% of patients who received epidural steroid injections.

Other approaches to adhesiolysis allow for direct visualization of the adhesions with an endoscope. This method is putatively effective in patients who have not

improved significantly with more conservative procedures, including percutaneous adhesiolysis without direct visualization. In another study of FBSS, Manchikanti et al.<sup>48</sup> showed the efficacy of endoscopic epidural adhesiolysis in 18- to 65-year-old patients who had chronic low back pain for more than 6 months, had no evidence of facet joint pain (negative medial branch blocks), and had failed to respond to epidural steroid injections or percutaneous adhesiolysis with hypertonic saline neurolysis. Patients were randomly assigned to 2 groups: one was treated with a combination of local anesthetic, steroid, and adhesiolysis, and the other was treated with anesthetic and steroid alone. Physicians used endoscopic guidance for the procedure in both groups. The results showed significant pain relief (> 50%) in 74% of patients in the adhesiolysis group at 1 and 3 months and in 57% at 6 months; in contrast, only 37% of patients in the non-adhesiolysis group had significant pain relief at 1 month and 0% had pain relief thereafter. Contrary to expectations engendered by this study, endoscopic adhesiolysis has not been shown to be more effective than traditional percutaneous adhesiolysis. In fact, a retrospective study by the same author compared non-endoscopic with endoscopic adhesiolysis and showed that the former provided more pain relief and was more cost-effective over a 12-month period.<sup>46</sup>

**Disc Interventions.** Several minimally invasive disc procedures have been used in patients with discogenic pain. The 2 general principles of management include direct treatment to the outer, annular fibrosis and broad relief of pressure. Based on the first principle, researchers developed thermal annular procedures, including intradiscal electrothermal therapy (IDET), discTRODE, and biaculoplasty, that use heat ligation to treat pain that originates from nerve endings in the annular fibrosis of the disc. A systematic review by Helm li et al.<sup>57</sup> showed the evidence for treating discogenic low back pain with IDET and discTRODE was fair and poor, respectively. This conclusion was based on only 3 randomized controlled trials and 1 observational study, as the number of qualifying studies was insufficient.

A number of procedures have been used to relieve pressure of disc structures, which are likely present in the annulus and are prospective pain generators. Two popular methods include nucleoplasty and mechanical decompression, which uses the Dekompressor device. Nucleoplasty uses radiofrequency energy to break down molecular bonds and dissolve internal disc material, which is then removed. A systematic review by Gerges



et al.<sup>58</sup> provided grade 1C recommendation (strong according to the Guyatt et al.<sup>59</sup> grading system) for use of the Nucleoplasty procedure for symptomatic herniated discs. Similarly, Dekompressor mechanical disc decompression was reviewed by Singh et al.<sup>60</sup> They determined that this procedure had poor therapeutic efficacy for discogenic pain. More investigation is required for a strong clinical guide to discogenic pain management.

**Spinal Cord Stimulation.** Spinal Cord Stimulation (SCS), first introduced by Shealy et al.<sup>61</sup> in 1967, is a modality used for a variety of chronic pain conditions, including neuropathic pain, complex regional pain syndrome, angina pectoris, and FBSS. Although the mechanism of action for SCS is largely unknown, 1 initial explanation has been related to the “gate control theory” proposed by Melzack and Wall.<sup>62</sup> The theory suggests that stimulation of large-diameter non-nociceptive sensory fibers in the dorsal column of the spinal cord can decrease activation of the small-diameter nociceptive sensory fibers through release of inhibitory GABA neurotransmitters.<sup>63</sup> Thus, by stimu-

lating these large-diameter sensory fibers, SCS can produce an inhibitory effect on pain sensation.<sup>64</sup> More recently, animal studies have shown that SCS can suppress tactile allodynia through increased inhibitory action of GABA. This mechanism has been supported by other studies in which concomitant use of intrathecal baclofen, a GABA agonist, enhanced SCS-induced anti-nociception. SCS may also increase levels of adenosine, serotonin, and/or substance P, which may play a similar role.<sup>65</sup> Others have proposed that SCS causes disinhibition of analgesic pathways from the periaqueductal gray matter.<sup>65,66</sup>

A recent study of SCS as a viable treatment option for FBSS was the Prospective Randomized Controlled Multicenter Trial of the Effectiveness of Spinal Cord Stimulation (PROCESS) by Kumar et al.<sup>67</sup> (Table 6) The study compared SCS to conventional medical management (CMM) for the treatment of FBSS. Patients were 18 years of age or older and suffered from neuropathic leg pain. Patients were included if they had had a pain score > 50 (0 to 100 on VAS) for at least 6 months after at least 1 surgery for HNP. Patients were excluded if they had a coagulation disorder or another

