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Coccygodynia: Evaluation and Management

Guy R. Fogel, MD, Paul Y. Cunningham III, MD, and Stephen I. Esses, MD

Abstract

Coccygodynia is pain in the region of the coccyx. In most cases, abnormal mobility is seen on dynamic standing and seated radiographs, although the cause of pain is unknown in other patients. Bone scans and magnetic resonance imaging may show inflammation and edema, but neither technique is as accurate as dynamic radiography. Treatment for patients with severe pain should begin with injection of local anesthetic and corticosteroids into the painful segment. Coccygeal massage and stretching of the levator ani muscle can help. Coccygectomy is done only when nonsurgical treatment fails, which is infrequent. Coccygectomy usually is successful in carefully selected patients, with the best results in those with radiographically demonstrated abnormalities of coccygeal mobility.


Coccygodynia, pain in the region of the coccyx, typically is triggered by or occurs while sitting. The intensity of the pain varies and sometimes is aggravated by arising from a seated position. Less severe symptoms may be managed by changing the sitting position or injecting the painful area with local anesthetic and corticosteroids. Orthopaedic surgeons often see patients with more severe and disabling symptoms, which in selected cases can be managed successfully with surgery.

Coccygodynia is five times more prevalent in women than men. Although it can occur over a wide age range, mean age of onset is 40 years. Coccygodynia has many causes, but it may be posttraumatic, beginning after a fracture or contusion or after a difficult vaginal delivery. In the largest number of cases, the tip of the coccyx is subluxated or hypermobile, which can be seen on dynamic radiographs taken with the patient standing and seated (Fig. 1). The cause of pain is unknown in patients with normal coccygeal mobility.

Anatomy

Five fused sacral and three or four fused coccygeal vertebrae form the terminal end of the spinal column. Primary ossification centers are evident in the 9th to 10th week of gestation in the axial skeleton, but the coccyx does not begin to ossify until after birth. In the sagittal plane, the sacrum is kyphotic and connects the lumbosacral junction to the coccyx. The inferior sacral apex at S5, the sacral cornu, articulates with the coccygeal cornu, a facet-disk complex on the dorsal articulating surface of the coccyx. This articulation can be a synphysis or a synovial joint. The coccyx is a triangular structure comprising three or four coccygeal units that usually are fused, although the first coccygeal segment may not fuse with the second. The sacrococcygeal joint also may be fused. The coccyx provides attachments for the gluteus maximus muscle, coccygeal muscle, and anococcygeal ligament.

Etiology

The clinical factors associated with coccygeal abnormalities are obesity,
antecedent trauma or childbirth, and exacerbation of pain with arising from sitting. Obesity, which decreases pelvic rotation when the patient sits, is three times more common in patients with coccygodynia than in the normal population. However, the incidence of radiographically demonstrated coccygeal instability is the same regardless of a history of remote trauma, which suggests that only recent trauma (within 3 months) causes coccygodynia. Patients with normal coccygeal mobility have the idiopathic type, which may be associated with pelvic floor spasticity or other anomalies of the midpelvic muscles. Coccygodynia occurring with an immobile coccyx frequently is associated with bursitis of the adventitia at the coccygeal tip. Other suggested etiologies include posttraumatic arthritis of the sacrococcygeal joint and ununited fractures or dislocations of the coccyx. Abnormal psychological states as a cause of coccygodynia have been largely disproved as behavioral testing of these patients reveals personality profiles similar to other patient groups. Other causes of pain in the region of the sacrum and coccyx are lesions of the lumbar disks, arachnoiditis of the lower sacral nerve roots, tumors of the coccyx or sacrum, pilonidal cysts and sinuses, and perirectal abscesses. Low back pain has occurred concurrently with coccygodynia. In one series, 24 of 50 patients (48%) also had lumbar disk herniation or bulge without sciatica or low back pain, so although low back pain is common, it appears to be separate from coccygodynia. In the series of Postacchini and Massobrio, 87% of patients with low back pain at the time of coccygectomy had an excellent or good result. The only poor results were in patients with low back pain and a configuration of the coccyx wherein the first coccygeal segment is partially fused to the sacrum.

Clinical Evaluation

Symptoms
Onset of pain may be insidious, resulting in a possibly long delay from onset to diagnosis. Patients usually present with pain in and around the coccyx without significant low back pain or radiating or referred pain. The pain is localized to the sacrococcygeal joint or mobile segment of the coccyx and may be relieved by sitting on the legs or on either buttock. Chronic pain is that which persists >2 months. Patients may feel a frequent need to defecate or may have pain with defecation. Women with a history of vaginitis, discharge, or associated pelvic pain should be referred for gynecologic consultation. Concomitant constipation should be managed appropriately. If the patient has blood in the stool, a tumor or metastasis should be considered.

Physical Examination
The surrounding skin and soft tissue should be inspected for evidence of pilonidal cysts or fistulas. External palpation or rectal examination may reveal bone spicules, local swelling, or coccygeal masses. The coccyx should be palpated externally, and the distal segment should be manipulated rectally to detect pain generated by motion of the coccygeal segments. Local tenderness may occur on the superficial coccygeal surface or only on manipulation of the coccygeal tip by rectal examination. Tenderness may be greatest at the sacrococcygeal joint rather than at the coccygeal tip. A palpable internal mass (eg, chordoma) on the anterior surface of the coccyx or sacrum may be evident on rectal examination. Every examination should include a stool guaiac to detect occult blood.

Imaging Evaluation

Single-Position Radiographs
Because orthogonal anteroposterior and lateral radiographs of the coccyx seldom show differences between normal individuals and those with coccygodynia, these views are usually not diagnostic. Postacchini and Massobrio reported that, in both healthy and symptomatic patients, 83% to 95% had two or three coccygeal segments. The sacrococcygeal joint was fused in 51% of the patients with idiopathic coccygodynia (26/51), usually the first intercoccygeal joint was mobile, and the second intercoccygeal joint was fused in 49% (25/51). The curvature of the sacrum was flexed or anterior in 68% of
asymptomatic patients and in 31% of patients with coccygodynia. The tip curved forward sharply in 23% and subluxated posteriorly in 22% of patients with coccygodynia.4

Dynamic Radiographs
Maigne and colleagues1-3,6 compared standing and sitting lateral radiographic views of the coccyx in a total of 582 patients with coccygodynia and reported abnormalities in 70%. The normal coccyx pivots slightly (5° to 25°) either posteriorly or anteriorly with sitting and returns to its original position with standing (Fig. 2, A). Abnormalities of the coccygeal segments in the seated views have anterior hypermobility >25° (Figs. 2, B and 3). Subluxation or posterior displacement of the mobile segment of the coccyx is seen when the patient is seated (Figs. 2, C and 4, A). A spicule of the distal tip (Fig. 2, D) is seen most commonly with an immobile coccyx (<5° of motion with sitting).2

Advanced Imaging Modalities
Technetium Tc 99m bone scans may show inflammation in the area of subluxation or hypermobility. Magnetic resonance images also may demonstrate edema in such areas of inflammation (Fig. 4, B). Neither imaging modality can definitively diagnose coccygodynia, nor are they as accurate as the compared standing and seated dynamic radiographs. Provocative tests, such as needling of the painful coccygeal joint to produce pain, and relief with injection of local anesthetic are helpful in diagnosing all patients with subluxation or hypermobility and nearly half of those with normal mobility.3

Nonsurgical Management
Nonsurgical management options include nonsteroidal anti-inflammatory and analgesic medications, rest, hot baths, and a cushion to protect the coccygeal region from repetitive trauma. Physical therapy consisting of diathermy and ultrasound may provide temporary relief.

Wray et al5 used a stepwise treatment, with each step somewhat more invasive than the previous. First, methylprednisolone (40 mg) and bupivacaine (10 mL 0.25%) were injected around the side and tip of the coccyx. With persistent coccygodynia, the coccyx was reinjected and manipulated under general anesthesia by repeatedly flexing and extending it for a minute. If the treatment was successful initially but pain recurred, the injections and manipulations were repeated. If the patient did not respond, a coccygectomy was done 6 weeks later. The cure rate with injection alone was 59% but was 85% with manipulation and injection.5 Although relapses occurred in the injection group (21%) and the manipulation group (28%), repeat treatment in each group achieved good success. Coccygectomy was done in 20% of patients and had a success rate of 91%. Maigne and Chatellier6 prospectively compared levator ani muscle massage, joint mobilization, and mild

Figure 2 The anatomic signs of coccygodynia.1 A, Normal standing appearance of the coccyx. B, Increased flexion mobility of the coccyx when patient is seated. C, Posterior subluxation of the coccyx when patient is seated. D, Coccygeal spicule (arrow) arising from the dorsal surface of coccygeal segment.

Figure 3 Lateral radiographic seated view of a 45-year-old woman with increased-flexion coccygodynia (arrow). She fell on her buttocks 2.5 years before presentation and had progressive symptoms, including painful bowel movements and inability to sit on a chair. Physical examination revealed a tender and nonmobile coccyx with an exquisitely tender distal coccygeal segment on rectal examination. At 1 year postcoccygectomy, she had complete relief from her symptoms and was able to sit normally. (Courtesy of Paul A. Anderson, MD, Madison, WI.)
stretching of the levator ani, without the addition of injections. At 6 months, successful treatment was 29.2% with massage, 16% with mobilization, and 32% with stretching, for a total of 25.7% overall success. When a patient had a satisfactory result, it was invariably achieved within a week. Good results tended to remain stable. Patients with normal mobility of the coccyx fared the best (43% success at 6 months). Those with an immobile coccyx fared the worst (16%). The outcomes for those with instability subluxation (22.2%) and hypermobility (25%) were modestly successful. Massage and stretching were more effective than manipulation. When therapy failed, patients went on to injections or surgery.

Based on these studies, we have developed an evaluation and treatment algorithm for coccygodynia5-7 (Fig. 5). When a patient presents with acute coccygodynia (≤2 months’ duration), 8 weeks of rest with use of a stool softener, adjustable seating, and nonsteroidal anti-inflammatory medication are prescribed. If this fails to relieve the symptomatic coccygodynia or the patient presents with chronic symptoms (>2 months’ duration), a workup is done, including standing and seated radiographs of the coccyx in addition to MRI to evaluate for injury edema, tumor, or other pathology. Stretching, massage, and injection are usually initiated at this time. If these treatments are unsuccessful or if pain recurs, coccygectomy may be offered.

**Surgical Management**

The indication for coccygectomy is significant, disabling coccygodynia with radiographic subluxation; instability; or a spicule, particularly on the tip of an immobile coccyx.5-7 Surgery consisting of complete coccygectomy or simply excision of the mobile segment, should be done only after nonsurgical management fails.4 Absence of physical findings or significant abnormal psychologic evaluation is a contraindication to surgery. In carefully selected patients, especially those with dynamic radiographic instability or hypermobility, success rates range from 60% to 91%.4,5,7-11 (Table 1). In a patient with normal coccygeal mobility who fails nonsurgical care, coccygectomy may be recommended. However, the surgical result is less predictably favorable than in patients with dynamic radiographic coccygeal instability or hypermobility.

**Technique**

The patient should take an oral mechanical bowel preparation, such as saline and polyethylene glycol solution (4 L), the day before surgery. Oral neomycin, erythromycin, or metronidazole are given three times the day before surgery. Appropriate prophylactic antibiotics for bowel surgery are given 1 hour before surgery. Postoperatively, most authorities recommend two or three more doses.12

Coccygectomy is done with the patient in the prone position with the hips and knees flexed. A vertical incision is made over the coccyx, extending from just above the sacrococcygeal joint into the buttock crease without extending it to the perianal skin. The incision is carried down through the fascia and gluteus maximus muscle with meticulous dissection directly to the bone. Subperiostal dissection should be done by gradually working side to side. The coccyx then should be elevated either by working from the tip proximally or from the side, under direct vision. All segments must be removed. The tip of the coccyx, which is most likely to be left inadvertently, should be separated sharply from the underlying rectum and dense fascia. With blunt dissection, the rectum and
dense fascia then are freed to the level of the sacroccygeal joint. This joint then may be transected and the coccyx removed.

The wound bed should be closely examined and palpated for any remaining segments of bone. Radiographs generally are not necessary. The end of the sacrum may be smoothed by rasp, rongeur, or burr. Bleeding from the hemorrhoidal venous complex of the rectum may require ligation. Meticulous hemostasis and a tight layered closure to obliterate dead space should be done. This technique should decrease fragmentation of the coccygeal specimen and limit damage to the rectum and its venous drainage, which can decrease postoperative drainage and increase the risk of infection.

**Complications**

The primary complication is perineal contamination of the wound. Usually a wound infection is superficial or is a simple wound dehiscence and will heal with intravenous antibiotics and local wound care. Deep infection must be debrided and drained. Antibiotics should be given. Even with healing by secondary intention, the result may be successful. Wound infection and delayed wound healing rates range from 2% to 22%. In a very thin patient with a kyphotic sacrum, the remaining end of the sacrum may be prominent and be a source of continued pain that is not easily managed.

**Summary**

Dynamic radiographs can help identify causative abnormalities in most patients with coccygodynia, and those with normal coccygeal mobi-
Corticosteroid and anesthetic injections combined with massage or stretching of the levator ani muscle are successful in most patients. When nonsurgical management fails, coccygectomy is usually successful in carefully selected patients with dynamic instability. Coccygectomy may be recommended in patients with normal coccygeal mobility who fail nonsurgical care, but results are less predictably favorable than in patients with dynamic radiographic coccygeal instability or hypermobility.

### Table 1

**Outcomes From Coccygectomy**

<table>
<thead>
<tr>
<th>Study</th>
<th>No. Patients</th>
<th>Follow-up (yrs)</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Postacchini and Massobrio⁴</td>
<td>36</td>
<td>7.8 (mean)</td>
<td>12 excellent, 20 good, 2 fair, 2 poor</td>
</tr>
<tr>
<td>Wray et al⁵</td>
<td>23</td>
<td>2.75 (mean)</td>
<td>21 excellent</td>
</tr>
<tr>
<td>Maigne et al⁷</td>
<td>37</td>
<td>2 (minimum)</td>
<td>23 excellent, 11 good, 3 poor</td>
</tr>
<tr>
<td>Hellberg and Strange-Vognsen⁸</td>
<td>55</td>
<td>15 (mean)</td>
<td>32 cured, 13 improved, 5 slightly improved, 5 dissatisfied</td>
</tr>
<tr>
<td>Grosso and van Dam⁹</td>
<td>9</td>
<td>4.7 (mean)</td>
<td>3 complete, 5 partial, 1 slight relief</td>
</tr>
<tr>
<td>Eng et al¹⁰</td>
<td>27</td>
<td>1.5 (minimum)</td>
<td>9 cured, 9 improved, 6 slightly improved, 3 not improved</td>
</tr>
<tr>
<td>Bayne et al¹¹</td>
<td>48</td>
<td>7 (mean)</td>
<td>29 acceptable</td>
</tr>
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### References

Hip spine syndrome: management of coexisting radiculopathy and arthritis of the lower extremity

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Abstract

Background context: Significant lumbar spinal stenosis and lower extremity arthritis may coexist in the elderly. This combination of lumbar stenosis with radiculopathy and lower extremity arthritis may lead to diagnostic uncertainty.

Purpose: To describe the findings of hip spine syndrome, a constellation of symptoms with extensive overlap of radiculopathy and lower extremity arthritis.

Conclusions: Evaluation of the patient with lower extremity pain in consideration for total joint arthroplasty should include functional inquiry of the spinal nerves. Diagnostic tests and injections may allow an informative weighting of the patient’s symptoms, leading to a better understanding of the patient’s pain syndrome. There is a group of patients who have a total hip arthroplasty and then develop or may continue to have pain of groin and buttock, secondary to sciatica of lumbar spinal stenosis. For the patient undergoing total hip arthroplasty with asymptomatic spinal stenosis, there may be increased neurological risk at surgery, related to the stenosis. The patient with both conditions may require surgical decompression of the lumbar stenosis as well as joint arthroplasty of the arthritic joint.

Keywords: Aged; Aged, 80 and over; Hip joint; Hip prosthesis/adverse effects; Laminectomy; Myelography; Pain/etiology/therapy; Spinal stenosis/complications/radiography/surgery

Introduction

Significant lumbar spinal stenosis and lower extremity arthritis may coexist in the elderly. Which diagnosis leads to the patient’s lower extremity complaints? Clinically, symptoms of lumbar spinal stenosis, radiculopathy and neurogenic claudication may be similar to the pain of an arthritic hip or knee. Additionally, an asymptomatic lumbar stenosis may become activated after a total joint arthroplasty and cause unacceptable levels of radicular pain or newfound muscular weakness, that is, foot drop, thigh or hip abductor weakness. Evaluation of the patient with lower extremity pain in consideration for total joint arthroplasty should include functional inquiry of the spinal nerves. Diagnostic tests and injections may allow an informative weighting of the patient’s symptoms leading to a better understanding of the patient’s pain syndrome. The patient with both conditions may require surgical decompression of the lumbar stenosis as well as joint arthroplasty of the arthritic joint.

Osteoarthritis is the most common musculoskeletal disease of aging. It has been reported radiographically in more than 80% of individuals older than 55 years. Arthritis is present in more than 40 million US citizens. Osteoarthritis of the spine, hip and knee may result in significant impairment, disability and loss of function. Radiographic evidence of osteoarthritis of the knee has been reported in 40% of patients 80 years or older. Similarly, radiographic arthritis of the hip has been reported in 12% of those older than 80 years [1]. Likewise, spondylosis of the lumbar spine is prevalent, and lumbar stenosis, a subset of arthritis, is not uncommon. Some aspects of stenosis, such as spondylolisthesis, may be seen in 6% of men and 9% of women from a Dutch cross-section study. Computed tomography (CT) scan may be a better measure of stenosis, with reported incidence of 3.4% in individuals older than 40 years. Magnetic resonance imaging (MRI) in asymptomatic individuals may report even higher incidence of stenosis. Borenstein et al. performed MRI studies of volunteers and reported a prevalence of 60% in those older than 60 years [2].
The causes of hip arthritis may be multifactorial and include osteoarthropathy, spondyloarthropathy and avascular necrosis. In general, these patients will have buttock and groin pain radiating to the knee, but not below, associated with decreased range of motion. As the arthritis progresses, gait disturbances may be seen. Total joint arthroplasty has made a significant positive impact on the treatment of patients with disabling arthritis. Total hip arthroplasty is one of the most successful surgical procedures. More than 120,000 primary arthroplasties are performed in the United States each year at an estimated cost of over $2.5 billion. Because most hip replacements are done in patients older than 65 years of age, the number of procedures is expected to increase as the population ages. Outcome studies have documented marked improvements in pain, sleep, range of motion and physical ability after total hip arthroplasty. Overall, the data have documented that there is a significant improvement in functional status and quality of life.

Beattie et al. [3] looked at lumbar MRI in the symptomatic lumbar stenosis patient and found that only the most severe compression situations, such as severe foraminal encroachment or large disc extrusion, would correlate with the patient’s symptoms. Mild to moderate compression, disc degeneration and central canal stenosis were not significantly associated with the reported patient pain pattern. Lawrence et al. [1] reviewed hospital discharge registry for the state of Washington from 1986 to 1988, reporting admissions for lumbar spine operations in 18,122 patients, of which 3,380 (18.6%) were for diagnosis of spinal stenosis. If 18.6% were representative of the United States, then 52,000 operations for stenosis nationwide were done yearly [1]. Stenosis may begin at an earlier age, related to developmental stenosis. Eighty percent of patients will have back and leg pain, 62% have symptoms of pseudoclaudication and 50% will have neurological deficit. Hall et al. [4] reported a known association of lumbar stenosis and peripheral vascular disease.

The true incidence of the combination of lumbar stenosis and hip arthritis is unknown. There can be a substantial overlap in symptoms of stenosis and hip arthropathy. The stenosis may be asymptomatic while the hip is symptomatic. Clinical symptoms arising from the hip often prompt medical treatment. Or the stenosis may be the more obvious problem, demanding more immediate surgical attention. Lumbar stenosis or spondylolisthesis causing radiculopathy is usually recognized and treated. There is a group of patients who have a total hip arthroplasty and then develop or may continue to have pain of groin and buttock, secondary to sciatica of lumbar spinal stenosis.

Diagnosis

Although a careful history and physical examination often may differentiate pain of radicular versus joint origin, sometimes the distinction is difficult. Leg pain should be described in detail to see whether it simulates a dermatomal pattern. The most common symptom of lumbar spinal stenosis is neurogenic claudication. Neurogenic claudication, or pseudoclaudication, refers to pain radiating to the lower extremities that begins and worsens as the patient ambulates. The pain worsens with the increased lordosis of the lumbar spine, with standing and walking, which may relatively pinch close the foramina and narrow the canal with infolding of the ligamentum flavum. The pain often resolves spontaneously or resolves rapidly as the patient bends forward or sits down. In contrast, muscular claudication of vascular origin will produce symptoms with walking up hills or bicycling. Alternately, absence of pulses below the hips, rubor and pallor changes with elevation are classic for vascular claudication but not neurologic claudication. In uncertain cases vascular Doppler, flow studies or arteriography may be required. Patients who present with concomitant osteoarthritis of the lower extremities (hip, knee, ankle), causing restricted and painful joint range of motion will require special consideration. In certain individuals, there may be isolated areas of extremity pain at the hip, knee, calf, ankle or heel, with asymptomatic areas between painful foci [5].

The most important features of the physical examination in stenosis are the strength, reflex and the palpatory examinations. Strength deficits, such as partial foot drop and hip flexor or quadriceps weakness may be subtle. In patients with more severe chronic lumbar spinal stenosis, there may be visible atrophy of calf musculature. The patient may be unable to walk. Reflexes often are diminished at the ankles in patients with more significant lumbar stenosis. Straight leg raising, a helpful clinical sign in disc herniation, usually is negative in patients with spinal stenosis, except in patients in whom disc herniation is superimposed in a region of stenosis. However, the femoral stretch test often is positive, even when only L5 and S1 roots are involved. This may occur because of the end effect of increasing lordosis and pelvic tilt increasing the stenosis and stretching the femoral roots. Areas of sensory deficit usually correlate poorly with patients’ pain and disability. Decreased range of motion of joints, with pain at extremes of motion, is commonly found in arthritis of the hip and knee. There may be an effusion or induration of the knee, associated with arthritis of the knee. The clinician must evaluate leg pain carefully. Leg pain not attributable to radiculopathy may result from hip bursitis, osteoarthritis of the hip or knee or myofascial pain.

Plain radiographs may demonstrate osteoarthritis of the hip and lumbar spine (Fig. 1). The plain radiographs are poor measures of lumbar stenosis, and CT myelography or MRI scanning is far better at defining stenosis. A block with local anesthetic at the most symptomatic location may be of diagnostic benefit. A hip injection with local anesthetic may allow the confident diagnosis of hip disease. Kleiner et al. [6] report injection of 10 mm of bupivacaine HCl into the hip with X-ray localization to discern the origin of hip pain [6]. They reported identification of the hip as the correct source of pain in 88% of the total cases. Alternatively, in the case of a suspected radiculopathy, a nerve root block with anesthetic will be nondiagnos-
tic. However, the addition of a steroid may give therapeutic pain relief [7]. If the radiculopathy is within a dermatome, implying a single or perhaps two nerve roots, these nerve roots may be anesthetized with a fluoroscopic guided selective block, but there is low specificity with such blocks. Adjacent nerve roots are affected by an injection, and in other cases there may be some effect of distal injection on referred pain.

**Pain after arthroplasty**

Although total hip arthroplasty is one of the most successful procedures in orthopedic surgery, a small percentage of patients have pain after surgery. A systematic approach to the evaluation of this pain, with careful attention to the patient’s history, physical examination and laboratory and radiographic studies, is necessary to reach a correct diagnosis. The time of onset of hip pain is important. Pain that occurs early after surgery and is out of proportion to the usual postoperative pain may indicate a postoperative infection, an unstable implant, heterotopic ossification or radiculopathy. Late pain may result from component loosening, hematogenous infection, soft-tissue problems such as tendonitis or bursitis or radiculopathy of lumbar stenosis. The location of the pain is important in identifying its source. Groin pain usually is caused by acetabular component loosening, which can also cause buttock pain. Iliopsoas inflammation is more common with collared implants overhanging the medial calcar, or impingement on prominent cementless sockets causing groin pain. Groin pain also may be caused by an L4–L5 stenosis [8]. Elderly patients with L4–L5 protruding herniation of the annulus fibrosus were most likely to experience groin pain. The sinuvertebral nerve that innervates the posterior annulus fibrosus, the posterior longitudinal ligament and the dura was indicated as the afferent nerve causing groin pain [9]. Thigh or knee pain may be the result of femoral component loosening.

The coexistence of lumbar stenosis with hip arthritis may be an increased risk factor for neurologic injury with total hip arthroplasty. Pritchett [10] reported 21 patients with lumbar stenosis who developed foot drop after total hip arthroplasty. This implies that less nerve compression is re-

![Fig. 1. Lumbar spinal stenosis Anteroposterior lateral radiographs. (Left) Previous total hip arthroplasty on right hip. (Right) Severe arthritis, left hip. Note associated aortic vascular calcification on lateral.](image-url)
quired to produce symptoms in the presence of these coexisting conditions. Pritchett concludes that if nerve injury occurs after hip surgery, lumbar spinal stenosis should be considered, and some patients will improve after lumbar stenosis decompression. Bohl and Steffee [11] theorized that increased walking endurance afforded by the new hip arthroplasty may unmask neurogenic claudication, in patients incapable of walking that distance before total hip arthroplasty [11]. Although clinically apparent nerve injury is uncommon, detectable neurological loss after total hip arthroplasty is more common than postoperative infection. Schmalzried et al. [9] found a 1.7% incidence of postoperative neuropathy, mostly sciatic, noted clinically. In most patients the cause of the neuropathy is unknown. This author did not comment about associated lumbar stenosis. McNamara et al. [12] report 14 patients who underwent lumbar stenosis release after total hip arthroplasty [12]. Five patients initially presented with symptoms of both joint disease and spinal stenosis. Nine patients began to have radicular pain after their total joint replacement. Eight of nine who underwent decompression of lumbar stenosis after the total joint arthroplasty were rated as “well” to “excellent” outcome. The authors noted the average time to presentation with symptoms for spinal stenosis after arthroplasty was 9.3 months.

It is important to determine whether the patient has pain with activity, pain at rest or both. Pain caused by component instability usually is activity related. Lumbar spinal stenosis with radiculopathy may be painful at rest or have a pseudoclaudication nature that may be confused with pain of component instability. Clinically, a history of “start-up” pain may indicate a loose component. The patient may report that after 5 or 10 steps there is less pain in the groin. Pain with a loose component often is triphasic in that the first few steps cause acute sharp pain, the pain lessens with more walking and then with a moderate amount of walking, pain again increases. With loose components, the pain is either in the groin or thigh, with occasional buttock pain caused by a loose socket. Pain that occurs at night, or at rest, should suggest the possibility of spinal stenosis. It also is important to determine the presence of peripheral vascular disease, because activity-related pain may also result from vascular claudication.

**Treatment**

Which element should be treated first? McNamara [12] recommended total joint arthroplasty first because of the demonstrable excellent results with arthroplasty. In patients with concomitant stenosis and coxarthrosis, the patient should be counseled that two operations may be required to treat the problem, a hip arthroplasty and a lumbar decompression. For the patient with asymptomatic spinal stenosis undergoing total hip arthroplasty, there may be increased neurological risk at surgery, related to the stenosis. However, the authors would not recommend a decompression of an asymptomatic lumbar stenosis. Again, the patient may be counseled that although the stenosis may be asymptomatic now, a lumbar decompression may be required in the future if the stenosis becomes symptomatic.

Although progressive neurologic deficit or cauda equina syndrome in association with lumbar spinal stenosis are indications for urgent operative intervention, Bohl and Steffee [11] suggested that nonprogressive neurologic deficit (pin prick, vibration, reflexes, leg muscle power) correlated poorly with pain and physical disability and therefore should not be a reason for operative intervention.

**Summary**

Significant lumbar spinal stenosis and lower extremity arthritis may coexist in the elderly. Evaluation of the patient with lower extremity pain in consideration for total joint arthroplasty should include functional inquiry of the spinal nerves. Diagnostic tests and injections may allow a better understanding of the patient’s pain syndrome. There is a group of patients who have a total hip arthroplasty and then develop or may continue to have pain of groin and buttock, or neuro-claudication secondary to sciatica of lumbar spinal stenosis. For the patient undergoing total hip arthroplasty with asymptomatic spinal stenosis, there may be increased neurological risk at surgery, related to the stenosis. The patient with both conditions may require surgical decompression of the lumbar stenosis as well as joint arthroplasty of the arthritic joint.

**References**

Cervical plates: comparison of physical characteristics and in vitro pushout strength

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Abstract

Background context: There are many cervical plates available to the spine surgeon today. A single plate design may not be appropriate for every clinical situation. It is important for the surgeon to understand the differences of these plating systems. Plate systems are known to fail by screw pullout from the bone, screw and plate breakage and a less frequent but clinically observed screw pushout from the plate. Pushout testing of the screws from the plate have not previously been subjected to study.

Purpose: This compares the features of cervical plating systems and the strength of the locking mechanisms to allow the surgeon to make a knowledgeable choice of plating system.

Study design: This is a review of descriptive geometric characteristics of cervical plate systems and a biomechanical evaluation of locking mechanism screw pushout strength.

Methods: Physical characteristics of each plate were determined. Features of plates and screws were cataloged. Each of the test plate systems had a different locking mechanism. Biomechanical testing of the locking mechanism–screw-plate constructs was performed to determine the pushout strength of the fixation screw from the plate-locking mechanism.

Results: Physical characteristics of the plating systems, including lengths, widths, shortest screw lengths and distance from edge of plate to nearest screw, were determined. Biomechanical testing showed significant differences in pushout strength, in part explained by the type of locking mechanism.

Conclusions: Biomechanical screw pushout data demonstrate that a significant range of pushout strengths exist across the available cervical plate systems today. Knowing the physical characteristics of the cervical plating systems available may allow the selection of a plate best suited for a given clinical situation. © 2003 Elsevier Science Inc. All rights reserved.

Keywords: Biomechanics; Bone plates; Bone screws; Cervical vertebrae; Surgery; Equipment design; Spinal fusion/instrumentation

Introduction

Anterior plating systems have become increasingly popular for fixation of the subaxial cervical spine. Internal fixation of the anterior cervical spine using instrumentation in patients with fracture instability is well recognized [1,2]. The role of instrumentation for cervical degenerative disorders has been more controversial but recent studies support the use of plating, especially for multiple-level fusions [3–8]. The plate systems have been recommended to decrease the pseudarthrosis rate in cervical surgery [9–15]. Other advantages of the plate include prevention of graft extrusion and decreased need for external postoperative immobilization [7,8,14–19]. The disadvantages may include the cost, stress shielding of a bone graft, fixation failure from the bone with loosening of the screws and the risk of neurological or vascular injury [12,15,17,18,20–24]. Currently, cervical plating systems incorporate a bone fixation screw secured by a locking mechanism. The locking mechanism makes the screw-plate construct more rigid without using bicortical fixation [25,26] and prevents pushout of the bone screw.
This screw-plate construct thus acts mechanically as a single-piece implant. Without the need for posterior cortical penetration in the vertebral body, there is a decreased risk of screw misplacement and resultant spinal cord injury [27]. These plating systems are subject to failure. These are not common complications but may include screw pullout from the bone or from the plate and hardware breakage.

There has been a proliferation of plating systems with variable locking mechanisms in recent years, all with their own purported advantages. No information exists in the spine surgery literature about the physical characteristics of these plating systems. The first purpose of this study was to consolidate physical information for 10 commonly used plates. Secondly, six of the systems were evaluated for screw pushout strength. The goal was to expand the spine surgeon’s understanding of the versatility of each plating system.

Materials and methods

Test systems included cervical spine locking plate (CSLP) (Synthes, Paoli, PA); Orion, Premier, Zephr and Atlantis (Sofamor-Danek, Memphis, TN); Vuelock (EBI, Parsippany, NJ); PEAK and DOC (Depey-AcroMed, Cleveland, OH); Aline (Surgical Dynamics, Memphis, TN) and the Blackstone (Blackstone Medical, Inc., Springfield, MA). These 10 plate systems are not inclusive of all plating systems available today. Additionally, only six of the systems were made available for the biomechanical pushout testing. These systems were CSLP, Orion, Vuelock, PEAK, Aline and the Blackstone.

Using a caliper accurate to 0.1 mm, repeated physical measurements were made for each plate variable. Characteristics studied for each system included the height or profile, the maximal width, the distance between the nearest screw hole to the end of the plate and the shortest normalized and rescue screw. Details were obtained to demonstrate the range of lengths for plates designed for one, two, three and four levels of fusion, as well as the incremental length increases for each of these plate designs.

Biomechanical testing was carried out with six different plate styles. Each plating system tested was prepared for screw pushout testing by potting the plate in a polyvinyl chloride cup with lead epoxy with a pit beneath the screw to allow the pushout of the single screw being tested (Fig. 1). The plate was stabilized with additional screws to the potted surface to prevent motion of the plate. Each plate was tested with the locking mechanism in place at the manufacturers’ recommendations, including appropriate torque settings for the locking mechanism screws. The fixation screw was tested at manufacturers’ optimal position to the plate, either 90 degrees or slight angulation away from the center of the plate. All constructs were maintained at body temperature (37 degrees Centigrade) for the testing. Testing was performed with a materials testing system (model 1321; Instron Corporation, Canton, MA). The pushout strength value was the force at which the screw uncoupled from the plate.

![Fig. 1. Potting technique used for each plate. PEAK plate demonstrated. Pit beneath each of the upside down screws allows pushout of the individual screw.](image)

Statistical analysis

A single-factor analysis of variance (ANOVA) was performed to compare the pushout strengths of the screw-plate constructs for the different plate systems.

Results

Table 1 summarizes height, width, screw length and distance from the end of the plate to the nearest screw hole. Heights ranged from 1.8 to 3.2 mm, widths form 14.9 to 20.7 mm, and end of the plate to near screw measurement ranged from 1.4 to 3.2 mm. Of note also, four systems had rescue screws for which the minimum length was longer than the minimum length standard screw. Table 2 summarizes the locking mechanism and angulation position of the screw to the plate. Some are fixed angle and some are variable.

Table 3 details the variation in plate length. The Orion has a continuous slot and therefore has a non–level-specific design for any number of fusion levels. A single screw may be placed at any point between the two ends of the plate, as the surgeon desires. The multilevel style of plate assumes that the surgeon is trying to place screws in separate vertebral bodies after individual anterior discectomies. These designs are specific for a given number of fusion levels depending on the number of levels of screw holes between the ends of the plate. The variability is in the overall length of the plate, the increment in plate length, and the number of intermediate holes.
Each of the plate systems reviewed had some differences in locking mechanism. However, the plates could be loosely grouped into general categories by type of locking mechanism (Table 4). The types were 1) expansion screw; 2) locking ring; 3) blocking plate, set screw or flange and 4) a separate threaded bushing within the plate. The expansion screw locking mechanism (Type 1) is characterized by a hollow head of the bone fixation screw head, with longitudi-

Table 1
Physical measurements of cervical plates

<table>
<thead>
<tr>
<th>Name of plate</th>
<th>Height (profile)</th>
<th>Width</th>
<th>Distance edge of plate to near screw</th>
<th>Shortest normal</th>
<th>Screw rescue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aline*</td>
<td>2.4</td>
<td>19.0</td>
<td>1.7</td>
<td>10</td>
<td>12</td>
</tr>
<tr>
<td>Blackstone†</td>
<td>2.6</td>
<td>17.8</td>
<td>1.4</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>Premier‡</td>
<td>2.6</td>
<td>17.9</td>
<td>3.1</td>
<td>10</td>
<td>13</td>
</tr>
<tr>
<td>Orion‡</td>
<td>2.6</td>
<td>17.9</td>
<td>3.2</td>
<td>10</td>
<td>11</td>
</tr>
<tr>
<td>Atlantis‡</td>
<td>2.7</td>
<td>17.8</td>
<td>2.6</td>
<td>10</td>
<td>13</td>
</tr>
<tr>
<td>Zephyr‡</td>
<td>1.8</td>
<td>14.9</td>
<td>1.7</td>
<td>13</td>
<td>13</td>
</tr>
<tr>
<td>PEAK§</td>
<td>3.2</td>
<td>18.1</td>
<td>2.9</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>DOC§</td>
<td>2.4</td>
<td>17.7</td>
<td>2.0</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>CSLP§</td>
<td>2.0</td>
<td>20.7</td>
<td>2.2</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>CSLP SS§</td>
<td>2.1</td>
<td>16.4</td>
<td>2.1</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>CSLP VA§</td>
<td>2.6</td>
<td>18.1</td>
<td>2.3</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>Vuelock¶</td>
<td>2.4</td>
<td>18.0</td>
<td>1.8</td>
<td>12</td>
<td>12</td>
</tr>
</tbody>
</table>

SS = short stature; VA = variable angle.
* Surgical Dynamics, Memphis, TN.
† Blackstone Medical, Inc., Springfield, MA.
‡ Sofamor-Danek, Memphis, TN.
§ Depuy-AcroMed, Cleveland, OH.
¶ Synthes, Paoli, PA.
§§ EBI, Parsippany, NJ.

Table 2
Locking mechanisms and screw angulation to plate

<table>
<thead>
<tr>
<th>Name</th>
<th>Locking mechanism</th>
<th>Allowable angulation of screws to plate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aline*</td>
<td>Inner expansion screw compresses head of screw to plate.</td>
<td>Screw to plate variation</td>
</tr>
<tr>
<td>Blackstone†</td>
<td>Top-locking cover plate</td>
<td>Variable screw alignment 0–30 degrees</td>
</tr>
<tr>
<td>Premier‡</td>
<td>Locking screw covers head of plate screws.</td>
<td>Fixed angle screw</td>
</tr>
<tr>
<td>Orion‡</td>
<td>Locking screw covers head of plate screws.</td>
<td>Fixed at one end but may angle 0–12 degrees away. A variable slot at other end, ideal 12 degrees up to 20 degrees away</td>
</tr>
<tr>
<td>Atlantis‡</td>
<td>Locking screw covers head of plate screws.</td>
<td>Variable angulation middle screws. Single screw placed through a slot that allows placement anywhere top to bottom of plate. End screws fixed at 15 degrees away from middle of plate</td>
</tr>
<tr>
<td>Zephyr‡</td>
<td>Locking flange blocks screw from backing out.</td>
<td>Fixed 12 degrees away, variable 2 degrees to center, 0–22 degrees away</td>
</tr>
<tr>
<td>PEAK§</td>
<td>Plate bushing with separate threads locks screw to plate.</td>
<td>Cephalic and caudal screws 0–16 degrees. Middle screws 0–7 degrees arc. Two screws at each end, but only one for middle segment</td>
</tr>
<tr>
<td>DOC§</td>
<td>Inner expansion screw compresses head of screw to plate.</td>
<td>Up to 25 degrees angulation in a conical arc. Two screws fixed at 0 degrees</td>
</tr>
<tr>
<td>CSLP§</td>
<td>Inner expansion screw compresses head of screw to plate.</td>
<td>Fixed 0 degrees caudal and 12 degrees cephalic</td>
</tr>
<tr>
<td>CSLP SS§</td>
<td>Inner expansion screw compresses head of screw to plate.</td>
<td>Fixed 0 degrees caudal and 6 degrees cephalic</td>
</tr>
<tr>
<td>CSLP VA§</td>
<td>Inner expansion screw compresses head of screw to plate.</td>
<td>Fixed 0 degrees caudal and 6 degrees cephalic</td>
</tr>
<tr>
<td>Vuelock¶</td>
<td>Preattached expansive ring design locks screw below the ring.</td>
<td>20 degrees variable in conical arc</td>
</tr>
</tbody>
</table>

SS = short stature; VA = variable angle.
* Surgical Dynamics, Memphis, TN.
† Blackstone Medical, Inc., Springfield, MA.
‡ Sofamor-Danek, Memphis, TN.
§ Depuy-AcroMed, Cleveland, OH.
¶ Synthes, Paoli, PA.
§§ EBI, Parsippany, NJ.
nal slots in the head to allow expansion of the head of the screw. There is an inner screw applied to expand the head of the fixation screw, which increases the rigidity of the coupling of the fixation screw to the plate. The CSLP was the initial design of the expansion screw locking design, and the Aline plate has a modification on the expansion screw mechanism with a more bulbar head and a longer inner screw. The inner screw can apply more torque slowly through its longer threaded length. The DOC has a similar expansion screw locking mechanism. The locking ring type of locking mechanism (Type 2) is characterized by a ring device pressed into the plate. The Vuelock has a snap-ring that the fixation screw passes through and is locked beneath. This ring locks the screw beneath the ring and the surface of the plate but does allow a degree of conical screw positioning for optimal screw placement, without locking the screw rigidly to the plate. The DOC has a similar expansion screw locking mechanism. The locking ring type of locking mechanism (Type 2) is characterized by a ring device pressed into the plate. The Vuelock has a snap-ring that the fixation screw passes through and is locked beneath. This ring locks the screw beneath the ring and the surface of the plate but does allow a degree of conical screw positioning for optimal screw placement, without locking the screw rigidly to the plate. The blocking type of mechanism (Type 3) is characterized by a second screw, flange or blocking cover that is screwed down onto the heads of the fixation screws to block the fixation screw from pushing out. The blocking type includes the plates of Sofamor-Danek (Atlantis, Orion, Prestige and the Zephyr) and the Blackstone plate. Type 4, the PEAK, has a movable polyaxial bushing, which secures the screw to the plate by a separate threaded area mating the screw to the plate.

Pushout strengths were tested for six systems and ranged from 215 neutons (N) to 2662 N. Fig. 2 tabulates the pushout strengths of the six plate systems with statistical comparison (ANOVA). The CSLP and the Aline failed with a pushout of the screw from the plate The Vuelock failed by a pushout of the locking ring from the plate, carrying the screw with it. The Orion failed by pushing out the central locking screw. The Blackstone failed by the screw pushing the cover plate up and away from the main plate. The PEAK failed by pushing out the bushing from the plate carrying the screw with it. Comparison of pushout strengths showed a significant difference between all the plates, with p values ranging from $1.5 \times 10^{-3}$ to .007. Of the six systems, the expansion screw locking mechanism demonstrated the weakest pushout values.

**Discussion**

As the usage of cervical plates has increased, so too has the number of cervical plating systems. There is variability in these plates. Technical problems arise during surgery, and certain features within the plating systems more easily address these. For example, some patients have a smaller bone surface area of the anterior cervical spine and do not accommodate wide plates and longer screws. Lordosis is variable also. Therefore, optimal screw to plate angles vary as well. There is generally an optimal plate length, one that clearly spans the fusion levels but does not abut or overhang adjacent levels. Sometimes there is a wide range of acceptable lengths, but other times, particularly in the presence of a partial corpectomy, there is a narrow range of optimal lengths. Features of the optimal plate include not only the incremental distance between holes, but also the distance from the end of the plate to the near hole. Lastly, particularly with three- or four-level fusions, it has been our expe-

---

**Table 3**

Length of plates designed for one- to four-segment coverage

<table>
<thead>
<tr>
<th>Name of plate</th>
<th>One-segment</th>
<th>Two-segment</th>
<th>Three-segment</th>
<th>Four-segment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Length</td>
<td>Increment</td>
<td>Length</td>
<td>Increment</td>
</tr>
<tr>
<td>Aline*</td>
<td>22–28</td>
<td>2</td>
<td>28–48</td>
<td>4</td>
</tr>
<tr>
<td>Blackstone†</td>
<td>23–36</td>
<td>2</td>
<td>38–54</td>
<td>2</td>
</tr>
<tr>
<td>Premier‡</td>
<td>23–25</td>
<td>2</td>
<td>25–90</td>
<td>2.5</td>
</tr>
<tr>
<td>Orion‡</td>
<td>21.5–23</td>
<td>1.5</td>
<td>23–25</td>
<td>2</td>
</tr>
<tr>
<td>Atlantis‡</td>
<td>14–25</td>
<td>2</td>
<td>35–47.5</td>
<td>2.5</td>
</tr>
<tr>
<td>Zephyr‡</td>
<td>22.5–25</td>
<td>2</td>
<td>27.5–47.5</td>
<td>2.5</td>
</tr>
<tr>
<td>PEAK‡</td>
<td>24–30</td>
<td>2</td>
<td>39–63</td>
<td>3</td>
</tr>
<tr>
<td>DOC§</td>
<td>16–28</td>
<td>2</td>
<td>30–42</td>
<td>3</td>
</tr>
<tr>
<td>CSLP SS¶</td>
<td>20–34</td>
<td>2</td>
<td>34–54</td>
<td>3</td>
</tr>
<tr>
<td>CSLP VA¶</td>
<td>23–35</td>
<td>2</td>
<td>37–55</td>
<td>3</td>
</tr>
<tr>
<td>Vuelock§</td>
<td>12–24</td>
<td>2</td>
<td>26–42</td>
<td>2</td>
</tr>
</tbody>
</table>

SS = short stature; VA = variable angle.
* Surgical Dynamics, Memphis, TN.
† Blackstone Medical, Inc., Springfield, MA.
‡ Sofamor-Danek, Memphis, TN.
§ Depuy-AcroMed, Cleveland, OH.
¶ Synthes, Paoli, PA.
§§ EBI, Parsippany, NJ.
rience that there is a much greater variation in usual length of plates. Sometimes, the ideal length plate does not correspond to the number of fusion levels for which it is intended. In this situation the surgeon is unable to use most if not all of the intermediate fixation screws. Overlap in lengths of plates designed for three- and four-level fusions helps prevent this problem.

Familiarity with plating system features should allow the surgeon to individualize and optimize plate selection. Ideally, plates should have narrow and wider choices, small increments in plate length, with short end of plate to near hole distances, overlap in lengths from two- to three- and from three- to four-level implants, low profiles and good visibility of the grafted levels. Screws should ideally come in variable lengths starting at 10 mm, have variable placement angulation capability, have rescue screws of the same length as the corresponding standard screw and be easily placed with a reliable locking mechanism.