**Table 6. Spinal Cord Stimulation Studies**

Study	Participants	Method*	Results*	Comments
Kumar et al. <sup>67</sup> PROCESS trial	100 patients ≥ 18 years who had history of radicular pain in legs for at least 6 months and at least 1 anatomically successful surgery for HNP	Group I—CMM alone Group II—SCS and CMM combined	At 6 and 12 months Group II > Group I percentage of significant pain relief	An extensive study in support of SCS for FBSS treatment
Kumar et al. <sup>68</sup>	42 of the 52 original participants in the SCS group from original PROCESS study evaluated at 24 months	Evaluated leg pain relief, functional capacity via the Oswestry Disability Index, and quality of life	Continued leg pain relief at 24 months with enhanced quality of life 45% had SCS-related complications	Though SCS provides long-term pain relief, one must monitor for complications related to SCS
Manca et al. <sup>69</sup>	Used data from the 100 participants of the PROCESS trial detailed in Kumar et al. <sup>67</sup> above	Evaluated medical costs and relative HRQoL over 6 months of the trial	Group I averaged CAN \$3,994; Group II averaged CAN \$19,486 HRQoL greater in Group II	The overall improvement in quality of life may justify use of SCS despite its expense
North et al. <sup>70</sup>	42 patients with FBSS and without significant neurological impairment, psychological disease, spine instability, unresolved secondary gains, axial pain exceeding radicular pain, or significant opioid dependency	Group I—participants received SCS Group II—participants received repeat surgery Participants allowed to cross over Measured difference in cost with regard to success (cost-effectiveness) and mean quality-adjusted life years (cost-utility)	At 3.1 years, more crossed over from the re-operation group than from the SCS group Cost for SCS = US \$48,357 Cost for repeat surgery = US\$105,928 Cost for those that achieved long-term success after crossing over from re-operation to SCS = US \$117,901	SCS appears to be more cost-effective than repeat surgery. This fact is further demonstrated by the tendency of patients who received repeat operation to cross over to SCS, compounding their expenses

\*Results included are as mentioned in this article. Other results may not be mentioned here. Please refer to the articles for more details. SCS, spinal cord stimulation; CMM, conventional medical management; FBSS, failed back surgery syndrome; HRQoL, health-related quality of life.

clinically significant chronic pain condition such as lupus erythematosus, diabetic neuropathy, rheumatoid arthritis, or ankylosing spondylitis. Also excluded were those with active psychiatric disorder, life expectancy of < 1 year, or planned pregnancy. The participants were randomly assigned to 1 group (48 participants) that received CMM only—which included oral medications, nerve blocks, epidural corticosteroids, physical and psychological rehabilitation, and/or chiropractic care—or another group (52 participants) that received CMM and SCS. At 6 and 12 months of follow-up, 44 and 41 patients, respectively, remained in the CMM group compared with 50 and 47, respectively, in the SCS group. At 6 months, 48% of the SCS group, but only 9% of the CMM group, had > 50% leg pain relief ( $P < 0.001$ ). Similarly, at 6 months the SCS group reported a lower intensity of axial pain, enhanced health-related quality of life, and greater treatment satisfaction. At 12 months, 48% of the SCS group and 18% of the CMM group reported leg pain relief of > 50%. Although this study had few limitations, direct comparisons between SCS and individual treatments could not be determined because all possible treatments were combined into the CMM group. Additionally, the study had no placebo group, although using one would have raised ethical concerns given the risks involved in stimulator placement.

The authors found it difficult to continue a comparison between the 2 groups at 24 months because only 11 patients remained in the CMM-only group, a large number having crossed over to the SCS group. They provided results for 42 of the 52 participants who were initially randomized to the SCS group.<sup>68</sup> These 42 participants showed continued relief of leg pain compared with baseline but no significant relief in axial back pain. They also showed improved functional capacity as indicated by the Oswestry Disability Index and enhanced health-related quality of life. Of the 42 participants, 19 (45%) experienced SCS-related complications. These complications included electrode migration (14%), loss of paresthesia (12%), pain at the generator incision site (12%), and infection or wound breakdown (10%). The health care-related quality of life for the SCS group was markedly greater than that for the CMM group. The total healthcare cost of the SCS group at 6 months was CAN\$19,486 per patient compared with CAN\$3,994 per patient in the CMM group.<sup>69</sup>

A study by North et al.<sup>70</sup> showed the average cost per patient who achieved long-term success at 3 years with

SCS was US\$48,357, whereas the cost was US\$105,928 for reoperation. The cost was US\$117,901 for those who underwent reoperation and then achieved long-term success after crossover to SCS. This study suggests that SCS may be a cost-effective treatment option, especially if revision surgery is being considered, given the high rate of patients who eventually receive SCS even after revision surgery.