The contemporary cervical plating system is designed for unicortical placement to prevent posterior bicortical penetration of the cervical vertebra and injury to neurologic structures. The locking mechanism has evolved for two functions; one is to increase plate-screw rigidity while allowing unicortical fixation of the plate to the vertebra [25]. The second is to prevent pushout failure of the screw from the plate [25].

Lowery and McDonough [28] found hardware failure in the cervical spine is more common the longer the patient is observed after surgery. There was a 35% failure rate overall but only 18% failure of constrained cervical plates [28]. Most hardware failures are inconsequential when the patient is not symptomatic. Long-term observation is suggested, and immediate removal of hardware is rarely necessary. They reported no patient had tracheal-esophageal erosion or neurovascular compromise as a result of the instrumentation failure [28,29].

Although not common, cervical plate bone screws do fail with pushout from the plate. Geyer and Foy [30] described erosion through the esophagus with subsequent oral extrusion of a locked expansion type screw originating from a cervical plate. In this case initial failure was pullout of the screw from the bone, followed by later pushout failure of the screw from the plate [30]. The authors have had two additional cases that required revision because of symptomatic screw pushout (Figs. 3 and 4).

This pushout testing may be criticized because the forces may be higher than are physiologically possible, and clinically, failure may not be purely a pushout mechanism. Each plate was tested to failure of the screw from the plate, and some plates required large pushout forces. In vivo, theoretically one might not require such large forces. Perhaps the failure of a locking mechanism may occur more slowly, first

<table>
<thead>
<tr>
<th>Statistical Analysis (p value)</th>
<th>Aline</th>
<th>Vuelock</th>
<th>Peak</th>
<th>Orion</th>
<th>Blackstone</th>
</tr>
</thead>
<tbody>
<tr>
<td>CSLP</td>
<td>p=4.3E-09</td>
<td>p=2.9E-09</td>
<td>p=2.7E-12</td>
<td>p=9.5E-08</td>
<td>p=3.6E-07</td>
</tr>
<tr>
<td>Aline</td>
<td>p=1.1E-06</td>
<td>p=6.5E-11</td>
<td>p=0.007</td>
<td>p=6.1E-06</td>
<td>p=0.002</td>
</tr>
<tr>
<td>Vuelock</td>
<td>p=1.1E-07</td>
<td>p=1.5E-09</td>
<td>p=0.006</td>
<td>p=4.1E-05</td>
<td></td>
</tr>
</tbody>
</table>

Fig. 2. Pushout strengths of six plate systems with statistical comparison (analysis of variance).
after failure of the fixation to the bone. The authors acknowledge there are differences in failure from a single pushout force and failure from physiological cyclical stress, as might occur from nonunion or after failure of the screw from the bone. This mode of testing of a locking mechanism is a new method to demonstrate differences of characteristics of the cervical plate locking mechanisms. It does not prove that one pushout strength is necessarily better, only that there are differences between the locking mechanisms. The clinical significance of this difference requires further investigation.

Conclusions

All locking mechanisms significantly increased the pushout strength of the tested screw-plate systems. The expansion screw had the lowest pushout values. These data demonstrate a range of pushout strengths exists across the selections of available cervical plate systems today. Further study is needed to understand the optimal or minimal pushout strength to avoid this mode of failure. In addition, each plate has several unique physical characteristics, which permits the knowledgeable surgeon to choose the best plating system for each individual patient.

References

Two Hundred Fifty Years Ago in Spine . . .

The prototype of the controlled therapeutic trial was the experimental work done on scurvy by James Lind, which he reported in 1753. Lind, a native of Scotland, was a physician in the Royal Navy. Various reports of the use of citrus to treat or prevent scurvy among sailors preceded Lind’s work, but his organized trial and thorough report convinced the Admiralty and led to measures that eradicated scurvy from the Navy.

References

Physical Characteristics of Polyaxial-Headed Pedicle Screws and Biomechanical Comparison of Load With Their Failure

Guy R. Fogel, MD, Charles A. Reitman, MD, Weiqiang Liu, PhD, and Stephen I. Esses, MD

Study Design. Pedicle screw strength or load to failure was biomechanically evaluated, and the geometric characteristics of pedicle screw instrumentation systems were compared.

Objectives. To compare the features of pedicle screw systems, and to demonstrate the failure point of the polyaxial pedicle screw head.

Summary of Background Data. Many pedicle screw instrumentation systems are currently available to the spine surgeon. Each system has its unique characteristics. It is important for the surgeon to understand the differences in these pedicle screw systems. Pedicle screw load to failure has not been subjected to a comparison study.

Methods. The physical characteristics of each pedicle screw instrumentation system were determined. Features of rods, instruments, and pedicle screws were cataloged. Biomechanical testing of the pedicle screw construct was performed to determine the site and force of the load to failure. Nine pedicle screw systems were evaluated. Testing was performed with a pneumatic testing system under load control. Three polyaxial screws were used for each test at a load rate of 100 N/second. The load failure value was the force at which the pedicle screw or polyaxial head–screw interface initially deflected.

Results. Biomechanical testing demonstrated in all instances that the polyaxial head coupling to the screw was the first failure point. Although there have been subtle design differences in the instruments over time, the features of the pedicle screw instrument sets have become remarkably similar.

Conclusions. Biomechanical pedicle screw load-to-failure data demonstrated that the polyaxial head coupling to the screw is the first to fail and may be a protective feature of the pedicle screw, preventing pedicle screw breakage. Knowing the physical characteristics of the available pedicle screw instrumentation systems may allow the choice of pedicle screw best suited for a given clinical situation. [Key words: biomechanics, equipment design, pedicle screws, spinal fusion/instrumentation, surgery] Spine 2003;28:470–473

Polyaxial heads have made the pedicle screw more versatile, particularly improving ease of connecting rod application.

Clinically, the senior author has observed that the incidence of broken pedicle screws has diminished over the past several years coincidentally with the usage of polyaxial screws. A hypothesis was developed to explain the decreased breakage of pedicle screws. It may be that there is a subtle loosening or failure of the polyaxial head that removes some of the stress from the pedicle screw. By decreasing the stiffness in the coupling of the polyaxial head to the pedicle screw, the bending stresses on the pedicle screw would be lessened. A MEDLINE search showed no biomechanical evidence in the English spine literature regarding the testing of polyaxial screws. In addition, polyaxial-headed pedicle screw load-to-failure testing has not been subjected to a comparison study.

Methods

Nine pedicle screw systems were evaluated: the Silhouette (Sulzer Spine-Tech, Minneapolis, MN), Blackstone (Blackstone Medical, Springfield, MA), Click-X (Synthes, Paoli, PA), Xia (Stryker-Howmedica, Warsaw, IN), M8 (Sofamor-Danek, Memphis, TN), Miami-MOSS, Monarch, and Magnum (Depuy-AcroMed, Cleveland, OH), and the SD-90 (Surgical Dynamics, Memphis, TN). Not all of the commercially available pedicle screws were available for testing. The screw lengths were standardized at 45 mm, and the diameters varied from 6 to 7.5 mm.

Each tested screw was mounted perpendicularly on the appropriate rod provided by the vendor at the manufacturer’s recommended torque settings. The distal half of the screw body was potted in the shape of a ceramic cylinder to enhance contact with the MTS machine. Testing was performed with a materials testing system (Model 1321; Instron, Canton, MA) (Figure 1). The MTS force was applied at a point 30 mm from the rod perpendicular to the long axis of the screw. The MTS compressed the screw at a load rate of 100 N/second until failure occurred. The load failure value was the force at which the pedicle screw initially deflected or uncoupled from the polyaxial head.

Results

The geometry of the coupling between the screw and head shows a conforming hemispherical interface that allows for polyaxial motion of the head on the screw. The fixation of the polyaxial head to the rod is with an internal screw, external nut, or both, pushing the rod into the slot of the head. The Silhouette has an external nut securing the rod into the head of the screw, whereas the Miami MOSS and the Magnum have an inner screw head and an external nut both securing the rod into the screw head. The other five systems have an internal screw device securing the rod to the pedicle screw head. To gain
final fixation, all the screws and nuts require torque to specified levels except the Surgical Dynamics SD-90. The SD-90 has a helical wedge that requires only a 90° turn of the inner screw to gain the final fixation. The Monarch also has a dovetail top with a center screw that locks the head to the rod.

The Silhouette had the lowest mean failure load of 213 N, whereas the Magnum was the highest at 486 N. The full results from load-to-failure testing of the pedicle screws are shown in Table 1. Figure 2 shows that the statistical differences ranged from a $P$ of 0.13 to a $P$ of 0.0009. The statistical power was limited in some cases by the small sample size.

### Discussion

Pedicle screw systems have undergone continual modifications over the past several years. As recently as 1 to 2 years ago, there were substantial differences in the design features of these sets. However, the systems have evolved to match the strengths of each other such that there currently are very few differences between instrument sets (Table 2). There have been design changes in the screws themselves. The crosslink systems have been updated, and there currently is a wide selection of screw diameters, lengths, and sizes of cross-links. Two of the systems do offer more than one rod diameter.

The results from the load-to-failure testing of the polyaxial pedicle screws demonstrates that the weakest point of the construct is the head-to-screw coupling (Table 1 and Figure 2). This failure of the polyaxial head may be a protective factor for the pedicle screw shaft, preventing early breakage.

The polyaxial head has three tasks: 1) to secure the rod to the head, 2) to prevent the head from deforming in diameter, and 3) to secure the polyaxial head to the pedicle screw. The outside nut, pin-nut, helical or dovetail wedges, and thicker walled polyaxial head are designed to prevent the head from deforming. The inner screw locks the rod in the head and the head to the screw. The helical wedge actually can do all three tasks with one locking device. All pedicle screw heads have some method to stabilize the diameter of the head and a method to hold the rod in the head. The single outside nut–locking mechanism was statistically weaker than any other design.

Biomechanical tests of pedicle screw constructs have demonstrated the fundamental importance of the bone implant interface, bone density, and screw pullout strength. The essential need for fit and fill of the screw in the isthmus of the pedicle has been proved. The direct relation between pullout strength and insertion torque has been well demonstrated, and the fundamental improvement in pullout strength obtained by cross-linking has been documented. The stabilizing influence of using converging screws has been shown. The major diameter of a pedicle screw has been shown to control pullout strength. Bicortical purchase increased pullout strength fundamentally both in individual vertebrae and in the sacrum. However, bicortical

### Table 1. Load to Failure of Polyaxial Head of Pedicle Screw

<table>
<thead>
<tr>
<th>Screw System</th>
<th>Mean (N)</th>
<th>SD</th>
<th>Screw Diameter (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silhouette</td>
<td>213.21</td>
<td>25.71</td>
<td>6.5</td>
</tr>
<tr>
<td>BMI</td>
<td>268.88</td>
<td>38.06</td>
<td>6.5</td>
</tr>
<tr>
<td>Moss Miami</td>
<td>280.02</td>
<td>13.31</td>
<td>6</td>
</tr>
<tr>
<td>M8</td>
<td>340.57</td>
<td>31.18</td>
<td>6.5</td>
</tr>
<tr>
<td>Click’X</td>
<td>349.54</td>
<td>42.53</td>
<td>7</td>
</tr>
<tr>
<td>SD90</td>
<td>357.99</td>
<td>25.44</td>
<td>6.75</td>
</tr>
<tr>
<td>Xia</td>
<td>397.72</td>
<td>25.5</td>
<td>7.5</td>
</tr>
<tr>
<td>Monarch</td>
<td>447.67</td>
<td>28.38</td>
<td>7</td>
</tr>
<tr>
<td>Magnum</td>
<td>486.24</td>
<td>24.05</td>
<td>7</td>
</tr>
</tbody>
</table>

SD = standard deviation.
purchase, except at the sacrum, has not been widely adopted by surgeons because of the risk for vascular injury. Nevertheless, bicortical sacral purchase has been proved extremely safe and has gained widespread acceptance.

Biomechanical testing of the load characteristics of the polyaxial pedicle screw was not reported in the literature reviewed for this study. This testing has further detailed the biomechanical characteristics of the polyaxial pedicle screw. The results of this testing demonstrate a range of load tolerances for the various systems. Although the testing does show that some polyaxial pedicle screws are stronger, it is important to note that it is not clear whether a stronger coupling of pedicle screw to head is better. There may be instances in which more or less rigid fixation is preferable. Further study is needed to investigate the physical properties and their clinical application.

### Conclusions

Biomechanical pedicle screw load-to-failure data demonstrated that the polyaxial head coupling to the screw was the first failure point and may be a protective feature of the pedicle screw and rod, preventing pedicle screw or rod breakage. Knowing the physical characteristics of the available pedicle screw instrumentation systems may allow the choice of pedicle screw best suited for a given clinical situation.

### Key Points
- The polyaxial head coupling of the pedicle screw is the first feature to fail.
- This may protect the pedicle screw from breaking.
- There is a wide range of pedicle screw construct failure loads.

### Table 2. Pedicle Screw Sets Characteristics

<table>
<thead>
<tr>
<th>Screw Diameter (mm)</th>
<th>Rod Diameter (mm)</th>
<th>Screw-rod Locking Mechanism</th>
</tr>
</thead>
<tbody>
<tr>
<td>Danek CDH</td>
<td>4.5, 5.0, 5.5, 6.5, 7.5, 8.5</td>
<td>4.5, 5.5, 6.35, Inner set screw, Buttress thread</td>
</tr>
<tr>
<td>Surgical Dynamics SD-90</td>
<td>4.75, 5.75, 6.75, 7.75, 8.75</td>
<td>5.5, Twisting saddle nut</td>
</tr>
<tr>
<td>Depuy Miami-MOSS</td>
<td>4.35, 5.0, 6.0, 7.0, 8.0</td>
<td>5.0, 5.5, 6.35, Inner pin nut in 5.5 mm diameter rod.* Inner and outer nut for 5.0 and 6.35 mm rod</td>
</tr>
<tr>
<td>Monarch</td>
<td>4.75, 5.5, 6.25, 7, 7.75, 8.5</td>
<td>5.5, Dove tail cap with prethreaded set screw</td>
</tr>
<tr>
<td>Magnum</td>
<td>6.7-8</td>
<td>6.35, Inner set screw</td>
</tr>
<tr>
<td>Blackstone</td>
<td>4.5, 5.5, 6.5, 7.5, 8.5</td>
<td>5.5, Outer nut</td>
</tr>
<tr>
<td>Spine-Tech Silhouette</td>
<td>4.5, 5.5, 6.5, 7.5, 8.5</td>
<td>5.5, Inner set screw</td>
</tr>
<tr>
<td>Synthes Click-X</td>
<td>5.2, 6.2, 7.0, 8.0, 9.0</td>
<td>6.0, Inner set screw</td>
</tr>
<tr>
<td>Stryker XIA</td>
<td>4.5, 5.5, 6.5, 7.5, 8.5</td>
<td>6.0, Inner set screw, Buttress thread</td>
</tr>
</tbody>
</table>

* Currently the Miami Moss 5.5 Titanium system uses the pin nut, while 5.0 and 6.35 mm rods in both steel and Titanium use the inner screw and outer nut locking mechanism.
References

CASE CONFERENCE

Management of Chronic Limb Pain with Spinal Cord Stimulation

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Abstract:

Background: Spinal Cord Stimulation (SCS) is a treatment option for chronic pain patients. The most common indication for SCS is the failed back syndrome with leg pain. In the last decade, advances in our understanding of appropriate stimulation programming, lead placement and the physiology of SCS, have led to changes in multi-site stimulation, and stimulation with differing programs. In the past, low back, axial neuropathic type pain was not responsive to SCS. With dual electrode arrays, and dual stimulation with alternating programs of stimulation, steering of stimulation paresthesia, and versatile programmable stimulation parameters, SCS has become a more versatile form of analgesia.

Purpose: To describe the current treatment rational for SCS and the results of that treatment.

Results: The SCS is most efficient in patients with neuropathic pain of the extremities and less efficacious in patients with axial pain.

Conclusion: SCS is the most effective treatment for limb pain not amenable to surgical decompression. The success of SCS in this chronic pain group is 80% successful in treatment of leg pain, and much less effective in treatment of axial pain.

INTRODUCTION

The rational use of implantable technologies for pain control should be founded on the knowledge of the neurobiology of pain, and the clinical presentations of pain syndromes. The treatment modalities of the pain management practitioner include all of the modalities and therapies, conservative, pharmacologic, and invasive, used to treat chronic pain syndromes. The purpose of this paper is to describe the basis for the rational use of 1 implantable modality, Spinal Cord Stimulation (SCS).

Electrical stimulation was first considered for treatment of intractable pain based on the publication of the gate control theory of pain by Melzack and Wall in 1965. Shealy et al, in 1967, first introduced electrical stimulation of the spinal cord and peripheral nerves for chronic limb pain. In the decade following the studies, several thousand stimulators were implanted. The initial enthusiasm was dampened by reports of high complication and failure rates. At issue, were increased breakage and displacement of electrical leads, and failure of the implanted receiver, the high cost of the implant, and difficulty defining the patient population, which could respond with a reasonable pain relief percentage.

SCS has been applied to a variety of diagnoses, including tumors, brachial plexus injuries, spinal cord injury, multiple sclerosis, peripheral vascular disease and ischemic limb pain, ischemic cardiac angina, arachnoiditis, and pain after failed back surgery. However, even among those with intractable lower extremity pain, the outcome results have shown wide variability.

In the last decade, advances in our understanding of appropriate stimulation programming, lead placement and the physiology of SCS, have led to changes of multisite stimulation, and stimulation with differing programs. In the past, low back, axial neuropathic type pain was not treatable, but with dual electrode arrays, and dual stimulation with alternating programs of stim-
ulation, steering of stimulation paresthesia, and versatile programmable stimulation parameters, SCS has become a more versatile form of analgesia. However, based on results, the SCS is most efficient in patients with neuropathic pain of the extremities and less efficacious in patients with axial pain.11,12

CHARACTERISTICS OF CHRONIC PAIN
Chronic physical pain may be divided into 2 types: nociceptive and neuropathic pain. The differences are important in predicting the efficacy of SCS to treat the chronic pain. Nociceptors are the nerves which sense and respond to injury of the body. They signal tissue irritation, impending injury, or actual injury. When activated, they transmit pain signals (via the peripheral nerves as well as the spinal cord) to the brain. The pain is typically well localized, constant, and often with an aching or throbbing quality. This is normal pain in response to injury of the body.

Neuropathic pain is the result of an injury or malfunction in the peripheral or central nervous system. Neuropathic pain is not caused by nociceptors; however, the pain is often triggered by an injury. The pain frequently has burning, lancinating, or electric shock qualities. Hyperpathia and allodynia are symptoms of neuropathic pain. Hyperpathia is an increased pain from a stimulus which would be painful normally. Allodynia is pain from stimuli, which are not normally painful, or pain that occurs other than in the area stimulated. Persistent allodynia is also a common characteristic of neuropathic pain. The pain may persist for months or years beyond the apparent healing of any damaged tissues. Examples include post herpetic neuralgia, reflex sympathetic dystrophy, causalgia, components of cancer pain, phantom limb pain, entrapment neuropathy, and peripheral neuropathy. Neuropathic pain is frequently chronic, and tends to have a less robust response to treatment with opioids.

In some conditions the pain appears to be caused by a complex mixture of nociceptive and neuropathic factors. An initial nervous system dysfunction or injury may trigger the neural release of inflammatory mediators and subsequent neurogenic inflammation. For example, Failed back syndrome probably represent a mixture of neuropathic and nociceptive pain. A second example, myofascial pain is probably secondary to nociceptive input from the muscles, but the abnormal muscle activity may be the result of neuropathic factors.

Spinal Cord Stimulation is indicated for patients suffering from chronic intractable pain of the trunk or limbs. In terms of pain type, SCS is most effective for treating peripheral neuropathic pain which results from actual damage to the peripheral nerves. Causalgia is an example of peripheral neuropathic pain. SCS is generally not effective for treating 2 other types of pain: (1) nociceptive pain, which results from nerve irritation (not damage) caused by noxious stimuli such as heat, pressure, or chemicals (burn pain, muscle injury pain, and cancer pain are examples of nociceptive pain and (2) central pain which is caused by Central Nervous System (CNS) damage from a stroke or spinal cord injury.

HISTORICAL REVIEW
Application of electrical current through the skin began in the mid 1790 and by the early 20th century, different types of electrical devices were available. However, with the increased availability of different types of analgesic drugs and ablative pain relieving procedures such as rhizotomy, cordotomy, and thalamotomy, the electrical devices had little use and were abandoned. Modern pain control with electricity started with the report of Melsack and Wall who proposed the gate theory of pain.1 Within the year, Wall and Sweat demonstrated peripheral nerve stimulation could bring pain relief. 13 Shealy devised an implantable type of stimulator for the spinal cord known as a dorsal column stimulator.2 In the seventies, Long and Sweat independently reported implantable peripheral nerve stimulators.3,4 Soon afterward, an implantable deep brain stimulator was reported by Hosobuchi and Adams.14 The initial theory of the function of the stimulator was to inhibit the C-fibers by stimulating the larger myelinated fibers.2 Even today, the mechanism of pain relief is poorly understood.

Initially, stimulation was difficult to promote widely for several reasons. There was the general lack of experience with treatment of this difficult group of pain patients. Also a lack of understanding of the co-morbidities of the patient’s chronic pain syndrome, and inappropriate patient selection, all lead to poor widespread acceptance. With the advent of electrodes implanted through a needle under local anesthesia and a decrease in complications such as breakage and migration of leads, and the infection rate, the usage of the spinal cord stimulators has risen again.

INDICATIONS
The patient with intractable pain who is most likely to be helped by a spinal cord stimulator would have leg
pain of greater intensity than back pain, chronic pain of more than 6 months duration that failed to respond to conservative measures, or was not a candidate for conventional surgical treatment. Many have had multiple back surgeries. Some had reflex sympathetic dystrophy. In addition to the long history of back and leg complaints, many patients have additional health problems, including diabetes, hypertension, arthritis, renal and cardiac disease, multiple nonspinal operations, history of Hodgkin’s lymphoma, other cancers, gastrointestinal maladies and Paget’s disease. These patients are of any age 20–85 years. They have all been treated with narcotic medications for pain relief before the spinal cord stimulator. The patient is found to be refractory to conservative modalities of pain relief. All patients should have a benign form of intractable pain with an organic basis. The pain may be radicular or nonspecific but should be worse in the extremities, usually legs. Some axial pain is acceptable. There should not be a major psychiatric condition. Testing may include visual analog scales to assess leg and back pain intensity. Pain Drawings identify the extent of the painful areas of the back and extremities.

SCS has been most effective in treating neurogenic pain of peripheral origin. The SCS will relieve pain only if paresthesias are induced in the area of the patient’s pain, and some say, if the pain returns after the stimulation is stopped, although there is no scientific substantiation.

The most common diagnosis treated by SCS, is failed back syndrome. Failed back syndrome (FBS) may be defined as chronic pain associated with degenerative spondylosis usually lumbar, associated with a history of previous surgery and absence of current surgical indications. The FBS patients have lower extremity pain and dysesthesias associated with axial back pain. The limb pain may be in a particular dermatome, however many FBS will not have an anatomic radiculopathy. Most series do not differentiate in the types of diagnosis or leg pain. Many authors report less satisfactory outcome in treatment of axial pain. This may be related to the presence of less receptive nociceptive pain or during the trial setting, that paresthesias may not be reproduced in the axial locations of the pain. Relief of cancer pain is also reported as poor. Usually SCS is not effective in central pain such as stroke or spinal cord injury. However, SCS may be effective, if paresthesias are reproduced in the patient’s painful area. SCS has been effective in angina and claudication of peripheral vascular disease.

The stimulator is commercially available. The basic principles have remained the same, since the early pioneering work of Shealy. The electrode is designed to fit the field of stimulation, spinal cord, peripheral nerve, or deep brain. The electrode may be monopolar or quadripolar. A bipolar lead was evaluated and discarded. There is no particular difference in the electrode performance. However, the need for subsequent revision of the electrode is 24.5% in the quadripolar versus 68.4% in the monopolar. There is less “lead migration,” breakage, and a lower infection rate. One factor in the difference of revision rates between the 2 electrode types may be that the monopolar is always used in trial stimulation and may be incorporated in the permanent placement of an implant. The quadripolar is only used in permanent implant group.

The electrode is connected to a passive receiver, or a battery powered stimulator. The battery powered units are self powered and activated by external control. The passive receivers are activated by a radio signal transmitted by antennae. The patient has complete control of the duration and strength of stimulation. Incorporation of the trial stimulation period had improved the selection of long term implant patients.

The trial procedure

There should be a separate trial stimulation procedure and a permanent implantation in those patients who have a favorable pain relief response with paresthesias produced in the area of the patient’s pain. The implantation of trial electrodes may be done with a local anesthetic in a day surgery, or as an overnight hospital stay. Most trial and permanent electrodes are inserted through an epidural Tuohy needle. Sometimes a laminectomy is required in the lower thoracic spine to place the electrode in the epidural space under direct vision. The laminotomy is usually required in the presence of previous surgery, technical difficulty, or epidural scarring. After implantation, the electrode is connected to a handheld programmer that allows various levels of stimulation to be tested during the trial period. Patients are encouraged to increase their activities to near normal during the trial. This should give some indication of the extent to which the permanent stimulator could be expected to control pain levels. After demonstrating greater than 50% reduction of pain, the patient will undergo the permanent implantation of the stimulating system. The pulse generator is implanted in a sur-
induced analgesia, using microdialysis has demonstrated taurine and glycine have been studied in relation to SCS-to participate in nociception. Inhibitory transmitters like various aminoacid neurotransmitters have been shown have been demonstrated. The effects of SCS are release is caused by SCS. No increase in opiod peptides analgesia. There is no evidence that endogenous opiod neurochemical mediators may mediate the SCS induced chronic nociceptive pain could be suppressed. This has not turned out to be accurate. The SCS is almost exclusively beneficial for neuropathic pain and not helpful for nociceptive pain. In the patients with ischemia of angina and peripheral vascular disease, which would be described as nociceptive pain, the SCS may actually have its beneficial effect because of improved ischemia rather than any nociceptive pain relief. In addition to the electrophysiologic mechanism of Melzack and Wall, neurochemical mediators may mediate the SCS induced analgesia. There is no evidence that endogenous opiod release is caused by SCS. No increase in opiod peptides have been demonstrated. The effects of SCS are unchanged by Naloxone, an opiod antagonist. Various aminoacid neurotransmitters have been shown to participate in nociception. Inhibitory transmitters like taurine and glycine have been studied in relation to SCS-induced analgesia, using microdialysis has demonstrated SCS increases the concentration of glycine in spinal cord tissue, and proposes glycine as a reasonable candidate to explain SCS-induced analgesia. Another neurotransmitter, gama-amino butyric acid(GABA), is increased with SCS. Linderoth demonstrated SCS is capable of inducing significant increases of GABA in the dorsal horn of the rat. Further investigations by Linderoth demonstrated increases of serotonin with SCS in decerebrate cats. Serotonin is an important mediator of analgesia at the spinal level; therefore, it is possible that serotonin could be a mediator in SCS-induced analgesia. Catecholamines in SCS induced analgesia may be increased. Noradrenergic mechanisms may modulate the nociception at the spinal level.

SCS is applied with low intensity and generally in the 50–70 Hz and pulse width of 0.2–0.5 msec. Stimulation paresthesiae must cover the entire painful area. SCS must be applied continuously for periods of at least 20–30 minutes. Effective pain relief with SCS is most likely to occur in cases with neuropathic pain. There is little evidence that purely nociceptive forms of pain, whether acute or chronic, will respond. SCS is most effective for on-going spontaneous pain and less for pain evoked by load and posture.

CHARACTERISTICS OF THERAPEUTIC STIMULATION

Recently, some insight has been gained in the physiologic mechanisms underlying the pain relief of SCS. Initially, SCS evolved as a direct clinical application of the well known gate-control theory of Melzack and Wall. However their gate theory would imply all acute and chronic nociceptive pain could be suppressed. This has not turned out to be accurate. The SCS is almost exclusively beneficial for neuropathic pain and not helpful for nociceptive pain. In the patients with ischemia of angina and peripheral vascular disease, which would be described as nociceptive pain, the SCS may actually have its beneficial effect because of improved ischemia rather than any nociceptive pain relief. In addition to the electrophysiologic mechanism of Melzack and Wall, neurochemical mediators may mediate the SCS induced analgesia. There is no evidence that endogenous opiod release is caused by SCS. No increase in opiod peptides have been demonstrated. The effects of SCS are unchanged by Naloxone, an opiod antagonist. Various aminoacid neurotransmitters have been shown to participate in nociception. Inhibitory transmitters like taurine and glycine have been studied in relation to SCS-induced analgesia, using microdialysis has demonstrated

RESULTS

Some patients (20% to 40%) will fail the trial stimulation. There are several reasons reported. There may be a failure to get paresthesias in the area of pain. There may be no response to less than 50% relief of pain to stimulation. Patients who receive 50% relief are usually implanted with permanent stimulator. Kim et al noted 20% immediate failures after permanent implantation. Kim et al noted 20% immediate failures after permanent implantation. Kim et al noted the electrode was the same for the trial and permanent, allowing some placebo effect. An additional 25% to 40% may work well long term and then lose pain control, usually for technical reasons. Most of the technical late failures will improve with revision of the stimulator or electrodes. However, there is a small group that may lose efficiency and not regain it with revision. These are termed “late failures” and current thought is that this may be a manifestation of “tolerance” to the stimulator. Tolerance is described as the gradual loss of pain relief while stimulated, without mechanical problems. This tolerance has been reported with deep brain stimulation also. Kumar notes Amtyriptylline and L-Tryptophan have no benefit in tolerance cases.

See Table 1 for a summary of results from the literature of the last 10 years.
Chronic Limb Pain and Spinal Cord Stimulation

Pain, narcotic usage, return to work, and activities of daily living are deemed measures of success at last follow-up. Pain criteria for success of the SCS have been difficult to decide. Most authors consider SCS successful if there continues to be greater than 50% relief of the index pain level at 1 year after implantation. Narcotic usage is a highly variable follow-up parameter. Some series report reduction in drug usage, and changes to less potent analgesics. Other studies find no reduction. Many authors avoid treating patients who use narcotics excessively. Improved return to work data again is equivocal. Some authors report a higher incidence of return to work. However, a high percentage of the patients are disabled, or retired, skewing the data.7,8,10,37

RESULTS IN DIFFERENT DIAGNOSES

Non-specific limb pain may be treated as effectively as neuropathic pain if a peripheral nerve is the root cause of the pain. Central pain is amenable if paresthesias are obtained in area of pain.8 SCS is the most important pain technique available for treatment of intractable pain of benign origin. SCS may be most valuable in failed back syndrome (FBS).6,11,18–20,37,38,39 SCS has clearly been more effective in relieving intractable leg pain, than in treating axial back pain. SCS is at least as good if not better than re-operation in patients with FBS. For those who have failed surgery, it may be the only pain relief available. In a systematic literature review of patients treated for FBS with SCS, Turner and associates found an average of 50% to 60% of patients with FBS report >50% pain relief with the use of the SCS at follow-up.20

SCS has been very effective in treating Reflex Sympathetic Dystrophy (RSD), in well-defined indications including a history of limb trauma; pain of more than 1 peripheral nerve distribution; physical findings of dystrophy; and a positive response to a sympathetic blockade.40–44 Kemler and associates conducted a randomized, controlled trial of SCS for reflex sympathetic dystrophy.40 The results show that SCS reduces the intensity of pain caused by this disorder in patients in whom all conventional treatments have failed. The success rate was 56% at 6 months in permanently implanted SCS. Kumar et al, reported 12/12 patients with RSD experienced pain relief with trial stimulation and had permanent stimulators implanted.9 At follow-up, 8 patients reported excellent and 4 good results. Kumar concluded SCS is an effective treatment for the pain of RSD and that SCS is superior to ablative sympathectomy in the management of RSD.

SCS with peripheral neuropathy of diabetes and causalgia may have up to 75% success rate.6,7,8,9 Kumar reported only moderate success with peripheral neuropathy. Cases showing the best results were causalgia (100%) and diabetic neuropathy (75%).

Table 1. A Decade of SCS Clinical Series

<table>
<thead>
<tr>
<th>Reference</th>
<th>Study Design</th>
<th>Size</th>
<th>Type Pain</th>
<th>Follow-up</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Devulder J et al 1990</td>
<td>Retrospective</td>
<td>45</td>
<td>Mixed: failed back</td>
<td>5yr</td>
<td>77% Very good pain relief</td>
</tr>
<tr>
<td>Kumar K 1991</td>
<td>Retrospective</td>
<td>121</td>
<td>Mixed: most failed back</td>
<td>6mo to 10yr ave 40mo</td>
<td>40% Pain control by SCS</td>
</tr>
<tr>
<td>North RB 1991</td>
<td>Retrospective</td>
<td>50</td>
<td>Failed back</td>
<td>2.2yr (5yr max)</td>
<td>53% &gt;50% pain relief; 5.0yr: 47% &gt;50% pain relief</td>
</tr>
<tr>
<td>Simpson BA 1991</td>
<td>Retrospective</td>
<td>60</td>
<td>Mixed trauma and failed back</td>
<td>2-9yr (ave 20mo)</td>
<td>Modest 23.3%; significant 46.7%</td>
</tr>
<tr>
<td>Spiegelmann R 1991</td>
<td>Retrospective</td>
<td>43</td>
<td>Mixed, RSD, Failed surgery</td>
<td>3-33mo (ave 13mo)</td>
<td>63% Pain relief</td>
</tr>
<tr>
<td>Tasker RR 1992</td>
<td>Retrospective</td>
<td>35</td>
<td>Mixed, iatrogenic, inflammation, vascular</td>
<td>30yr experience</td>
<td>50% success. 25pts had &gt;than 50% pain relief at 1yr.</td>
</tr>
<tr>
<td>De La Porte C 1993</td>
<td>Retrospective</td>
<td>64</td>
<td>Failed back surgery</td>
<td>1-7yr (ave 4yr)</td>
<td>55% had &gt;50% pain relief</td>
</tr>
<tr>
<td>North RB 1993</td>
<td>Retrospective</td>
<td>205</td>
<td>Mixed</td>
<td>2-20yr (ave 7.1yr)</td>
<td>52% HAD &gt;50% relief pain.</td>
</tr>
<tr>
<td>LeDoux 1993</td>
<td>Retrospective</td>
<td>32</td>
<td>Failed back syndrome</td>
<td>2yr</td>
<td>76% Good at 1yr, 37% 5yr.</td>
</tr>
<tr>
<td>Ohrmeiss 1996</td>
<td>Prospective</td>
<td>40</td>
<td>Failed back syndrome</td>
<td>1-2yr</td>
<td>53% at 6wks, 26% at 1-2yr</td>
</tr>
<tr>
<td>Burchiel 1996</td>
<td>Prospective</td>
<td>219</td>
<td>Failed back and leg pain</td>
<td>1yr</td>
<td>55% success in 70pts at 1yr.</td>
</tr>
<tr>
<td>Kumar et al 1998</td>
<td>Retrospective</td>
<td>66mo ave</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kim 2001</td>
<td>Retrospective</td>
<td>122</td>
<td>Mixed Non-specific limb pain evoked pain</td>
<td>3.9yr (0.3-9yr)</td>
<td>60.7% received implant 79% success.</td>
</tr>
</tbody>
</table>

De La Porte C 1993

North RB 1993
LeDoux 1993
Ohrmeiss 1996
Burchiel 1996
Kumar et al 1998
Kim 2001

Pain, narcotic usage, return to work, and activities of daily living are deemed measures of success at last follow-up. Pain criteria for success of the SCS have been difficult to decide. Most authors consider SCS successful if there continues to be greater than 50% relief of the index pain level at 1 year after implantation. Narcotic usage is a highly variable follow-up parameter. Some series report reduction in drug usage, and changes to less potent analgesics. Other studies find no reduction. Many authors avoid treating patients who use narcotics excessively. Improved return to work data again is equivocal. Some authors report a higher incidence of return to work. However, a high percentage of the patients are disabled, or retired, skewing the data.7,8,10,37

RESULTS IN DIFFERENT DIAGNOSES

Non-specific limb pain may be treated as effectively as neuropathic pain if a peripheral nerve is the root cause of the pain. Central pain is amenable if paresthesias are obtained in area of pain.8 SCS is the most important pain technique available for treatment of intractable pain of benign origin. SCS may be most valuable in failed back syndrome (FBS),6,11,18–20,37,38,39 SCS has clearly been more effective in relieving intractable leg pain, than in treating axial back pain. SCS is at least as good if not better than re-operation in patients with FBS. For those who have failed surgery, it may be the only pain relief available. In a systematic literature review of patients treated for FBS with SCS, Turner and associates found an average of 50% to 60% of patients with FBS report >50% pain relief with the use of the SCS at follow-up.20

SCS has been very effective in treating Reflex Sympathetic Dystrophy (RSD), in well-defined indications including a history of limb trauma; pain of more than 1 peripheral nerve distribution; physical findings of dystrophy; and a positive response to a sympathetic blockade.40–44 Kemler and associates conducted a randomized, controlled trial of SCS for reflex sympathetic dystrophy.40 The results show that SCS reduces the intensity of pain caused by this disorder in patients in whom all conventional treatments have failed. The success rate was 56% at 6 months in permanently implanted SCS. Kumar et al, reported 12/12 patients with RSD experienced pain relief with trial stimulation and had permanent stimulators implanted.9 At follow-up, 8 patients reported excellent and 4 good results. Kumar concluded SCS is an effective treatment for the pain of RSD and that SCS is superior to ablative sympathectomy in the management of RSD.

SCS with peripheral neuropathy of diabetes and causalgia may have up to 75% success rate.6,7,8,9 Kumar reported only moderate success with peripheral neuropathy. Cases showing the best results were causalgia (100%) and diabetic neuropathy (75%). Kumar
reported less responsiveness in post-herpetic neuralgia, other inter-costal neuralgias, spinal cord injury with dysesthesias and pain.\textsuperscript{9,45}

SCS is less effective in treating amputation stump and phantom limb pain, cauda equina syndrome, and bone and joint pain syndrome. These cases responded initially with early pain relief, but all subsequently lost pain relief. In a small number of cases of amputation stump and phantom limb pain, none were internalized.\textsuperscript{9,45}

Multiple Sclerosis showed high early pain relief producing a 92\% internalization rate. However, perhaps due to the development of tolerance, there have been good short term then progressive worsening of pain relief in multiple sclerosis.\textsuperscript{7,8}

More recently, excellent results have been obtained in vascular claudication, Kumar reported 69\% success.\textsuperscript{23,28,37,45} There is an interesting side effect in the vascular patient, with the blockade of sympathetic control of the vessels there is a relative increase in perfusion.

In spinal cord injury, cases of complete paraplegia did not respond. All cases with satisfactory responses had incomplete paralysis, with the majority of their pain below the level of the spinal cord lesion. Cauda equina syndrome had early success with erosion to poor pain control.\textsuperscript{6,7,8,10,46}

Average short-term success is 66\% to 75\% while long-term success is about 50\%. North points out in 1993 that the late success rate is better if one excludes the implants needing revision of electrode or receiver.\textsuperscript{36} These equipment failures should have pain relief restored once the implant is re-activated.

**SUMMARY**

Chronic pain remains one of the most debilitating of all medical disorders. Chronic pain may lead to loss of employment, destruction of interpersonal relationships and drug addiction. Reasonable long-term success with SCS may be achieved by adhering to these principles.

1. Modest selection criteria. All patients should have exhausted all conservative treatments. Narcotic usage alone should not be a non-exclusionary finding. Many patients will decrease drug usage after stimulator.
2. State of the art SCS equipment should be used.
3. A trial period should be undertaken in all cases. Some patients (15\% to 55\%) will be excluded from the expense and possible risk of permanent implantation, by failing a trial period.

In conclusion, SCS is an effective and safe therapy that improves the quality of life and activities of daily living, in patients disabled by their chronic pain. The mode of action of SCS is not completely known, but is better defined now, and may be related to controlling neurotransmitters, such as glycine and GABA. With dual stimulation further inroads in the treatment of FBS are made. SCS continues to be most effective for neuropathic pain and less effective for nociceptive mediated pain.

**REFERENCES**


Biomechanical Evaluation of Relationship of Screw Pullout Strength, Insertional Torque, and Bone Mineral Density in the Cervical Spine

Charles Alan Reitman, MD, Lyndon Nguyen, and Guy R. Fogel

Background: Understanding of implant failure mechanisms is important in the successful utilization of anterior cervical plates. Many variables influence screw purchase, including the quality of the bone. The purpose of this study was to assess the relationship of screw pullout and screw insertional torque across a wide range of bone mineral densities (BMDs).

Methods: A total of 54 cervical vertebrae in 12 cervical spines were evaluated for BMD using dual-energy x-ray absorptiometry scanning. Actual and perceived peak torques of 3.5-mm anterior cervical screws were determined at each level followed by screw pullout strength testing.

Results: A high correlation was observed between screw pullout strength and BMD. However, there was a low correlation of peak insertional torque to pullout strength.

Conclusion: These findings suggest the quality of the bone is more instrumental in the success or failure of anterior cervical screws than is the insertional torque with which the screws are placed.

Key Words: cervical spine, bone mineral density, screw pullout strength, insertional torque, biomechanics

Anterior cervical disectomy and fusion is frequently employed in the surgical management of the cervical spine. Recently, the benefit of the addition of anterior cervical plates has been established.1,2 There are several plates available, each with their own characteristics, with variation in features such as implant thickness, rigidity, and dimensions.3 Success of these implants is in part dependent on secure screw anchoring of the plate to the vertebral column.

These systems initially used bicortical fixation screws but have now evolved to safer unicortical cancellous screws. All of these screws are locked to the plate in some fashion to help prevent implant loosening and add rigidity to the plate-screw construct. Some screws actually lock to the plate, while in most cases, there is some kind of blocking plate or screw head expansion to secure the screw to the plate. In these cases, the screws are initially placed securely per the surgeon’s own perception, in most instances without specific torque control.

Screw pullout and stripping (exceeding maximal insertional torque) are possible modes of failure. Some factors affecting the pullout strength of a cancellous bone screw are specific to the screw design and include the major diameter of the screw, the length of engagement of the thread, and screw thread depth and pitch.4 Furthermore, tapping was found to reduce pullout force by an average of 8% compared with non-tapped holes. In addition to these characteristics of the instrumentation, the quality of the bone probably plays an important role in the strength of fixation. As a result, there is particular concern regarding implant failure when used in the osteoporotic spine. Since bone mineral density (BMD) is one clinical measure of bone quality, there is interest in determining the relationships between BMD and internal fixation. Although studies in the cervical spine in particular are limited, these data combined with more extensive reports in the thoracic and lumbar spine would suggest that there is a linear relationship of insertional torque and BMD to pullout force of vertebral body fixation screws.

The purpose of this study was to define the relationships of insertional torque and pullout strength of anterior cervical plate locking screws to a wide range of BMDs. In addition, the difference in maximum torque and the torque applied by the feel of the surgeon was evaluated. We hypothesized that screw pullout strength would be dependent on both BMD and peak insertional torque. Additionally, it was felt that a linear relationship of torque to BMD could be established such that optimal forces of screw application could be predicted based on BMD. Furthermore, it was suspected that a minimal BMD existed below which screw purchase would be unreliable.

MATERIALS AND METHODS

A total of 54 fresh-frozen human vertebral bodies from 12 different cadaveric cervical spines (3 female, age 59–88 years; 8 male, age 47–88 years) procured from ScienceCare Anatomic (Phoenix, AZ, USA) were used for this experiment.

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All 12 specimens contained C3–C7 vertebral bodies with parts of C2 and T1 and were kept frozen until the time of testing. Five screws failed to provide data owing to poor placement or a weak area of the bone consistent with a fracture, and one pullout test failed owing to failure of the coupling mechanism.

Prior to testing, each cervical spine was vacuum sealed, frozen, and submitted for BMD testing (Dexascan; River Oaks Imaging, Houston, TX, USA). In addition, each specimen was subjected to radiographic evaluation to rule out any tumors or significant destructive changes. All specimens were allowed to reach room temperature and kept moist throughout the testing period.

Two bone screws from the PEAK Polyaxial Anterior Cervical Plate System (DePuy AcroMed, Raynham, MA, USA) were inserted into each cervical vertebral body, C3–C7. All screws were inserted by a single orthopedic spine surgeon. These were cancellous screws specifically designed for unicortical placement in the cervical spine. All screws were 14 mm in length. At this length, all screws resulted in unicortical bone fixation in this sample of spines. Each screw was passed through an aluminum custom sleeve adapter prior to implantation to allow for mechanical pullout testing. The thickness of the adapter simulated the thickness of an average cervical plate. A special screwdriver with a torque transducer (Transducer Techniques, Temecula, CA, USA) mounted to the handle enabled continuous acquisition of torque measurements as the surgeon was placing the screws. Predrilled holes using a 2.5-mm bit were made in the vertebral bodies to accommodate each screw. One bone screw was inserted until it stripped the bone (actual peak insertional torque). A second screw was threaded until the physician felt that a sufficient amount of torque was achieved to maximize holding force without stripping the bone (perceived peak insertional torque). Torque values were documented and analyzed in Microsoft Excel (Microsoft, Redmond, WA, USA). During insertion of all screws, the surgeon was blinded to the BMD of the specimen as well as the torque being generated with each screw.

Destructive mechanical pullout testing was performed by means of a custom pneumatic testing apparatus (Fig. 1). One pneumatic cylinder (Parker Hannifin Corp., Cleveland, OH, USA) applied a uniaxial tensile load at a constant rate of 5 N/s. The pneumatic cylinder was powered by an individual pneumatic valve (Proportion-Air, McCordsville, IN, USA) and controlled by LabView (National Instruments, Austin, TX, USA). A universal "S" load cell fixed between the pneumatic cylinder and sleeve adapter noted the tension force at a rate of 30 Hz throughout the loading process. Each specimen was securely mounted to a multiaxial adjustable table vise and floating x-y table to permit self-alignment during the testing procedure. Use of the multiaxial vise allowed us to carefully adjust the alignment. Owing to the intentional and careful design of the sleeve and various adapters, the sleeve could be connected to load cell and testing apparatus only if it was positioned directly parallel to the configuration of the screw. High tolerances during the machining process required that the sleeve be within approximately 0.2° of vertical to couple with the load cell. This ensured that the pullout force was directed parallel to the alignment of the screw. The sleeve adapter was threaded to the force transducer and loaded to failure. Only screws placed by feel were tested for pullout. Stripped screws were not tested in this manner and were placed only to determine peak insertional torque. Maximum failure load was verified by graphing the force data over time and visually identifying the critical load.