Many technological enhancements have been made to SCS over the years such as advanced leads that are less susceptible to breakage or migration, the most common causes of SCS complications. Better anchors have been developed, including mechanical products, to further offset the risk of lead migration. More powerful implantable power generators and MRI-compatible and position-adaptable leads have also been developed.<sup>71</sup> Although this technology has been developed to make the SCS system safer and more durable, no improvements in efficacy have been proven. Additional research is required to correlate clinical trends of SCS treatment with technological progress.

**Peripheral Nerve Stimulation.** Increasingly, less invasive strategies of neuromodulation are being used for chronic neuropathic pain conditions that are impervious to more traditional treatments. Analgesic effects have been documented when electrode leads are placed directly over a peripheral nerve (peripheral nerve stimulation) or over the area of the most intense pain (peripheral nerve field stimulation). The mechanisms are likely similar to those of SCS.<sup>72</sup> Verrills et al.<sup>73</sup> demonstrated that peripheral nerve stimulation provided an average pain reduction in 3.77 visual analog points in patients with FBSS at an average follow-up time of 7 months. A study by Yakovlev et al.<sup>74</sup> showed similarly promising results for peripheral nerve field stimulation. Several studies, including one by Navarro et al.<sup>75</sup> have combined SCS and peripheral nerve field stimulation; all have shown encouraging outcomes. Building upon the current literature, higher quality, randomized studies with more subjects are required for evidence-based support of this interventional approach.

### Pharmacological Management

Any discussion of treating chronic pain will include pharmacological management, as it is the most common mode of therapy. In our experience, those who undergo surgery for the treatment of pain have failed to experience sufficient relief with conservative medication alone.

Surgery is often intended to minimize medication requirement. When surgery fails to provide significant improvements, patients often find themselves returning to their previous regimen of pharmacotherapy.

White et al.<sup>76</sup> reviewed a number of Cochrane reports regarding the safety and efficacy of the foremost drug classes for chronic back pain treatment: NSAIDs, opioids, and antidepressants. NSAIDs were found to have strong evidence for efficacy but were also associated with significant side effects (such as risk of stroke, gastrointestinal bleeding, and renal impairment) that require close monitoring and consideration. Opioids, on the other hand, had weak evidence for analgesic efficacy. Inadequate efficacy, combined with the known potential for habituation and paradoxical hyperalgesia, make opioids a poor option for chronic back pain management. In our experience, patients are often already on high-dose regimens of opioids leading up to and following surgery, thereby complicating FBSS management. Similarly, little evidence supports the use of antidepressants for routine care of chronic back pain. For patients with neuropathic pain, clear guidelines have been established and can be reviewed elsewhere.<sup>77</sup>

### Interdisciplinary Management

As with other areas of chronic pain management, treatment for FBSS also entails a multidisciplinary approach that incorporates physical and psychological therapies. Such an approach does not mandate a tiered strategy where more conservative treatments are tried first followed by more invasive modalities. Rather, a comprehensive multimodal therapeutic approach that combines conservative treatments with interventional procedures has been shown to be efficacious per the PROCESS study described above.<sup>67</sup>

**Physical Therapy.** A number of studies have shown that physical and exercise therapy can be efficacious for the treatment of low back pain<sup>78,79</sup> and FBSS,<sup>80</sup> and such therapies continue to be a staple for any pain-management program. In 1 Cochrane review of 10 randomized trials, researchers evaluated rehabilitation for the treatment of low back pain and found strong evidence that multidisciplinary rehabilitation was effective in restoring function.<sup>81</sup> Another Cochrane review of 13 studies that addressed rehabilitation for patients who had undergone first-time lumbar surgery concluded that rehabilitation immediately after surgery lacked strong

evidence of efficacy. However, intensive exercise therapy begun at 4 to 6 weeks proved to be more effective than mild exercise therapy at restoring function and shortening the time until patients could return to work.<sup>82</sup> Rainville et al.<sup>83</sup> reported that patients who underwent lumbar surgery followed by rehabilitation had less pain improvement than those who had rehabilitation alone. In contrast, Jousset et al.<sup>84</sup> showed those who had the greatest strides in functional restoration were more likely to have had previous surgery. Although rehabilitation may not be as effective for some parameters in patients with FBSS, the best rehabilitation is intensive and multidisciplinary.<sup>85</sup>