Average failure loads and statistical comparisons were calculated using a statistical analysis package to determine linear regression and square correlation coefficient as well as analysis of variance (ANOVA).
RESULTS

A total of 54 vertebra from 12 cervical spines were tested. This provided data for a broad range of BMDs from 0.256 to 1.273 g/cm².

The relationships of BMD, torque, and pullout strength were evaluated by linear regression analysis. Figure 2 demonstrates a high correlation of average BMD to pullout strength ($R^2 = 0.710$). There was also a strong relationship of average BMD to maximum torque ($R^2 = 0.707$) (Fig. 3). However, there was much less correlation of torque to pullout strength ($R^2 = 0.422$) (Fig. 4). ANOVA was also used to assess interactions of BMD, torque, and pullout strength (Figs. 5 and 6). Relationships of torque to average BMD were significant ($P = 0.000087$), while pullout strength to average BMD showed a trend ($P = 0.093$).

Maximum torque compared with the perceived peak torque results were assessed. On average, the surgeon’s perceived peak torque was about 85% of the actual peak torque. Average maximum torque was found to be $2.56 \pm 1.47$ Nm, while average perceived torque was $2.16 \pm 1.28$ Nm ($P = 0.003$) (paired $t$ test).

DISCUSSION

Screw pullout strength is a critical factor in the success of an anterior cervical implant. These data showed that screw pullout strength was substantially related to BMD as expected but had a much lower correlation with peak insertional torque. These relationships imply that the critical variable for screw purchase was the density of the bone into which it was placed, and not the force with which it was applied. Clearly, there was a correlation of torque to BMD, which was also expected. However, despite the fact that denser bone could accommodate more torque, the amount of torque did not appear to be critical in preventing screw pullout.

These findings are consistent with those of Lim et al. They were based on biomechanical evaluation of 6.5-mm anterior lumbar screws, but results were similar in that pullout strength was strongly related to BMD but not to the peak insertional torque of the screws. Several other human and animal studies have been done in the thoracic and lumbar spine that support the high correlation of BMD to screw pullout force. Fewer studies have been conducted in the cervical spine. Zink et al evaluated several variables including relationships of BMD and screw torque and axial forces for anterior cervical fixation of Caspar screws. They did not measure pullout strength directly. They found that torque was related to BMD. They also established that larger rescue screws generated higher torques than standard screws. They concluded that for BMD under 150 mg/mL, unicortical fixation with 3.5-mm screws was inadequate fixation without additional reinforcement and recommended that all patients get BMDs prior to surgery to help determine fixation and need for postoperative immobilization.
FIGURE 3. Relationship of BMD to torque: \( y = 31.343x - 3.8488 \) \((R^2 = 0.707)\).

FIGURE 4. Relationship of pullout strength to torque: \( y = 1.8503x + 14.363 \) \((R^2 = 0.422)\).
**FIGURE 5.** Relationship of maximum torque to average BMD ($P = 0.000087$).

**FIGURE 6.** Relationship of pullout strength to average BMD ($P = 0.093$).
Ryken et al\textsuperscript{14} also looked at properties of Caspar screws in the cervical spine. Contrary to our findings, they found a significant correlation of torque to pullout strength as well as BMD to pullout. These findings were more significant for bicortical purchase versus unicortical placement, and range of bone densities was fairly narrow (0.787 ± 0.154 g/cm\textsuperscript{2}). A recent report also found positive correlations with pullout strength and BMD as well as pullout strength and insertional torque of anterior unicortical cervical screws.\textsuperscript{15} However, in this study, midrange insertional torque was evaluated rather than peak insertional torque. They additionally observed that longer screws (14 and 16 mm) had greater pullout strength than shorter screws (12 mm), and in general, their pullout strength findings were much more significant in the presence of longer screws. BMD has also been shown to be important in implant fixation in the posterior cervical spine.\textsuperscript{16}

It appears to be clear that pullout strength is affected by BMD. This has been demonstrated in multiple studies. However, effects of insertional torque have been less well established for anterior cervical screws. While a recent study suggests a high correlation of insertional torque to pullout strength, they did not measure peak insertional torque, and the torque in the midranges of screw placement was probably more directly dependent on BMD. This is the first study to look at relationships of peak insertional torque to pullout strength of unicortical anterior cervical screws over a large range of BMD. Results of this study imply that it is not as important to attain near peak insertional torque values, and, in fact, care should be taken not to overtighten and strip the screw as this would more likely alter and weaken pullout properties. Of interest, we did look at the comparison of the surgeons’ perceived peak torque versus the actual torque to failure. The average perceived torque was 85%. We initially hypothesized that peak insertional torque would be important and were set to establish optimal torque values for screw placement depending on the BMD. The study invalidated this hypothesis and supports placement of screws by feel without the need to reach a measured optimal torque.

We did observe a linear relationship between pullout strength and BMD down to about 0.4 g/mL. Below this density, pullout strength seems to reach a minimum of 106.8 N. Although we feel that the knowledge of BMD preoperatively is important to help determine the relative stability of internal fixation, this analysis does not establish a threshold safety value above which implant failure in pullout would reliably be decreased. This question would have to be answered with further study. Furthermore, we did not standardize torque values prior to pullout testing. One of the goals was to mimic the insertional torque that would be present during surgery and to assess the need for a torque feedback device in placing screws. Therefore, all pullout testing was done on screws placed by feel and not to a designated torque value. Although it was demonstrated that the surgeon was able to place the screws satisfactorily without the need for feedback, had we been able to standardize torque, there would have been further direct measure of pullout versus BMD, which would have provided additional support to our conclusions.

**CONCLUSIONS**

BMD significantly influences pullout strength of anterior cervical screws. Peak insertional torque is related to BMD but as an independent variable does not demonstrate a strong influence on pullout strength. It is important for the clinician to acknowledge that the critical factor contributing to pullout strength is the density of the bone and not the force with which the screw is placed into the bone. The surgeon is capable of placing a screw by feel that has adequate torque. Specific torque screwdrivers should not be necessary to ensure optimal bone purchase, and the surgeon then does not risk exceeding the peak insertional torque capacity of the bone. BMD should be considered when choosing a cervical implant.

**REFERENCES**

Spinal epidural lipomatosis: case reports, literature review and meta-analysis

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Abstract

BACKGROUND CONTEXT: Symptomatic spinal epidural lipomatosis (SEL), a rare cause of spinal cord compression, has most often been associated with exogenous steroid use.

PURPOSE: Identify four associations with SEL, correlate the associated groups with level of disease and compare treatment with outcome data in these groups.

STUDY DESIGN/SETTING: Case reports of three patients and analysis of 104 cases from the literature.

PATIENT SAMPLE: Three patients from the senior author’s practice.

OUTCOME MEASURES: Not applicable.

METHODS: The authors report three new cases of SEL not associated with steroid use. They review all available English literature and present a table of all 104 reported cases.

RESULTS: The clinical course of three new patients is reported.

CONCLUSIONS: Associated conditions are exogenous steroid use, obesity, endogenous steroid excess, and some remain idiopathic. Although SEL is a rare condition, our review of the literature reveals many more reported cases than previously thought. With increased awareness of this condition and improved imaging techniques, further studies of this disease should be undertaken. © 2005 Elsevier Inc. All rights reserved.

Keywords: Dura mater/pathology; Lipoma/complications/pathology/radiography/surgery; Spinal cord compression/etiology

Introduction

Spinal epidural lipomatosis (SEL) is a disease consisting of an excessive deposition of normal adipose tissue in the spinal canal, compressing the spinal cord. Symptomatic SEL is exceedingly rare and often associated with exogenous steroid use. Although less common, obesity and Cushing syndrome/disease (hypercortisolism) have also played a role in SEL. Epidural lipomatosis becomes symptomatic in rare occasions by causing compression of the spinal cord or nerve roots. Because SEL can mimic other common spine conditions, such as spinal stenosis and degenerative joint disease, it was often underdiagnosed. Symptomatic epidural lipomatosis was first described in 1975 [1]. Since that time, a number of other cases have been diagnosed with the use of imaging in combination with clinical symptoms, history, surgical findings and the absence of other identifiable causes. Patients may present with progressive and longstanding complaints of pain, weakness, numbness, incontinence, ataxia, abnormal reflexes and even rarely paralysis. We report three new cases of SEL.

Case report 1

A 47-year-old man presented with low back pain of 2 years’ duration that began after a work-related injury. The pain was situated in his lower back with radiation to the buttocks and thighs bilaterally. It was associated with decreased sensation and weakness in both lower extremities. This pain was not associated with any bowel or bladder incontinence. The patient also had a history of neck pain with associated...
numbness, weakness and loss of sensation in the right upper extremity. His past medical history was significant for renal cancer that was treated by nephrectomy 6 years prior. The patient had no history of steroid use.

On physical examination, the patient was 5 feet 6 inches tall and weighed 140 pounds, with a body mass index (BMI) of 23.4. He had no structural spinal deformity. His range of motion was limited on both flexion and extension. Some tenderness was noted over his lower back bilaterally. Neurological examination revealed that the patient was intact with no nerve root tension signs. A computed tomography (CT) myelogram revealed prominent epidural fat from L2 to S1 with thecal sac compression. Complete cutoff of the intrathecal dye occurred at the L4–L5 level. CT scan cuts through the L4–L5 and L5–S1 levels demonstrated thecal sac compression by an extrinsic circumferential mass consistent with epidural lipomatosis (Figs. 1 and 2).

A laminectomy and decompression was performed from L2 to L5. Operative findings included marked adipose tissue in the spinal canal and stenosis. The patient lacked any neurological abnormalities postoperatively, although he did still complain of lower back pain.

Case report 2

A 48-year-old man developed an acute onset of low back pain that he attributed to a work-related fall. The patient continued to work, and his pain eventually resolved. Subsequently, the patient sustained a lifting injury at work, causing him severe low back pain. He denied leg pain after this injury. The patient participated in physical therapy and took leave of work. Two days later, he was unable to continue the physical therapy because of pain.

Magnetic resonance imaging (MRI) sagittal spin-echo T1-weighted images demonstrated widening of fat tissue in the epidural spinal canal rounding and compressing the thecal sac and nerve roots. Hypertrophic spondylosis of L2–S1 in the lumbar spine was noted. Axial T1-weighted MRI of the lumbar spine just cephalic to L5–S1 shows circumferential hyperintense and homogenous tissue elevating the dural sac and the nerve root. A sagittal T2-weighted image showed a high contrast between adipose tissue, and the dural sac on T2-weighted image permitted an accurate evaluation of the extent of pathologic overgrowth of epidural fat in the spinal canal. Hypertrophy of facet joints and end plates with discal bulging resulted in mild canal stenosis at multiple levels and increased epidural fat posterior to the dural sac that appeared compressed and indented below L2 (Figs. 3 and 4).

The patient received an epidural steroid shot. He reported that the pain became worse and began to radiate to both buttocks after the steroid injection. He was unable to walk after the steroid injection. He reported that his symptoms were occasionally accompanied by left leg numbness that extended to the bottom of the foot.

His past medical history was negative. His past surgical history was significant for a gunshot wound to the stomach sustained during the Gulf War. He denies taking steroids. His only medication was tramadol.

On physical examination, the patient was 6 feet tall and 270 pounds, with a BMI of 36.6. The patient had no spinal deformities. He stood with his lumbar spine flexed to 20 degrees, because of pain. He was unable to lie flat. Paravertebral muscle spasm was noted. He had no tenderness to palpation. His neurological examination showed that the patient was intact. A laminectomy and decompression was performed from L3–S1 with bilateral foraminotomy. Direct removal of the epidural lipomatosis was not reported.
Fig. 3. Second patient: magnetic resonance imaging (MRI) sagittal spin-echo T1-weighted images demonstrate widening of fat tissue in the spinal canal rounding and compressing the thecal sac and nerve roots. This abnormal fat-density compression is thicker between the disc levels and thinner at the areas of degenerative discal bulging. MRI sagittal image also shows hypertrophic degenerative changes at L2–S1.

Postoperatively, the patient improved, although he still complained of low back pain and the inability to stand completely erect. The patient started a supervised physical therapy program with some improvement of his back pain.

Case report 3

A 43-year-old man developed an acute onset of back pain after sustaining a lifting injury. The pain was situated in his mid-thoracic spine and radiated into his neck. Several days later, the pain became much worse and he was unable to walk or stand. He was immediately brought to the emergency room and admitted. His past medical history was negative. The patient had had three prior operations on his back for work-related injuries. The patient had no history of steroid use.

On physical examination the patient weighed 270 pounds and measured 6 feet 4 inches, with a BMI in excess of 30. On palpation, the patient complained of tenderness throughout his spine. His range of motion was severely limited by pain. His motor examination revealed flexor paralysis of both lower extremities. There was also weakness in handgrip bilaterally. Deep tendon reflexes were absent in the lower extremities and for the triceps tendon bilaterally. Plantar stimulation elicited no response. Sensory examination revealed decreased sensation to pinprick from and including the T1 level and down.

MRI of the thoracic spine with axial and sagittal T1-weighted images showed a marked high contrast between adipose tissue and the dural sac on T1-weighted images. The contrast permits an accurate evaluation of the extent of pathologic overgrowth of epidural fat in the spinal canal. On the sagittal T1-weighted image, the posterior epidural stripe of hyperintense lipomatosis is 8 to 10 mm in width throughout the thoracic spine. Axial views of T5–T6 showed extradural compression from epidural fat. Axial cuts from T10–T11 showed restoration of the symmetry of the dural contents and cerebrospinal fluid without the extradural compression (Figs. 5 and 6).

The patient was diagnosed with thoracic SEL and cervical spondylosis. A laminectomy and decompression was performed from C5 to C7 and T1 to T7. Although the patient made some improvement, at time of discharge he was unable to stand or walk and lacked bowel and bladder continence.

Discussion

We conducted a complete review of the available English literature, charting all reported cases of SEL, noting the most common associations of SEL, correlating these associations to the location of the disease process and examining the treatment to outcome data. We found 104 cases of SEL reported in the literature, including our three cases (Table 1).

Pathogenesis

The underlying pathological mechanism of SEL is unknown. A review of the literature and the data reported in the chart below reveal four categorical associations with SEL: exogenous steroid use, obesity, endogenous steroid excess or Cushing syndrome and an idiopathic group. The most common association is exogenous steroid use. SEL has been
documented in association with steroid use for many conditions, including transplantation, systemic lupus erythematosus, rheumatoid arthritis, Graves disease, chronic hepatitis, dermatomyositis, nephritic syndrome, glomerulonephritis, sarcoidosis, Crohn’s disease, multiple sclerosis, chronic obstructive pulmonary disease, atopic dermatitis, diabetes mellitus, prostatic cancer, lichen ruber planus, pineoblastoma, cerebral lymphoma, polyarthritis, asthma and polyarteritis nodosum. It is well established that hypercortisolism leads to an accumulation of adipose tissue in a typical distribution, on the face, neck, trunk and mediastinum [2]. Hypertrophy of adipose tissue already present in the spinal canal is theorized to be the cause of SEL in certain cases of exogenous steroid use [3]. Based on our review, 55.3% of all reported cases in the English literature were associated with exogenous steroid use. Although the majority of these cases were associated with long-term steroid use, three of the cases arose from multiple epidural steroid injections: cases 13, 43 and 47. Patient 13 received a total of 103 injections over 12 years, eventually resulting in an abrupt onset of neurologic deficits at the end of this period. Patient 43 received a series of injections over a period of 3 years totaling 1,200 mg of methylprednisolone. Her physical examination revealed sequelae of Cushing syndrome, including moon facies and buffalo hump. Patient 47 received a total of five injections; the last three injections reportedly exacerbated his symptoms. In fact, one of these patients developed Cushing syndrome sequelae from these local injections [3–5].

Obesity is the second most common associated category of SEL. Koch et al. [2] hypothesized that obesity in this patient class may be caused by a pseudo-Cushing state exhibiting elevated urinary free cortisol levels. Unfortunately, no studies of obese patients with SEL have reported cortisol levels to date. Furthermore, some investigators question whether obesity plays a causal role in SEL or is merely a predisposing factor [6]. Borre et al reported 53 severe cases of SEL with 39 obese patients. Additionally, 4 were on steroids, 2 were hypothyroid and 1 was obese, had hypothyroidism and was taking steroids [18]. Our case review revealed 24.5% of reported cases attributable to obesity alone (It is important to note that this percentage includes only those patients who did not take steroids and were classified as obese by either the case reporter or BMI.)

Cushing syndrome/disease from endogenous sources is the third associated category in SEL. To date, only three cases of Cushing syndrome associated with SEL have been reported in the English literature accounting for 3.2% of SEL cases [7–9].

We found no identifiable association with SEL in 17% of the cases. This patient group includes those patients who did not take exogenous steroids, were not obese and did not have an underlying Cushing syndrome/disease to account for the SEL. Unfortunately, some of these patients also lacked certain of the data criteria. Of the 16 cases, 2 of these lacked data on the patient’s BMI. However, after consideration, we opted to include these cases in our analysis to be complete in analysis of all known cases in the English literature.

Hypothyroidism in previous papers has been associated with SEL [4,6,10,11]. Upon review, we disagree with this conclusion. There has been only one reported case of hypothyroidism associated with SEL [11]. This patient was obese,
Table 1
One hundred and four cases of spinal epidural lipomatosis from English literature review with diagnosis, presence of steroid usage or obesity, type and outcome of treatment

<table>
<thead>
<tr>
<th>Case</th>
<th>Reference</th>
<th>Pathology</th>
<th>Levels</th>
<th>Steroids</th>
<th>Obesity</th>
<th>Treatment</th>
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<td>Medical: metyrapone, ketaconazole</td>
<td></td>
</tr>
<tr>
<td>94</td>
<td>[3]</td>
<td>Cushing syndrome</td>
<td>T5–T10</td>
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<td>NR</td>
<td>Laminctomy</td>
<td>Improved</td>
</tr>
<tr>
<td>95</td>
<td>[72]</td>
<td>Diabetic, paraplegic</td>
<td>T1–T9</td>
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<td>Yes</td>
<td>Improved</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Klippel-Trenaunay-Weber syndrome</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>96</td>
<td>[73]</td>
<td>Obese posttraumatic cauda</td>
<td>Thoracic</td>
<td>No</td>
<td>NR</td>
<td>Laminctomy</td>
<td>Improved</td>
</tr>
<tr>
<td>97</td>
<td>[74]</td>
<td>Cushing syndrome</td>
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<td>Yes</td>
<td>Laminctomy</td>
<td>Improved</td>
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<tr>
<td>98</td>
<td>[75]</td>
<td>Cushing syndrome</td>
<td>Thoracic</td>
<td>No</td>
<td>NR</td>
<td>Medical management</td>
<td>Improved</td>
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<td></td>
<td></td>
<td>with pituitary tumor (macroprolactinoma)</td>
<td>Thoracic</td>
<td>No</td>
<td>NR</td>
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<tr>
<td>99</td>
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<td>Becker nevus associated</td>
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<td>NR</td>
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<td>Improved</td>
</tr>
<tr>
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<td>Lumbar</td>
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<tr>
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<td>No</td>
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<td>Yes</td>
<td>Laminctomy</td>
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<tr>
<td>103</td>
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<td>Lumbar</td>
<td>No</td>
<td>Yes</td>
<td>Laminctomy</td>
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<tr>
<td>104</td>
<td>[78]</td>
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<td>Lumbar</td>
<td>No</td>
<td>Yes</td>
<td>Laminctomy</td>
<td>Improved</td>
</tr>
</tbody>
</table>

CR=complete recovery; FU=follow-up; LE=lower extremity; NR=not reported.

the second leading association with SEL. There is the persuasive argument that hypothyroidism is associated with generalized fat deposition resulting from decreased lipolysis. However, the data are insufficient to link hypothyroidism and SEL [3,4,10,11]. This linkage would require cases of nonobese patients with hypothyroidism and SEL to be considered an independent risk factor. The case of an obese patient with hypothyroidism and SEL can only be considered a case of obesity associated with SEL.

**Imaging**

Most case reports relied heavily on CT imaging and myelography [12,13]. However, MRI is now recognized as the most sensitive and specific modality for evaluating fatty tissue [14–16]. T1-weighted images differentiate epidural fat from dural content with a high degree of specificity and allow for measurement of adipose thickness. Quint et al. [17] conducted a study in which 28 normal patients were imaged and their epidural adipose measured. The mean sagittal thickness of their epidural fat was 4.6 mm with a normal range of 3 to 6 mm. In contrast, imaging in 6 patients with SEL revealed a mean thickness of 8 mm [17]. Borre et al. [18], on the lumbar MRIs of 2,258 patients, measured the anterior posterior diameters of the dural sac and spinal canal and the thickness of the epidural fat. Borre et al. developed an MRI classification based on these ratios. Grade 0 or normal was defined as epidural fat less than 40% of canal width, and dural 150% width of epidural fat. Grade I was defined as epidural fat less than 50% of the canal width and less than 50% of the dural width. Grade I was not symptomatic. Grade II was defined as the epidural fat 50% to 75% of the canal and 100% to 150% of the width of the dural sac. Grade II SEL was symptomatic in 14% of cases. Grade III was defined as the epidural fat more than 75% of canal width and the dural 30% the width of the fat. All Grade III SEL cases were symptomatic. In Grade III cases, there was a 42% rate of associated substantial pathology, such as disc herniation or stenosis. Also in the Grade III SEL, the epidural fat produces centripetal pressures on the thecal sac changing the morphology or shape. Most commonly a trifid or Y shape may be seen. Borre et al. [18] report six other patterns seen in axial magnetic imaging.

**Level of disease**

Examining all available case reports, we were able to determine incidences of spinal level involvement. From the reported cases, 45.8% had thoracic involvement only, 43.6% had lumbosacral involvement only and 10.6% had involvement in both thoracic and the lumbosacral area. We correlated location of disease to the associated categories to ascertain whether any trends existed. Of the 52 patients with a history of steroid use, 55.8% were found to have thoracic involvement only, 32.7% with lumbosacral involvement only and 11.5% with both thoracic and lumbosacral involvement. Data from the patients in the obese category reveal a stronger trend: 69.6% had lumbosacral involvement only, and 30.4% had thoracic involvement only. The idiopathic group consisted of 16 patients. Of the 16 patients, 37.5% had thoracic spine involvement only, 32.7% with lumbosacral involvement only and 11.5% with both thoracic and lumbosacral involvement. Data from the patients in the obese category reveal a stronger trend: 69.6% had lumbosacral involvement only, and 30.4% had thoracic involvement only. The idiopathic group consisted of 16 patients. Of the 16 patients, 37.5% had thoracic spine involvement only, 32.7% with lumbosacral involvement only and 11.5% with both the lumbosacral and thoracic spine. Of the three patients with Cushing syndrome/disease from endogenous sources, 66.6%, had both thoracic and lumbosacral involvement and 33.3% had thoracic involvement only. Although four of the
cases reported cervical involvement, these cases had SEL throughout the spine and were included in the percentages of thoracic and lumbosacral involvement. We have found no cases of SEL isolated to the cervical region.

Investigators initially reported a significantly higher incidence of thoracic SEL. This was theorized to be secondary to the fact that the thoracic region has the largest amount of epidural fat [10,17,19]. Contrary to this popular belief, our case review indicates that SEL is found in approximately the same number of cases in both the thoracic and the lumbosacral region. The previous causal relationship is no longer present with this new information. It is clear that further studies into the etiology of SEL are required.

Treatment

Treatment of SEL ranges from conservative management to surgical excision. The success rates were calculated assuming that none of the patients in the surgical group were first treated conservatively. In the event that the reviewed data revealed a failed conservative treatment that then proceeded to surgery, these patients were included in both groups or were specifically discussed. In the steroid patient group, three of the cases lacked outcome data and are therefore considered to have no improvement for purposes of this analysis. Thirty-nine patients received a laminectomy and debulking, accounting for 75% of those patients in the steroid group (39 of 52). The success rate of this modality was 77% (31 of 39 patients receiving a laminectomy had results ranging from improved symptoms to complete recovery). The remaining 13 patients (25%) received a combination of different medical treatments, including weight loss, steroid taper, analgesics, bed rest and observation. One of the 13 received high-dose steroids for symptoms. The success rate of medical management of these patients was 77%. Borre et al. [18] reported that 26 patients were treated medically and surgically. In the surgical group 16 of 18 had associated spinal pathology treated, such as disc herniation and stenosis decompression. Two patients were decompressed surgically with such a high ratio of epidural fat to canal and dural width and presented with neurologic compromise and cauda equina syndrome [18]. Although both modalities appeared to treat SEL successfully in approximately 75% of the cases, these data do not reveal criteria for selecting a treatment modality.

The obese patient group was split between surgical correction and weight loss treatment modalities: 52.2% were treated by laminectomy and debulking, 47.8% by weight loss. The success rate of the surgically managed group was 66.7%. The patients managed conservatively by weight loss improved in 81.8% of the cases, with the one patient lacking outcome data considered having no improvement. Two patients not included in the conservative group previously failed conservative treatment before surgical treatment was administered. One of the patients was managed by physiotherapy and nonsteroidal anti-inflammatory medication, not weight loss. The other patient failed to lose weight. Because conservative care was not successful, they were not included in that group. Based on these data, weight loss as a treatment modality appears to be very successful and should be considered the first line of treatment in this patient group, with surgical correction reserved for those patients who fail to respond clinically to a weight loss plan or are unable to lose weight.

One of the patients in the idiopathic group lacked outcome data and was therefore considered to have a poor outcome. All of the patients in this group were treated by laminectomy, with a success rate of 93.75%. The only patient without improvement lacked outcome data. Surgical treatment of patients with no discernable cause for SEL appears to be the treatment of choice. The three patients who were diagnosed with SEL associated with endogenous steroid excess or Cushing disease/syndrome were treated differently. Because all three of these patients had an underlying disorder causing endogenous steroid excess, the underlying disorder was treated. Two of the patients had surgical removal of the tumor causing the steroid excess, and the remaining patient was treated with ketoconazole, an inhibitor of steroidogenesis. All three of the patients improved.

Conclusions

Symptomatic SEL is a rare condition consisting of excess adipose tissue in the spinal canal causing compression of the spinal cord and resulting neurologic symptoms. Four categories have been identified as associated with SEL: exogenous steroid use, obesity, endogenous steroid excess and idiopathic. Thoracic and lumbosacral levels are usually affected by SEL, with the incidence between the two roughly equal. No case of isolated cervical involvement was found. A new MRI grading scale may help define those patients who will improve expectantly (Grade I) from those who may require surgical decompression (Grade III). Surgical treatment in the Grade III SEL may also treat commonly associated degenerative stenosis, and facet pathology. Obese patients tend to develop SEL in the lumbosacral region three times more often than in the thoracic, whereas steroid use tends to cause SEL in the thoracic region slightly less than twice as often as in the lumbosacral region. Obese patients should be managed by diet alone initially, with surgery reserved for those without a significant clinical response. Although SEL is a rare condition, our review of the literature reveals many more reported cases than previously thought. With increased awareness of this condition and improved imaging techniques, further studies of this disease should be undertaken.

References


Surgical Evaluation and Management of Symptomatic Lumbosacral Meningeal Cysts

Guy R. Fogel, MD, Paul Y. Cunningham III, MD, and Stephen I. Esses, MD

Abstract

Sacral meningeal cysts are a fairly common finding in the workup of sciatica. In most instances, a cyst causes no symptoms. Occasionally, a symptomatic sacral cyst may present with chronic low back pain (radiculopathy), sensory loss in sacral dermatomes, perineal pain, or bowel or bladder dysfunction. Compared with computed tomography, magnetic resonance imaging shows meningeal cysts more often and allows better localization of sacral cysts.

In this article, we present clinical guidelines that may be used to distinguish symptomatic cysts from asymptomatic cysts. We conclude that surgical treatment of a symptomatic cyst may include laminectomy with fenestration and imbrication of the cyst—or percutaneous treatment methods. Surgery for sacral meningeal cysts can lead to successful improvement of pain and function in activities of daily living in more than 80% of cases.

Sacral cysts are a fairly common finding in the workup of sciatica. On myelography for investigation of leg and back pain, the incidence of sacral cysts is 17%. On magnetic resonance imaging (MRI) of 500 asymptomatic patients, the incidence is 4.6%. These cysts are usually considered incidental findings on MRI investigations, but occasionally they may cause sciatica and other symptoms such as bowel and bladder problems and perineal pain. In this article, we describe the clinical presentation, the MRI and computed tomography (CT) findings, and the surgical treatment options for sacral meningeal cysts.

Types of Sacral Cysts

In 1988, Nabors and colleagues classified sacral cysts into 3 types—extradural cysts (type I); extradural cysts with nerve roots included within the cyst, including the Tarlov perineural cyst (type II); and intradural cysts (type III). Most sacral meningeal cysts are dural diverticula that are of congenital or acquired onset and that may develop a pedicle with an ostium that works in an all-valve fashion to collect cerebrospinal fluid (CSF). Normal fluctuations in CSF pressure may account for growth of the cyst and erosion of adjacent bone surfaces.

Type I extradural meningeal cysts are dural diverticula that may arise anywhere along the thecal sac. Type I sacral cysts often have a pedicle at the caudal tip that connects to the thecal sac adjacent to dorsal nerve roots.

Type II cysts are dilations of the nerve root sleeve. The dura may have tears, which can be microscopic to fairly large. The wall of type II cysts contains nerve root fibers. Bone erosion (eg, canal-widening pedicular erosion, foraminal enlargement, scalloping of vertebral bodies or sacrum) is usual in type II cysts. Figure 1 shows types of extradural cysts that may be surgically treated.
TABLE. LITERATURE REVIEW FOR MENINGEAL CYSTS

<table>
<thead>
<tr>
<th>Measure</th>
<th>Extradural Type I</th>
<th>Extradural Type II</th>
<th>Intradural Type III</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. patients</td>
<td>67</td>
<td>20</td>
<td>7</td>
</tr>
<tr>
<td>Cyst location</td>
<td>Throughout spine</td>
<td>Lumbosacral</td>
<td>Throughout spine</td>
</tr>
<tr>
<td>Cyst size</td>
<td>2–5 cm</td>
<td>Unknown</td>
<td>Unknown</td>
</tr>
<tr>
<td>Surgery</td>
<td>Laminectomy cyst excision</td>
<td>Cyst wall excision, oversewing</td>
<td>Cyst excision</td>
</tr>
</tbody>
</table>

*Identified from the 1960-2001 English-language literature.1-3,6-23

Type III cysts are intradural and may occur anywhere along the posterior subarachnoid space. In compression, symptomatic type III cysts act as any intradural masses may. The Table lists the meningeal cyst cases found in the literature and classifies them by type.

Clinical Presentation

Symptomatic sacral cysts may present in various forms. Typically, a patient complains of low back pain for several years. The patient has minimal neurologic deficits, absent deep tendon reflexes, and bowel and bladder abnormalities, including constipation, incontinence, or recurring urinary tract infections. Usually, the lower extremity sensation is spared. Radicular pain often is relieved or disappears when the patient is recumbent, and it is aggravated often by the Valsalva maneuver. Perineal pain may be present in approximately 50% of patients.\(^1\)Sacral meningeal cysts have been associated with childbirth, papilledema, sacral fracture, neurofibromatosis, and dysraphism of the caudal spine.

MRI and CT Findings

MRI is the best single test. Compared with CT, MRI shows meningeal cysts more often and allows better localization of sacral cysts. MRI determines whether cysts are filled with fluid and thereby excludes solid tumors. When the signal intensity of the mass is the same as that of the thecal sac, a diagnosis of CSF-containing structure may be confidently made. MRI shows a higher intensity on \(T_2\) weighting compared with CSF, probably related to increased protein and solute content and absence of CSF motion effects. Tsuchiya and colleagues\(^4\) stated that MRI with myelography may be especially sensitive with postoperative patients because myelographic material may highlight cysts despite the bony changes related to surgery or the scalloping associated with the cyst itself. Figure 2 shows meningeal cyst changes in the lumbosacral area on MRI.

Routine radiographs of the sacrum and lumbar spine may show bone erosions, but this result is uncommon. CT myelogram is important in determining whether a cyst communicates with the subarachnoid space. If intrathecal dye does not fill the cyst even with some delay, then simple oversewing of the posterior cyst wall is all that is required. If the cyst communicates with the subarachnoid space, the pedicle or communication must be found and ligated to prevent recurrence of the cyst. CT myelogram may show the presence or absence of the free communication of the cyst with the spinal subarachnoid space. Delayed myelographic images are important and may show an extradural arachnoid cyst that fills slowly through a small pedicle connecting the cyst with the thecal sac. Myelography may produce a false-negative result if the pedicle of the cyst is too narrow to allow entry of intrathecal contrast material. Another problem is that CT seldom shows sacral roots, except S1, because CT is limited to pedicle-to-pedicle scanning in most cases, and lumbar CT seldom is ordered below L5–S1. CT of the lumbar and sacrum, sacral tomography, and epidurography and intraoperative ultrasound may be helpful but remain unproved in any large number of cases.

Figure 2. Sagittal magnetic resonance imaging views of 2 lumbosacral meningeal cysts. The L4-L5 cyst, which extends into the left foramina, was causing radicular pain in the left leg.
Authors' Clinical Guidelines

Clinical guidelines for distinguishing a symptomatic cyst from an asymptomatic cyst are useful.

First, it is important to rule out any other possible causes of back and leg pain. It is absolutely necessary not to ascribe complaints of back and leg pain to a cyst unless it is reasonably certain that the cyst is causing the pain. Unfortunately, this is not always possible, and there is not a reliable test for determining the clinical relevance of a sacral cyst. It is important to rule out disc herniation, spinal stenosis, and spondylolisthesis as causing the patient’s pain.

Second, it is important to determine that the cyst corresponds anatomically to the patient’s complaints. A symptom-producing sacral cyst should cause sacral radiculopathic symptoms, with radiculopathy to the buttock and S1 distribution in the leg associated perhaps with bowel or bladder symptoms. The symptoms should correspond anatomically with the cyst; they should correspond to the same side as the cyst and to symptoms affecting the same level of nerve roots as the cyst location suggests.

Third, it is useful to see whether pulsatile changes in CSF pressure increase symptoms. Postural changes in CSF pressure may affect complaints. Radicular pain often is relieved or disappears when the patient is lying down. Increased pain with Valsalva maneuver, cough, or sneeze tends toward a diagnosis of symptomatic cyst.

Fourth, aspiration of the meningeal cyst may be diagnostic of a symptomatic cyst if the symptoms decrease at least temporarily. This may be done with CT or fluoroscopic guidance. Aspiration may be repeated if initially successful and symptoms recur.

If all 4 criteria are met, then it is reasonable to suggest that a cyst is symptomatic (Figure 3).

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**Evaluation and Treatment Algorithm: Symptomatic Sacral Cyst**

- **Consider Diagnoses**
  - Low back sprain
  - Osteoarthritis
  - Herniated disc
  - Spinal stenosis
  - Spondylolisthesis

- **Activity modification:** according to severity of symptoms
  - Pharmacologic pain control
  - Bracing, modalities, exercises
  - Epidural steroid injections

- **Patient with a sacral cyst and**
  - Chronic low back pain
  - Normal lower extremity sensation
  - Absent deep tendon reflexes
  - Bowel and bladder abnormalities

- **Does the cyst cause back and leg pain?**
  - Rule out non-sacral etiology of pain
  - MRI, CT-myelography
  - Electromyography
  - Postural changes: recumbent and Valsalva

- **Diagostic aspiration relieves pain?**

- **Repeat aspiration**
  - Percutaneous drainage of the cyst
  - Closure of the cyst with fibrin glue

- **Surgical treatment—Considerations**
  1. Delay of 2-6 months to allow conservative treatment
  2. Documented failure to respond to treatment; physical signs and radiographic findings of a surgically treatable lesion
  3. Goal is correction of pathological condition, to attain functional recovery.

- **Surgical treatment**
  - Decompression laminectomy with
  - Oversewing of cyst neck and partial or total excision of the cyst
  - Shunting of cerebrospinal fluid from the cyst to the subarachnoid space

---

*Figure 3.* Evaluation and treatment algorithm for symptomatic sacral cysts.
Surgical Treatment

Surgical management usually includes extensive bony decompression with laminectomy alone or combined with either partial resection and oversewing of the cyst or total cyst excision, which may include sacrifice of the involved sacrococcygeal nerve roots. Additional treatments may include cyst drainage (percutaneous aspiration or external drain placement); incision, drainage, and plication of the cyst wall; CSF shunting to the peritoneum or the subarachnoid space; and closure of the connection between the cyst and the thecal sac. Type I meningeal cysts are treated by closing the pedicle between the cyst and the subarachnoid space. With type II meningeal cysts, because there is no pedicle to block off, the aim of surgery is to obliterate the cyst by partial resection and oversewing of the cyst wall. One must move or protect the nerve roots if they are within the wall of the cyst, as in the Tarlov variety of type II cysts. Type III intradural cysts should be excised by marsupialization, opening to the surrounding intradural fluid. These cysts are likely to recur. Recently, cyst drainage, either percutaneous or open, has been recommended to decrease symptoms, but cysts treated this way are likely to recur. In 2001, Morio and colleagues reported on a case successfully managed with cyst subarachnoid shunting (as a variation). In a preliminary report, Patel and colleagues suggested that fibrin glue may be definitive therapy for sacral meningeal cysts. They extended their method for sealing dural tears to a CT-guided percutaneous procedure for delivering fibrin glue to sacral cysts. Aseptic arachnoiditis has been a worrisome complication of this percutaneous glue technique.

The most popular treatment may be a combination of laminectomy, fenestration, and drainage of the cyst; blockage repair of the communication with the arachnoid space; and suture use, perhaps supplemented with as-needed placement of fibrin glue to seal drainage. Figure 4 (A–C) shows a symptomatic extradural cyst that was ligated at its base and aspirated. The surgical outcome was good, but the patient reported having mild radiculopathy-type pain without weakness intermittently at the 6-month interval; at the time of his report, this pain was improving.

Summary

Sacral meningeal cysts have fascinated spine surgeons for decades. In most instances, these cysts are asymptomatic. It is necessary to relate complaints of back and leg pain to a cyst only when it is reasonably certain that the cyst is causing the pain. Unfortunately, although MRI and CT can be used to determine the presence of a meningeal cyst, there is no reliable test for determining the clinical relevance of this cyst. Clinical guidelines are used to distinguish a symptomatic cyst from an asymptomatic cyst. Treatment options for a symptomatic sacral meningeal cyst range from aspiration and shunting of the cyst to laminectomy and closure of the communication of the cyst with the thecal sac. Percutaneous treatment with fibrin glue is interesting but may have residual aseptic arachnoiditis as a complication.
References


(continued from page 272)
Spinal epidural lipomatosis: case reports, literature review and meta-analysis

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Abstract

BACKGROUND CONTEXT: Symptomatic spinal epidural lipomatosis (SEL), a rare cause of spinal cord compression, has most often been associated with exogenous steroid use.

PURPOSE: Identify four associations with SEL, correlate the associated groups with level of disease and compare treatment with outcome data in these groups.

STUDY DESIGN/SETTING: Case reports of three patients and analysis of 104 cases from the literature.

PATIENT SAMPLE: Three patients from the senior author’s practice.

OUTCOME MEASURES: Not applicable.

METHODS: The authors report three new cases of SEL not associated with steroid use. They review all available English literature and present a table of all 104 reported cases.

RESULTS: The clinical course of three new patients is reported.

CONCLUSIONS: Associated conditions are exogenous steroid use, obesity, endogenous steroid excess, and some remain idiopathic. Although SEL is a rare condition, our review of the literature reveals many more reported cases than previously thought. With increased awareness of this condition and improved imaging techniques, further studies of this disease should be undertaken. © 2005 Elsevier Inc. All rights reserved.

Keywords: Dura mater/pathology; Lipoma/complications/pathology/radiography/surgery; Spinal cord compression/etiology

Introduction

Spinal epidural lipomatosis (SEL) is a disease consisting of an excessive deposition of normal adipose tissue in the spinal canal, compressing the spinal cord. Symptomatic SEL is exceedingly rare and often associated with exogenous steroid use. Although less common, obesity and Cushing syndrome/disease (hypercortisolism) have also played a role in SEL. Epidural lipomatosis becomes symptomatic in rare occasions by causing compression of the spinal cord or nerve roots. Because SEL can mimic other common spine conditions, such as spinal stenosis and degenerative joint disease, it was often underdiagnosed. Symptomatic epidural lipomatosis was first described in 1975 [1]. Since that time, a number of other cases have been diagnosed with the use of imaging in combination with clinical symptoms, history, surgical findings and the absence of other identifiable causes. Patients may present with progressive and longstanding complaints of pain, weakness, numbness, incontinence, ataxia, abnormal reflexes and even rarely paralysis. We report three new cases of SEL.

Case report 1

A 47-year-old man presented with low back pain of 2 years’ duration that began after a work-related injury. The pain was situated in his lower back with radiation to the buttocks and thighs bilaterally. It was associated with decreased sensation and weakness in both lower extremities. This pain was not associated with any bowel or bladder incontinence. The patient also had a history of neck pain with associated...
numbness, weakness and loss of sensation in the right upper extremity. His past medical history was significant for renal cancer that was treated by nephrectomy 6 years prior. The patient had no history of steroid use.

On physical examination, the patient was 5 feet 6 inches tall and weighed 140 pounds, with a body mass index (BMI) of 23.4. He had no structural spinal deformity. His range of motion was limited on both flexion and extension. Some tenderness was noted over his lower back bilaterally. Neurological examination revealed that the patient was intact with no nerve root tension signs. A computed tomography (CT) myelogram revealed prominent epidural fat from L2 to S1 with thecal sac compression. Complete cutoff of the intrathecal dye occurred at the L4–L5 level. CT scan cuts through the L4–L5 and L5–S1 levels demonstrated thecal sac compression by an extrinsic circumferential mass consistent with epidural lipomatosis (Figs. 1 and 2).

A laminectomy and decompression was performed from L2 to L5. Operative findings included marked adipose tissue in the spinal canal and stenosis. The patient lacked any neurological abnormalities postoperatively, although he did still complain of lower back pain.

Case report 2

A 48-year-old man developed an acute onset of low back pain that he attributed to a work-related fall. The patient continued to work, and his pain eventually resolved. Subsequently, the patient sustained a lifting injury at work, causing him severe low back pain. He denied leg pain after this injury. The patient participated in physical therapy and took leave of work. Two days later, he was unable to continue the physical therapy because of pain.

Magnetic resonance imaging (MRI) sagittal spin-echo T1-weighted images demonstrated widening of fat tissue in the epidural spinal canal rounding and compressing the thecal sac and nerve roots. Hypertrophic spondylosis of L2–S1 in the lumbar spine was noted. Axial T1-weighted MRI of the lumbar spine just cephalic to L5–S1 shows circumferential hyperintense and homogenous tissue elevating the dural sac and the nerve root. A sagittal T2-weighted image showed a high contrast between adipose tissue, and the dural sac on T2-weighted image permitted an accurate evaluation of the extent of pathologic overgrowth of epidural fat in the spinal canal. Hypertrophy of facet joints and end plates with discal bulging resulted in mild canal stenosis at multiple levels and increased epidural fat posterior to the dural sac that appeared compressed and indented below L2 (Figs. 3 and 4).

The patient received an epidural steroid shot. He reported that the pain became worse and began to radiate to both buttocks after the steroid injection. He was unable to walk after the steroid injection. He reported that his symptoms were occasionally accompanied by left leg numbness that extended to the bottom of the foot.

His past medical history was negative. His past surgical history was significant for a gunshot wound to the stomach sustained during the Gulf War. He denies taking steroids. His only medication was tramadol.

On physical examination, the patient was 6 feet tall and 270 pounds, with a BMI of 36.6. The patient had no spinal deformities. He stood with his lumbar spine flexed to 20 degrees, because of pain. He was unable to lie flat. Paravertebral muscle spasm was noted. He had no tenderness to palpation. His neurological examination showed that the patient was intact. A laminectomy and decompression was performed from L3–S1 with bilateral foraminotomy. Direct removal of the epidural lipomatosis was not reported.

Fig. 1. First patient: anteroposterior and lateral views of the lumbar myelogram demonstrate some extrinsic compression of the thecal contents at L3–L4 with complete blockage of the intrathecal dye above the L4–L5 disc space. Hypertrophic spondylosis is seen radiographically only at L5–S1.

Fig. 2. First patient: axial computed tomography myelogram views of L4–L5 shown in Fig. 1 demonstrate the extrinsic compression of the thecal sac just above the L4–L5 disc space. The compression is symmetrical and is close to water density, certainly less dense than ligamentum flavum, capsule or disc. There is an abnormal dural sac shape changed by the extrinsic pressures of the epidural lipoma.
Postoperatively, the patient improved, although he still complained of low back pain and the inability to stand completely erect. The patient started a supervised physical therapy program with some improvement of his back pain.

Case report 3

A 43-year-old man developed an acute onset of back pain after sustaining a lifting injury. The pain was situated in his mid-thoracic spine and radiated into his neck. Several days later, the pain became much worse and he was unable to walk or stand. He was immediately brought to the emergency room and admitted. His past medical history was negative. The patient had had three prior operations on his back for work-related injuries. The patient had no history of steroid use.

On physical examination the patient weighed 270 pounds and measured 6 feet 4 inches, with a BMI in excess of 30. On palpation, the patient complained of tenderness throughout his spine. His range of motion was severely limited by pain. His motor examination revealed flexor paralysis of both lower extremities. There was also weakness in handgrip bilaterally. Deep tendon reflexes were absent in the lower extremities and for the triceps tendon bilaterally. Plantar stimulation elicited no response. Sensory examination revealed decreased sensation to pinprick from and including the T1 level and down.

MRI of the thoracic spine with axial and sagittal T1-weighted images showed a marked high contrast between adipose tissue and the dural sac on T1-weighted images. The contrast permits an accurate evaluation of the extent of pathologic overgrowth of epidural fat in the spinal canal. On the sagittal T1-weighted image, the posterior epidural stripe of hyperintense lipomatosis is 8 to 10 mm in width throughout the thoracic spine. Axial views of T5–T6 showed extradural compression from epidural fat. Axial cuts from T10–T11 showed restoration of the symmetry of the dural contents and cerebrospinal fluid without the extradural compression (Figs. 5 and 6).