**Psychological Therapy.** Addressing psychological comorbidities has shown to be helpful for patients with chronic pain.<sup>86</sup> A meta-analysis showed that depressed patients who took anti-depressant medications experienced better pain relief than patients who took a placebo.<sup>87</sup> Recognizing the impact of psychological treatment, Esmer et al.<sup>88</sup> sought to compare mindfulness-based stress reduction (MBSR) therapy to other standard medical care. In MBSR therapy, patients are instructed to perform practices such as yoga, walking, or meditation and are taught to distinguish between pain's emotional, cognitive, and sensory components. By identifying these separate elements of pain, patients had an opportunity to control the emotional and cognitive suffering even while the nociceptive sensation persisted. Patients in the MBSR group demonstrated statistically significant improvements in all outcome measures used by the study relative to the control group at the 12-week follow-up. These gains were also maintained at 40 weeks. One can surmise that a cumulative effect might be realized if a multidisciplinary strategy is used, although more research is needed to prove this hypothesis.

### Considerations for surgical revision

The decision to perform surgical revision can be difficult. As shown in the study by North et al.,<sup>70</sup> 62% of patients opted to cross over to SCS, indicating that surgery failed to resolve their predominant pain symptoms. Their study also revealed that reoperation may not be the most cost-effective treatment for these patients. It has further been shown that each repeated surgery has a lower probability of success.<sup>23</sup> Such disappointing results must give pause to patients considering this option. However, certain absolute indications for surgery remain, such as impaired bowel or bladder

**Table 7. Indications for Revision Surgery<sup>89</sup>**

Absolute Indications	Relative Indications
Impairment of bowel or bladder functioning	Severe sciatica that persists or worsens despite 4 weeks of complete bed rest
Profound motor weakness	Recurrent episodes of incapacitating sciatica
Progressive neural deficit despite complete bed rest	Pseudarthrosis or instability
	Problems associated with surgical hardware such as screws or rods

function, significant myelopathy, or other progressive neurological impairments associated with spinal cord injury (Table 7). Other indications include pseudarthrosis, instability, or problems associated with surgical hardware such as screws or rods.<sup>89</sup>

### CONCLUSION

Treatment of patients with FBSS can be difficult. This difficulty can be exacerbated by the dissatisfaction expressed by patients who have undergone an invasive, painful, and often debilitating surgical procedure. This sense of frustration may carry over into other treatment options. Given the high failure rate of surgery, it may be argued that the best treatment for FBSS is prevention, either by strict patient selection or avoidance of surgery altogether. The latter option, however, may not be appropriate if patients present with absolute surgical indications such as neurological impairments.

It would be reasonable to begin treatment by identifying potential causes of FBSS, with a particular emphasis on the most common causes, such as new-onset stenosis, recurrent HNP, epidural fibrosis, and pseudarthrosis. Evaluation of etiology starts with a thorough history and physical examination in which the clinician should focus on differentiating between predominantly axial and peripheral (radicular) symptoms. Assessment may begin with a traditional standing X-ray for a general screen of the spinal structure and stability. The primary modality for a more detailed evaluation is MRI, which can be used to identify most etiologies. However, if substantial metal artifact is present, CT myelography may be used. Diagnostic injections such as SIJ, medial branch, or transforaminal nerve root blocks can then be used to confirm the source of pain and possibly to provide clinical improvement.

A multidisciplinary, comprehensive approach to FBSS treatment that involves exercise or physical therapy, psychological counseling, medication, and interventional procedures appears to be most effective. Many

of the studies used as evidence for procedures such as epidural and facet injections, RFA, IDET, and adhesiolysis are limited by small participation numbers or a lack of placebo (sham procedure)—the latter being difficult given ethical considerations of the risk involved with invasive procedures. The most invasive option, short of reoperation, is SCS, which was proven efficacious by the PROCESS trial<sup>67</sup> and is more cost-effective than surgical revision.<sup>70</sup> It is best to limit surgical revision to patients who have experienced equipment failure, instability, or obvious neurological impairment and to those who have been properly selected.

In conclusion, as lumbar surgery continues to grow in prevalence, so will the number patients suffering from FBSS. Therefore, it is important for physicians who treat this population to expand their knowledge of FBSS etiologies, appropriate diagnostic imaging modalities, confirmatory diagnostic injections, and proper techniques for interventional procedures. In doing so, the pain physician may be adequately prepared to manage these complex cases in the future, ideally with the support of stronger evidence.

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