The patient was diagnosed with thoracic SEL and cervical spondylosis. A laminectomy and decompression was performed from C5 to C7 and T1 to T7. Although the patient made some improvement, at time of discharge he was unable to stand or walk and lacked bowel and bladder continence.

Discussion

We conducted a complete review of the available English literature, charting all reported cases of SEL, noting the most common associations of SEL, correlating these associations to the location of the disease process and examining the treatment to outcome data. We found 104 cases of SEL reported in the literature, including our three cases (Table 1).

Pathogenesis

The underlying pathological mechanism of SEL is unknown. A review of the literature and the data reported in the chart below reveal four categorical associations with SEL: exogenous steroid use, obesity, endogenous steroid excess or Cushing syndrome and an idiopathic group. The most common association is exogenous steroid use. SEL has been...
documented in association with steroid use for many conditions, including transplantation, systemic lupus erythematosus, rheumatoid arthritis, Graves disease, chronic hepatitis, dermatomyositis, nephritic syndrome, glomerulonephritis, sarcoidosis, Crohn’s disease, multiple sclerosis, chronic obstructive pulmonary disease, atopic dermatitis, diabetes mellitus, prostatic cancer, lichen ruber planus, pineoblastoma, cerebral lymphoma, polyarthritis, asthma and polyarteritis nodosum. It is well established that hypercortisolism leads to an accumulation of adipose tissue in a typical distribution, on the face, neck, trunk and mediastinum [2]. Hypertrophy of adipose tissue already present in the spinal canal is theorized to be the cause of SEL in certain cases of exogenous steroid use [3]. Based on our review, 55.3% of all reported cases in the English literature were associated with exogenous steroid use. Although the majority of these cases were associated with long-term steroid use, three of the cases arose from multiple epidural steroid injections: cases 13, 43 and 47. Patient 13 received a total of 103 injections over 12 years, eventually resulting in an abrupt onset of neurologic deficits at the end of this period. Patient 43 received a series of injections over a period of 3 years totaling 1,200 mg of methylprednisolone. Her physical examination revealed sequelae of Cushing syndrome, including moon facies and buffalo hump. Patient 47 received a total of five injections; the last three injections reportedly exacerbated his symptoms. In fact, one of these patients developed Cushing syndrome sequelae from these local injections [3–5].

Obesity is the second most common associated category of SEL. Koch et al. [2] hypothesized that obesity in this patient class may be caused by a pseudo-Cushing state exhibiting elevated urinary free cortisol levels. Unfortunately, no studies of obese patients with SEL have reported cortisol levels to date. Furthermore, some investigators question whether obesity plays a causal role in SEL or is merely a predisposing factor [6]. Borre et al reported 53 severe cases of SEL with 39 obese patients. Additionally, 4 were on steroids, 2 were hypothyroid and 1 was obese, had hypothyroidism and was taking steroids [18]. Our case review revealed 24.5% of reported cases attributable to obesity alone (It is important to note that this percentage includes only those patients who did not take steroids and were classified as obese by either the case reporter or BMI.)

Cushing syndrome/disease from endogenous sources is the third associated category in SEL. To date, only three cases of Cushing syndrome associated with SEL have been reported in the English literature accounting for 3.2% of SEL cases [7–9].

We found no identifiable association with SEL in 17% of the cases. This patient group includes those patients who did not take exogenous steroids, were not obese and did not have an underlying Cushing syndrome/disease to account for the SEL. Unfortunately, some of these patients also lacked certain of the data criteria. Of the 16 cases, 2 of these lacked data on the patient’s BMI. However, after consideration, we opted to include these cases in our analysis to be complete in analysis of all known cases in the English literature.

Hypothyroidism in previous papers has been associated with SEL [4,6,10,11]. Upon review, we disagree with this conclusion. There has been only one reported case of hypothyroidism associated with SEL [11]. This patient was obese,
Table 1
One hundred and four cases of spinal epidural lipomatosis from English literature review with diagnosis, presence of steroid usage or obesity, type and outcome of treatment

<table>
<thead>
<tr>
<th>Case</th>
<th>Reference</th>
<th>Pathology</th>
<th>Levels</th>
<th>Steroids</th>
<th>Obesity</th>
<th>Treatment</th>
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(Continued)
Table 1

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<tr>
<th>Case</th>
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<th>Levels</th>
<th>Steroids</th>
<th>Obesity</th>
<th>Treatment</th>
<th>Outcome</th>
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<td>Yes</td>
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<tr>
<td>75</td>
<td>[63]</td>
<td>None</td>
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<td>No</td>
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<td>CR</td>
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<tr>
<td>76</td>
<td>[64]</td>
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<td>L2–L5</td>
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<tr>
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<td>[66]</td>
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<tr>
<td>78</td>
<td>[66]</td>
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<tr>
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<td>No</td>
<td>No</td>
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(Continued)
Table 1 Continued

<table>
<thead>
<tr>
<th>Case</th>
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<th>Levels</th>
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<th>Treatment</th>
<th>Outcome</th>
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<td>Tumor removal</td>
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<td>[74]</td>
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<td>Lumbar</td>
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<td>Yes</td>
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<tr>
<td>98</td>
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<td>(macroprolactinoma)</td>
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<td>NR</td>
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<td>100</td>
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<td>Becker nevus associated</td>
<td>T4–T7</td>
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<td>Laminectomy</td>
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<td>Yes</td>
<td>Laminectomy</td>
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<tr>
<td>104</td>
<td>[78]</td>
<td>None</td>
<td>Lumbar</td>
<td>No</td>
<td>Yes</td>
<td>Laminectomy</td>
<td>Improved</td>
</tr>
</tbody>
</table>

CR=complete recovery; FU=follow-up; LE=lower extremity; NR=not reported.

the second leading association with SEL. There is the persuasive argument that hypothyroidism is associated with generalized fat deposition resulting from decreased lipolysis. However, the data are insufficient to link hypothyroidism and SEL [3,4,10,11]. This linkage would require cases of nonobese patients with hypothyroidism and SEL to be considered an independent risk factor. The case of an obese patient with hypothyroidism and SEL can only be considered a case of obesity associated with SEL.

Imaging

Most case reports relied heavily on CT imaging and myelography [12,13]. However, MRI is now recognized as the most sensitive and specific modality for evaluating fatty tissue [14–16]. T1-weighted images differentiate epidural fat from dural content with a high degree of specificity and allow for measurement of adipose thickness. Quint et al. [17] conducted a study in which 28 normal patients were imaged and their epidural adipose measured. The mean sagittal thickness of their epidural fat was 4.6 mm with a normal range of 3 to 6 mm. In contrast, imaging in 6 patients with SEL revealed a mean thickness of 8 mm [17]. Borre et al. [18], on the lumbar MRIs of 2,258 patients, measured the anterior posterior diameters of the dural sac and spinal canal and the thickness of the epidural fat. Borre et al. developed an MRI classification based on these ratios. Grade 0 or normal was defined as epidural fat less than 40% of canal width, and dural 150% width of epidural fat. Grade I was defined as epidural fat less than 50% of the canal width and less than 50% of the dural width. Grade I was not symptomatic. Grade II was defined as the epidural fat 50% to 75% of the canal and 100% to 150% the width of the dural sac. Grade II SEL was symptomatic in 14% of cases. Grade III was defined as the epidural fat more than 75% of canal width and the dural 30% the width of the fat. All Grade III SEL cases were symptomatic. In Grade III cases, there was a 42% rate of associated substantial pathology, such as disc herniation or stenosis. Also in the Grade III SEL, the epidural fat produces centripetal pressures on the thecal sac changing the morphology or shape. Most commonly a trifid or Y shape may be seen. Borre et al. [18] report six other patterns seen in axial magnetic imaging.

Level of disease

Examining all available case reports, we were able to determine incidences of spinal level involvement. From the reported cases, 45.8% had thoracic involvement only, 43.6% had lumbosacral involvement only and 10.6% had involvement in both thoracic and the lumbosacral area. We correlated location of disease to the associated categories to ascertain whether any trends existed. Of the 52 patients with a history of steroid use, 55.8% were found to have thoracic involvement only, 32.7% with lumbosacral involvement only and 11.5% with both thoracic and lumbosacral involvement. Data from the patients in the obese category reveal a stronger trend: 69.6% had lumbosacral involvement only, and 30.4% had thoracic involvement only. The idiopathic group consisted of 16 patients. Of the 16 patients, 37.5% had thoracic spine involvement only, 32.7% with lumbosacral involvement only and 11.5% with both thoracic and lumbosacral involvement. Data from the patients in the obese category reveal a stronger trend: 69.6% had lumbosacral involvement only, and 30.4% had thoracic involvement only. The idiopathic group consisted of 16 patients. Of the 16 patients, 37.5% had thoracic spine involvement only, 32.7% with lumbosacral involvement only and 11.5% with both thoracic and lumbosacral involvement. Of the three patients with Cushing syndrome/disease from endogenous sources, 66.6%, had both thoracic and lumbosacral involvement and 33.3% had thoracic involvement only. Although four of the
cases reported cervical involvement, these cases had SEL throughout the spine and were included in the percentages of thoracic and lumbosacral involvement. We have found no cases of SEL isolated to the cervical region.

Investigators initially reported a significantly higher incidence of thoracic SEL. This was theorized to be secondary to the fact that the thoracic region has the largest amount of epidural fat [10,17,19]. Contrary to this popular belief, our case review indicates that SEL is found in approximately the same number of cases in both the thoracic and the lumbosacral region. The previous causal relationship is no longer present with this new information. It is clear that further studies into the etiology of SEL are required.

Treatment

Treatment of SEL ranges from conservative management to surgical excision. The success rates were calculated assuming that none of the patients in the surgical group were first treated conservatively. In the event that the reviewed data revealed a failed conservative treatment that then proceeded to surgery, these patients were included in both groups or were specifically discussed. In the steroid patient group, three of the cases lacked outcome data and are therefore considered to have no improvement for purposes of this analysis. Thirty-nine patients received a laminectomy and debulking, accounting for 75% of those patients in the steroid group (39 of 52). The success rate of this modality was 77% (31 of 39 patients receiving a laminectomy had results ranging from improved symptoms to complete recovery). The remaining 13 patients (25%) received a combination of different medical treatments, including weight loss, steroid taper, analgesics, bed rest and observation. One of the 13 received high-dose steroids for symptoms. The success rate of medical management of these patients was 77%. Borre et al. [18] reported that 26 patients were treated medically and surgically, accounting for 75% of those patients in the steroid group (39 of 52). The success rate of this modality was 77% (31 of 39 patients receiving a laminectomy had results ranging from improved symptoms to complete recovery). The remaining 13 patients (25%) received a combination of different medical treatments, including weight loss, steroid taper, analgesics, bed rest and observation. One of the 13 received high-dose steroids for symptoms. The success rate of medical management of these patients was 77%.

Borre et al. [18] reported that 26 patients were treated medically and surgically. In the surgical group 16 of 18 had associated spinal pathology treated, such as disc herniation and stenosis decompression. Two patients were decompressed surgically with such a high ratio of epidural fat to canal and dural width and presented with neurologic compromise and cauda equina syndrome [18]. Although both modalities appeared to treat SEL successfully in approximately 75% of the cases, these data do not reveal criteria for selecting a treatment modality.

The obese patient group was split between surgical correction and weight loss treatment modalities: 52.2% were treated by laminectomy and debulking, 47.8% by weight loss. The success rate of the surgically managed group was 66.7%. The patients managed conservatively by weight loss improved in 81.8% of the cases, with the one patient lacking outcome data considered having no improvement. Two patients not included in the conservative group previously failed conservative treatment before surgical treatment was administered. One of the patients was managed by physiotherapy and nonsteroidal anti-inflammatory medication, not weight loss. The other patient failed to lose weight. Because conservative care was not successful, they were not included in that group. Based on these data, weight loss as a treatment modality appears to be very successful and should be considered the first line of treatment in this patient group, with surgical correction reserved for those patients who fail to respond clinically to a weight loss plan or are unable to lose weight.

One of the patients in the idiopathic group lacked outcome data and was therefore considered to have a poor outcome. All of the patients in this group were treated by laminectomy, with a success rate of 93.75%. The only patient without improvement lacked outcome data. Surgical treatment of patients with no discernable cause for SEL appears to be the treatment of choice. The three patients who were diagnosed with SEL associated with endogenous steroid excess or Cushing disease/syndrome were treated differently. Because all three of these patients had an underlying disorder causing endogenous steroid excess, the underlying disorder was treated. Two of the patients had surgical removal of the tumor causing the steroid excess, and the remaining patient was treated with ketanazole, an inhibitor of steroidogenesis. All three of the patients improved.

Conclusions

Symptomatic SEL is a rare condition consisting of excess adipose tissue in the spinal canal causing compression of the spinal cord and resulting neurologic symptoms. Four categories have been identified as associated with SEL: exogenous steroid use, obesity, endogenous steroid excess and idiopathic. Thoracic and lumbosacral levels are usually affected by SEL, with the incidence between the two roughly equal. No case of isolated cervical involvement was found. A new MRI grading scale may help define those patients who will improve expectantly (Grade I) from those who may require surgical decompression (Grade III). Surgical treatment in the Grade III SEL may also treat commonly associated degenerative stenosis, and facet pathology. Obese patients tend to develop SEL in the lumbosacral region three times more often than in the thoracic, whereas steroid use tends to cause SEL in the thoracic region slightly less than twice as often as in the lumbosacral region. Obese patients should be managed by diet alone initially, with surgery reserved for those without a significant clinical response. Although SEL is a rare condition, our review of the literature reveals many more reported cases than previously thought. With increased awareness of this condition and improved imaging techniques, further studies of this disease should be undertaken.

References


Surgical treatment of dysphagia after anterior cervical interbody fusion

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Abstract

BACKGROUND CONTEXT: Dysphagia is a frequent complication after anterior cervical interbody fusion (ACIF). Although dysphagia usually improves over 6 months, it remains a significant and persistent problem for some patients. The etiology is poorly understood but has been reported to be associated with vocal cord paralysis, dislodgement of instrumentation and unidentified causes, such as hematoma, adhesion formation and denervation of the pharyngeal plexus. A surgical treatment of dysphagia after ACIF has not been reported.

PURPOSE: We report the surgical treatment of persistent dysphagia occurring after ACIF with instrumentation.

STUDY DESIGN/SETTING: A retrospective review of cervical discectomy and interbody fusion patients identified a subset of patients with symptomatic dysphagia who chose surgical treatment of the dysphagia. The hypothesis is that removal of the anterior cervical plate will release mechanical adhesions of the esophagus to the anterior spine around the plate. Outcome was graded by examination and a final telephonic interview with a dysphagia questionnaire.

METHODS: Thirty-one patients who elected surgical treatment for persistent dysphagia were assessed at clinic visits after surgery at 3, 6 and 12 months for symptomatic dysphagia, and with a final telephonic questionnaire. The average time from initial surgery to time of surgical treatment for dysphagia was 18 months. Final follow-up was an average 11 months (range, 6 to 25 months) with a dysphagia questionnaire using the Bazaz-Yoo dysphagia score. Thirty-one patients responded to a phone questionnaire with the Bazaz-Yoo dysphagia score.

RESULTS: The primary operative finding was extensive adhesions attaching the esophagus to the prevertebral fascia and anterior cervical spine around the periphery of the cervical plate. Seventeen patients (55%) were significantly improved to no dysphagia of solids and liquids (p<.0001). Ten patients (32%) reported mild dysphagia occasionally with specific foods. Three patients had persistent moderate occasional dysphagia with solid food. Two patients had persistent severe dysphagia of solids and liquids. Previous cervical surgery, particularly with pre-existing dysphagia, and unexpectedly extreme amounts of adhesions at surgery were contributing factors to the cases with persistent severe dysphagia.

CONCLUSIONS: Surgical treatment of dysphagia after ACIF has not been reported. Removal of the cervical instrumentation in patients will improve the dysphagia. This improvement with surgical management, as compared with the dissatisfaction before surgical treatment, documents that this surgical treatment is a reasonable option. © 2005 Elsevier Inc. All rights reserved.

Keywords: Dysphagia; Complications, cervical; Cervical plate

Introduction

Anterior cervical discectomy and interbody fusion is frequently performed for disc herniation and spondylosis. Although the procedure is associated with low morbidity, dysphagia is a common postoperative complaint [1–17]. Dysphagia is defined as difficulty with swallowing both solids and liquids and includes the inability to protect the airway from aspiration. Patients with dysphagia report
difficulty with solid and liquid food. Some report painful swallowing (odynophagia), difficulty with saliva, food sticking in the throat and coughing with eating. Common symptoms are listed in Table 1.

Postoperative dysphagia usually improves with time. However, there are some patients with persistent symptoms that do not improve spontaneously. Winslow et al. [5] in a questionnaire study of noninstrumented anterior cervical interbody fusion (ACIF) patients found early dysphagia in 60% and long-lasting dysphagia in 23% [5]. In a prospective consecutive series of both instrumented and noninstrumented ACIF, Bazaz et al. [2] described a significant rate of dysphagia that decreased over time and stabilized at a 12.5% rate at 12 months. Yue et al. [14] evaluated 74 patients of dysphagia that decreased over time and stabilized at a

In a questionnaire study of noninstrumented anterior cervical interbody fusion (ACIF) patients found early dysphagia in 60% and long-lasting dysphagia in 23% [5]. In a prospective consecutive series of both instrumented and noninstrumented ACIF, Bazaz et al. [2] described a significant rate of dysphagia that decreased over time and stabilized at a 12.5% rate at 12 months. Yue et al. [14] evaluated 74 patients at an average 7.2 years after instrumented ACIF and found a 35% incidence of persistent dysphagia with 17.6% moderate and severe symptoms.

Early in our experience, several patients were referred for otolaryngology evaluation for persistent dysphagia after instrumented anterior cervical interbody fusion. The patients returned without meaningful abnormalities detected on barium swallow, laryngeal endoscopy or esophageal manometry. The otolaryngology specialists suggested no remedy for the dysphagia. In the same time period, the senior author had noted a clinical improvement in dysphagia occurring after cervical instrumentation removal in two patients with severe preoperative symptoms of dysphagia. The hypothesis is that removal of the anterior cervical plate will release mechanical adhesions of the esophagus to the anterior spine around the plate.

With clinical success in two patients, cervical instrumentation removal was offered to patients with significant persistent dysphagia after ACIF. Our series of anterior cervical disectomy and interbody fusion (ACIF) for treatment of disc herniation and spondylisis was reviewed. Patients were identified who chose to have exploration of the anterior fusion with removal of anterior cervical instrumentation. We report the surgical treatment results in this group of ACIF patients with persistent dysphagia.

| Table 1 |
|________|
| Symptoms of dysphagia |
| More obvious symptoms |
| Pain with swallowing |
| Difficulty swallowing |
| Heartburn |
| Coughing or choking with swallowing |
| Regurgitation of old foodstuffs |
| Nasal regurgitation |
| Feeling of blockage |
| Weight loss |
| Less obvious symptoms |
| Food avoidance |
| Frequent throat clearing |
| Changes in breathing after swallowing |
| Wet voice quality |

| Table 2 |
|________|
| Dysphagia score symptoms |
| Severity | Liquid | Solid |
|________|________|________|
| 0.None | None | None |
| 1.Mild | None | Rare |
| 2.Moderate | None or rare | Occasionally with specific food |
| 3.Severe | None or rare | Frequent (majority of solids) |

From Bazaz et al. [2].
reviewed for patient’s age, gender, surgical procedure, tobacco use and number and location of surgical levels addressed.

The average age was 43 years with a range of 25 to 66 years. Twenty-eight (64%) were men and 18 (41%) women. The number of levels in the initial anterior cervical interbody fusion in the 31 patients ranged from one to four levels with a mean of three levels. Seventy percent of the fusions were at three or four levels.

All patients had indication of symptomatic anterior hardware and dysphagia categorized as moderate or severe. Additional indications at the time of surgical treatment of dysphagia were exploration for pseudarthrosis (five; 16%) or adjacent segment deterioration (six; 19%). Three patients had undergone previous surgery, and two of these had pre-existing dysphagia and dysphonia before the index ACIF.

**Results**

The Bazaz-Yoo dysphagia score before surgical treatment of dysphagia in the 31 patients was moderate dysphagia in 15 (48%) or severe dysphagia in 16 (52%). The patients had more severe dysphagia with solids than liquids (Table 3). The Bazaz-Yoo dysphagia score after instrumentation removal in the 31 patients at last examination showed significant improvement in dysphagia scores of liquids and solids (p<0.0001). One (3%) had continued severe dysphagia of solids and liquids. Three patients (10%) had persistent moderate dysphagia. In 17 patients (55%) there was no dysphagia at all. Ten (32%) reported mild occasional dysphagia with certain solids, such as steak and bread (Table 3).

At the time of cervical instrumentation removal, the primary operative finding was extensive adhesions attaching the esophagus-trachea midline structures to the prevertebral fascia and anterior cervical spine around the periphery of the cervical instrumentation and through any open aperture in the plate. Releasing the adhesions between the esophagus and the anterior cervical spine was the key to restoring mobility to the esophagus. Fig. 1 illustrates the plane of surgical release of adhesions accomplished with removal of the cervical plate. The status and condition of the plates at the time of surgery was uniformly benign. The plates were not fractured or corroded. There was no screw failure or screw loosening observed. In three cases, there was some tissue staining beneath the plate, typical of titanium plates and screws. There were no cases with visible metallic wear debris reported.

Approaching the cervical spine through the previous incision was not difficult. However, twice there was unusually dense and prolific adhesions found at the time of surgery. In these two cases, the dissection was more difficult. In both of the patients there was recurrent moderate to severe dysphagia. In one patient, there was a history of three additional previous surgeries, with pre-existing dysphonia and dysphagia rated as moderate. An otolaryngologist performed preoperative evaluation of the vocal cords and the approach at the index surgery and reported intense scarring but no damage to the vocal folds or visceral structures. At final examination, there was barium swallow evidence of a pharyngeal diverticulum. His dysphagia was rated severe. His dysphonia was mild. In the other patient with extreme scarring at surgery, there was an extraordinary odynophagia, choking of solids and liquids, and difficulty breathing before surgery rated as severe dysphagia and dysphonia. For 2 months after surgery, the dysphagia was improving; thereafter the symptoms recurred and worsened. At final examination there was severe dysphagia and a vocal fold paralysis that responded finally to a gelfoam implant. Complications of the surgical treatment of dysphagia were continued symptoms of dysphagia as severe in 2 (5%), moderate in 3 (7%) and mild in 16 (36%). Two were initially much improved in their dysphagia, but symptoms recurred 6 to 12 weeks after surgical treatment. One patient had a persistent vocal fold paralysis and 3 more had dysphonia without known vocal fold paralysis. One developed a symptomatic pharyngeal diverticulum.

### Table 3

<table>
<thead>
<tr>
<th>Severity</th>
<th>Liquid</th>
<th>Solid</th>
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<tr>
<td></td>
<td>Preoperative/last score (%)</td>
<td>p Value</td>
</tr>
<tr>
<td>0:None</td>
<td>0/81</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>1:Mild</td>
<td>26/16</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>2:Severe</td>
<td>63/3</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>3:Severe</td>
<td>10/0</td>
<td>.0377</td>
</tr>
<tr>
<td>Median</td>
<td>2.0</td>
<td>3.0</td>
</tr>
<tr>
<td>SD</td>
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<td>1/1</td>
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</table>
associated with severe dysphagia. One Horner syndrome resolved at 3 months after surgery (Table 4).

Discussion

The literature on the incidence of dysphagia is largely retrospective. The incidence varies widely from the literature, with reports varying from 2% to 60% [2,5,15,18,19]. From reports in the literature, persistent dysphagia occurs whether or not the anterior cervical spine is instrumented [1,2,10,17]. The incidence in the instrumented versus noninstrumented cases in the literature may be slightly higher in the instrumented group. Albert et al. [7] in the multicentric instrumented cervical plate study sponsored by the Cervical Spine Research Society are currently reporting incidence of 7.9% dysphagia in instrumented ACIF patients at 24 months and 5.3% in nonplated ACIF patients. Edwards et al. [8] compared the outpatient records of four spine surgeons from two different academic medical centers with the results of a brief survey mailed to patients. Dysphagia was recorded as present in surgeon records 25 times and 104 times by patient survey. Edwards et al. concluded that dysphagia was underreported by 76% in surgeon records with very poor correlation to the patients’ responses in the survey.

Bazaz et al. [2] found a 50% incidence of dysphagia at 1 month after anterior cervical surgery that improved to 12.6% at 12 months. Yue et al. [14] invited 74 patients to return for examination by two independent reviewers at an average 7.2 years (range, 5.4 to 11.1 years). Persistent dysphagia of mild to severe was present in 36% and moderate or severe dysphagia was found in 17.6% [14]. The persistent dysphagia rate in the current study is very similar to that determined by Yue et al. The dysphagia incidence in the current study may appear higher than expected, but it is clear from the Yue et al. and the Edwards et al. reports that the true incidence of persistent dysphagia is higher than that previously stated in the literature and is often underreported.

Risk factors for dysphagia, such as age, gender, primary versus revision surgery, usage of cervical plate and number of levels treated, have been previously described [1,5,10–12,20–23]. Dysphagia has been reported to be associated with vocal cord paralysis [1,15,16,24] or prevertebral edema [10]. Frempong-Boadu et al. [1] reported 48% of ACIF patients had preoperative evidence of radiographic swallowing abnormalities, and Doran et al. [25] found 50% of patients with prior cervical surgery had postoperative barium swallow abnormalities. Revision surgery with additional scarring, the risks of reoperation through a previous incisional scar and previous dysphagia and dysphonia may increase the risk of recurrent and persistent dysphagia. Increased prominence of the instrumentation, graft or screws could cause esophageal irritation, even erosion and death [26]. All current anterior cervical plating systems are designed with minimal profile and the screw lock to the plate by various methods to prevent screw back out, which could cause esophageal irritation and dysphagia [27]. The PEAK Plate system of Depuy-Acromed used in this study is a contemporary system with a profile height of 3.2 mm and a width of 18.1 mm. Dislodgement of the graft or instrumentation is a known cause of dysphagia [18,28]. No case of instrumentation dislodgement or bone graft displacement was identified in this series. Anterior instrumentation, screw heads and grafts should be kept flush with the surface of the spine to minimize local esophageal irritation.

Intense adhesions were found in each of our cases at instrumentation removal surgery. These adhesions seem to flow smoothly around the surfaces of the plate along all edges, without actually attaching to it. Adhesions extended from the esophagus through the holes in the plate down to the bone surface. The adhesions attach the esophagus to the anterior vertebral surfaces around the borders of the plate. While removing the plate, adhesions attaching the esophagus to the vertebral surface adjacent to the plate are removed. The esophagus is freed from the cervical surface below. With the initial ACIF, the magnitude of the adhesions is increased by the presence of raw and oozing bone exposed during the subperiosteal dissection, drilling and burring necessary for the adequate preparation of the site. The adhesion formation after plate removal may be less intense because there is no exposed bleeding bone surface to produce a significant hemotoma. The patient has a better chance of not adhering the esophagus to the bone again.

Table 4

<table>
<thead>
<tr>
<th>Levels</th>
<th>Complications</th>
<th>LFU Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>C3–C7</td>
<td>Dysphonia</td>
<td>Dysphonia mild with singing</td>
</tr>
<tr>
<td>C4–C6</td>
<td>None</td>
<td>Snoring increased</td>
</tr>
<tr>
<td>C3–C7</td>
<td>Dysphagia and dysphonia before surgery</td>
<td>Mild occasional choking on large solids, mild dysphagia, continued neck pain,</td>
</tr>
<tr>
<td>C3–C6</td>
<td>None</td>
<td>Diabetic</td>
</tr>
<tr>
<td>C3–C6</td>
<td>Most severe scarring, 1 inch thick</td>
<td>Severe residual dysphagia, pharyngeal diverticulum, severe neck pain and headaches</td>
</tr>
<tr>
<td>C3–C6</td>
<td>None</td>
<td>Initially good but recurrent dysphagia</td>
</tr>
<tr>
<td>C3–C7</td>
<td>Dysphonia</td>
<td>Continued dysphonia</td>
</tr>
<tr>
<td>C4–C6</td>
<td>Horner syndrome for 3 months</td>
<td>Horner syndrome resolved</td>
</tr>
<tr>
<td>C3–C6</td>
<td>Most intense scarring, VFP</td>
<td>VFP with implant; dysphagia improved 2 months, then worsened; normal barium swallow</td>
</tr>
<tr>
<td>C4–T1</td>
<td>Dysphagia and dysphagia before surgery</td>
<td>Good relief of dysphagia, mild dysphonia</td>
</tr>
</tbody>
</table>

LFU=last follow-up; VFP=vocal fold paralysis.
One shortcoming of this study is the inability to answer the question of whether relief of dysphagia with lysis of adhesions in other situations, such as noninstrumented cases or instrumented cases treated without plate removal, would be as effective in treatment of dysphagia. Unfortunately, this study, without a noninstrumented control group, cannot answer that question. In literature review, there is a similar incidence of dysphagia in the instrumented and noninstrumented cases. However, it is interesting that dysphagia may be improved in cases with revision for pseudarthrosis or extension for adjacent segment deterioration with removal and insertion of a new plate. Another shortcoming of the present study is the lack of pre- and postoperative barium swallow and otolaryngology evaluations. It is our opinion from the literature and our experience that the testing does not reflect the severity of the dysphagia, and it does not suggest any remedy for the severe symptoms. A last shortcoming is a proper assessment of the effect of the instrumentation’s contribution to dysphagia; for example, the thickness of the plate and such properties as corrosion and tissue staining may have some effect. This study did not find any direct contribution of the instrumentation to dysphagia.

Conclusions

Surgical treatment of dysphagia after ACIF has not been reported. Removal of the anterior cervical instrumentation in patients with residual significant dysphagia will improve the dysphagia. This improvement with surgical management, as compared with the dissatisfaction before instrumentation removal surgery because of dysphagia, documents that this surgical treatment is a reasonable option.

References

DISCUSSION: There are multiple clinical studies correlating a previous fusion with adjacent lumbar degeneration. Our study examines long-term survivorship of segments adjacent to lumbarosacral fusions. The adjacent segment degeneration in our study is in agreement with previous findings. The rate and type of repeat surgeries, however, differ from previous data.

CONCLUSIONS: Adjacent segment disease appears to be a real concern following lumbarosacral posterior spinal fusion. At an average follow-up of 6.9 years, 26% of patients required reoperation, with 91% of these being proximal lumbar fusions. Although the majority of the adjacent segment disease occurred at the immediately adjacent segment, levels more proximal were affected as well. There was radiographic progression of the adjacent segment disease, but preoperative grading did not correlate with the need for further surgery.

DISCLOSURES: No disclosures.

CONFLICT OF INTEREST: No conflicts.

doi: 10.1016/S1529-9430(03)00234-1

4:42

54. Adjacent level ossification disease (ALOD) secondary to anterior cervical plates

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HYPOTHESIS: There are few studies concerning the association between osteophyte formation and anterior cervical plates. It has been the senior author’s empiric experience that peri-plate ossification of the adjacent segment occurs commonly. Our hypothesis is that the closer the plate to the adjacent disc space, the greater the ossification.

METHODS: One hundred and eighteen patients, who had no previous cervical surgery and achieved a solid fusion following anterior cervical arthrodesis with a plate for degenerative cervical conditions, with a minimum of 1 year follow-up were identified from a database for inclusion in this study. All of the procedures were performed by the senior author and all of the radiographic analyses were independently performed by 2 experienced spine surgeons who were uninformed in the patients’ care. The mean age was 51.8 years. The mean duration of post-operative follow-up was 25.7 months (range: 12–76). Thirty-six patients underwent a 1-level arthrodesis; 47 a 2-level; 32 a 3-level; and 3 had a 4-level arthrodesis. The distance between the tip of the plate and the caudal as well as the rostral adjacent disc was measured (plate-to-disc distance). This distance was used to divide the patients into two groups: group A, plate-to-disc distance <5 mm and group B, ≥5 mm. The severity of ALOD (adjacent level ossification disease) at the 2 adjacent disc spaces were classified using the following grading system: 0: none; 1 (minimal): extends across <50% of the disc space; 2 (moderate): >50% of the disc space; 3 (severe): complete bridging of the disc space. Each observer determined the grade twice and the average of the four measurements was used as the final grade. Eighteen patients were excluded from the measurement of distal plate-to-disc distance due to bony overlapping of the shoulder and cervicothoracic junction. The incidence and severity of ALOD were compared between the groups by the Chi-square test and Mann-Whitney test.

RESULTS: The inter-observer variability for the measurement technique was 0.96 and the intra-observer variability was 0.98. An alarming 59.5% (70/118) developed adjacent level ossification at the rostral disc space while 29% (29/100) developed it at the caudal disc space. The incidence of rostral ALOD was 67.0% (65/97) in patients with a plate-to-disc distance <5 mm vs. 23.8% (5/21) for >3.5 mm (p<0.001). The severity grade of rostral ALOD was 0.96±0.88 in patients with a plate-to-disc distance <5 mm vs. 0.24±0.44 for >3.5 mm (p<0.001). The incidence of caudal ALOD was 45% (27/60) in patients with a plate-to-disc distance <5 mm vs. 5% (2/40) for >3.5 mm (p<0.001). The severity grade of caudal ALOD was 0.67±0.90 in patients with a plate-to-disc distance <5 mm and 0.10±0.44 for >3.5 mm (p<0.001).

DISCUSSION: We believe that the current findings definitively demonstrate that if the plate is placed <5 mm from either the rostral or caudal disc space, there is a markedly increased risk of moderate to severe ALOD. Based upon our data, we now strive to keep the plate as far away from the adjacent disc space as possible.

CONCLUSIONS: To our knowledge, the alarming rates of ALOD following anterior cervical plates, and its relationship to the plate-to-disc distance have not been previously reported. We recommend that anterior cervical plates be placed at least 5 mm away from the adjacent disc space in order to decrease the likelihood of ALOD. A greater initial distance would be necessary when using subsidence plates.


CONFLICT OF INTEREST: No conflicts.

doi: 10.1016/S1529-9430(03)00234-1

4:46

55. Anterior hardware removal improves dysphagia following anterior cervical discectomy and fusion

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HYPOTHESIS: Removal of the anterior cervical plate in patients with symptomatic dysphagia after anterior instrumented fusion of multiple cervical levels will improve dysphagia.

METHODS: Two hundred and ninety-one patients treated with instrumented anterior discectomy and interbody fusion (ACIF) were assessed at 3 months, 6 months, and 12 months for symptomatic dysphagia. Eighty-two patients had residual complaints of dysphagia of solids or liquids at 6 months. Forty-nine patients had moderate or severe symptoms. Ninety-eight patients had removal of the anterior cervical plate. Forty-six patients had the indication of dysphagia. 26 patients had moderate or severe symptoms. The average time follow-up from the index ACIF was 30 months. The average time to hardware removal was 16 months. These 46 patients were assessed at average 13 months after plate removal for dysphagia, with an extensive outcome questionnaire using the Bazaz dysphagia score (Bazaz, Lee et al. 2002), visual analog scale, the North American Spine Society Satisfaction Questionnaire, and a modified Oswestry Disability Index.

RESULTS: The primary operative finding was extensive adhesions attaching the esophagus-trachea midline structures to the pre-vertebral fascia and anterior cervical spine around the periphery of the cervical plate. All patients reported improvement in the level of dysphagia after hardware removal. Forty-one patients were improved to only rare dysphagia of solids and no problems with liquids. Five patients reported dysphagia occasionally with specific foods. No patients had persistent frequent dysphagia with solid food.

DISCUSSION: Dysphagia is a frequent complication at one month after ACIF. Although dysphagia usually improves over 6 months, it remained a significant and persistent problem at 6 month follow up in 18% of our ACIF patients. The etiology is poorly understood, but has been reported to be associated with vocal cord paralysis, dislodgement of hardware, and unidentified causes such as hematoma, adhesion formation, and denervation of the pharyngeal plexus (Frempong-Boadu, Houten et al. 2002). Intense adhesions were found in each of our cases at surgery. All patients improved with removal of instrumentation and lysis of adhesions. Adhesion formation is the primary cause of dysphagia after anterior cervical surgery. Surgical treatment of dysphagia after ACIF has not been reported. Removal of the cervical hardware in patients with residual significant dysphagia will improve the dysphagia.

CONCLUSIONS: Adhesion formation is the primary cause of dysphagia after anterior cervical surgery. Surgical treatment of dysphagia after ACIF has not been reported. Removal of the cervical hardware in patients with residual significant dysphagia will improve the dysphagia.
4:50
56. Vascular injury during anterior lumbar surgery
Salvador Brau, MD1, Rick Delamerat, MD2, Michael Schiffman1, Lynton Williams, MD3, Robert Watkins, MD4, 1Spin Access Surgery Associates, Los Angeles, CA, USA; 2Saint John’s Health Center, Santa Monica, CA, USA; 3OCLA, Los Angeles, CA, USA; 4Los Angeles Spine Surgery Institute, Los Angeles, CA, USA

HYPOTHESIS: Vascular injury is a known complication of the approach for anterior lumbar surgery. Case reports and reviews of complications have appeared in the literature, but the true incidence of both arterial and venous injuries is not well established. Our large study tries to more accurately establish this incidence by evaluating 1315 consecutive cases undergoing anterior lumbar surgery at various levels from L2 to S1.

METHODS: One of the authors (SAB) performed 1315 approaches on 1310 patients between August 1997 and December 2002 using a mini-open approach previously described by him. A concurrent database was kept on these patients to track the approach complications with particular emphasis on vascular injury. Calcification of the vessels alone was not considered a contraindication to surgery. All patients had pedal pulses evaluated pre-operatively, but no vascular studies were performed before surgery. Pulse oxymetry was used to measure oxygen saturation (SaO2) in the left foot during and for 4 hr. after surgery in our last 629 cases.

RESULTS: There were 643 males and 667 females. Age ranged from 19 to 84 years and weight from 94 to 337 lbs. Six of the 1315 cases (0.45%) (5 female 1 male) had left iliac artery thrombosis (LIAT). All six had exposure at L4-5. Five were diagnosed at surgery and one in the PAR after posterior surgery. All patients had 2+ pedal pulses pre-op except for 1 patient with a 1+ left pedal pulse who ended up having LIAT. Pulse oxymetry confirmed the diagnosis in the the last two patients when LIAT was not clinically obvious. Four had thrombectomy (1 with intimal tear repair) 1 a fem-fem bypass and 1 an axillo-femoral bypass. Four had no sequelae and 2 had compartment syndromes. There were 19 venous injuries (1.4%) to the left common iliac vein and all but 4 were at L4-5. All were repaired with blood loss ranging from 100cc to 3000cc (mean 650cc). In 2 patients the procedure was aborted following repair in one and ligation of the vena cava and both iliac veins in the other.

DISCUSSION: Our study shows that although the incidence of vascular injury is low (0.45% for LIAT and 1.4% for venous injury), the sequelae can be quite significant. Two patients with LIAT required bypass surgery and two that developed compartment syndrome had significant residual damage to the left leg. The two patients with venous injury that had to be aborted recovered without incident, but later required posterior instrumentation.

CONCLUSIONS: A prior study by one of the authors (SAB) has shown that the majority of patients undergoing anterior surgery at L4-5 have complete occlusion of the left iliac artery during retraction. Venous return is also obstructed at the same time. With the amount of exposure required it is seems likely that vascular injuries may occur. Ligation of the ilio-lumbar vein in exposing L4-5 is mandatory to avoid tearing it while mobilizing the left iliac vein to the right. If small venous lacerations occur during exposure and they can be repaired easily then the procedure can continue. The sequelae of LIAT can be minimised by monitoring SaO2 in the left leg with pulse oxymetry. Failure of the SaO2 to return to normal after removal of the retractors is diagnostic of LIAT and treatment should be instituted immediately. Since only 5 of 1315 patients suffered significant sequelae from vascular complications it appears that a mini-open, anterior approach is safe, though it must be carried out with great respect for the vessels to avoid possible catastrophic outcomes.

DISCLOSURES: No disclosures.

CONFLICT OF INTEREST: No conflicts.
CHAPTER 33

Complications, Pitfalls, and Their Management

John W. Brantigan, Guy R. Fogel

The Lumbar Interbody Fusion Cage (DePuy Spine, Raynham, MA) used for posterior lumbar interbody fusion (PLIF) had good results in its initial custom use and was approved by the FDA in 1999 based on favorable results in a multicenter prospective study in which no surgeon performed more than a few dozen cases. Although statistical results are best determined through prospective studies, other lessons may be best learned after a few surgeons have had an opportunity to perform several hundred cases. The goal of this study is to determine results, complications, pitfalls, and guidelines that can be described when the Lumbar Interbody Fusion Cage with pedicle screw fixation is used routinely in a clinical private practice setting for treatment of patients with disabling back pain secondary to degenerative disc disease.

The current study is a retrospective evaluation of the first 425 patients who have had surgery by a single group that originally included five orthopedic spine surgeons between February 1999 and October 2003, when the group included three surgeons. The study was initiated in October 2004 to ensure that each patient had the opportunity for a 1-year follow-up. Inclusion and exclusion criteria are listed in Box 33-1. Although 1 year is generally insufficient to determine surgical outcome on a statistical basis, it should be sufficient to identify pitfalls and complications.

All charts were reviewed and data placed in a computerized database by two experienced surgeons, one of whom had not participated in the surgery (G.R.F.). Because the endpoint of the study was the last recorded follow-up, patients were studied for variable intervals from 1 to 4 years. Many but not all radiographs were reviewed in this study. Radiographs were reviewed for every patient who had less than a good clinical outcome. In two cases, the surgeon’s interpretation of fusion success was reclassified as fusion failure in the database.
BOX 33-1 INCLUSION / EXCLUSION CRITERIA

<table>
<thead>
<tr>
<th>Inclusion</th>
<th>Exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disabling back pain resulting from degenerative disc disease at one or more lumbar levels</td>
<td>Infection of the spine</td>
</tr>
<tr>
<td>Primary degenerative disc disease</td>
<td>Significant osteoporosis</td>
</tr>
<tr>
<td>Failed discectomy</td>
<td>Metabolic bone disease</td>
</tr>
<tr>
<td>Spondylolisthesis</td>
<td>Long-term steroid disease</td>
</tr>
<tr>
<td>Failed fusion</td>
<td>Spinal malignancy</td>
</tr>
<tr>
<td>Degenerative spondylolisthesis</td>
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</table>

Demographic data were recorded including age, sex, compensation issues, neurologic function, number of prior back surgeries, operated levels, operative difficulties, complications, reoperations, or revisions.

Clinical evaluations included ratings of pain, function, economic status, and medication usage according to 5-point Likert scales used in the previous IDE study. The 5-point Likert scales were added to create a 4- to 20-point modified Prolo score to define excellent (17 to 20 points), good (13 to 16 points), fair (9 to 12 points), and poor (4 to 8 points), consistent with previous literature and described fully in Chapter 9.

Fusion success was defined as radiographic evidence of bone bridging the fusion area with no lucencies. If any lucency was seen extending across the disc interspace, the level was considered not fused. In multiple-level surgeries, all levels had to be fused for the patient to be considered a fusion success. Because carbon fiber reinforced polymer (CFRP) cages are radiolucent, bridging bone can be accurately assessed on plain radiographs.

After the original review of 425 charts, 1-year data were available on 327 patients (76.9%). Because 98 patients had been lost to follow-up, G.R.F. supervised the office staff to contact these patients and obtain further information by telephone interview (Boxes 33-2 and 33-3). Forty-seven patients were contacted and provided new information. Of these 47 patients, 26 (55.3%) were doing well and felt no need to return, and seven (14.9%) failed to return because their surgery was unsuccessful and they were consulting other doctors. The computer database was updated to include the clinical information provided by telephone interview. Of the 31 patients sent to collection agencies, many had excellent early surgical results when last seen. If these patients were last seen less than a year postoperatively, their status was considered lost to follow-up. We are unaware of any other study determining the reasons that patients are lost to follow-up.
Over time additional information was obtained on several other patients, resulting in clinical follow-up of 373 of 425 or 87.8% of patients. In this group, clinical success was achieved in 292 of 357 (81.8%) and fusion success was achieved in 333 of 350 patients (95.1%). Note that some patients had only clinical or fusion data but not both. These success statistics are consistent with numbers previously reported. * No statistically significant differences in outcomes existed among the participating surgeons.

The surgical technique in Chapter 27 recommends placement of additional bone graft between and beside the cages whenever possible. Some surgeons recommend filling the anterior disc space with bone graft before placement of shorter cages,' and some have used only local bone graft from the decompression. In the current series, all patients had surgery by a senior surgeon assisted by a second senior surgeon. The operations were performed on a cosurgeon basis in that each surgeon did the work on their respective side. All cages were filled with cancellous bone harvested through a small window in the iliac crest. The only difference in technique among the participating surgeons was that one surgeon did not wish to place additional bone in the disc space, stating that

*References 1-3, 5, 14, 20, 22, 26.
placement of extra bone was "gilding the lily." In analyzing the data of the study, we tried—but were unable—to prove that this surgeon had a lower fusion rate.

If a very complete discectomy is done, the space is filled with blood after surgery. The side openings of the cages provide contact with bone graft, and the previously empty space becomes essentially a fracture hematoma. We have seen cases in which no extra bone was added, but radiographs taken 2 years postoperatively show that the bone has extended to fill the entire disc space. We still believe that surgical principles require filling the entire disc space with as much bone as can be placed. However, if there is insufficient space, insufficient bone, or insufficient time available, the fusion rate is still satisfactory. We caution against multiple compromises of technique.

Complications in the 425 patients are summarized in Box 33-4 and can be compared with those reported in the IDE study in Table 33-1. There were 26 device-related complications, 13 involving the cage and 13 involving the pedicle screws. There were fewer broken pedicle screws in the current study (0.47%) than in the IDE study (6.3%) and fewer loose screws in the current study (1.18%) than in the IDE study (2.7%). All screws in the IDE study were made of stainless steel; all screws in the current study were made of titanium. Overall, the number of screw complications trended lower in the current study. The current study confirmed the low rate of these complications reported in the original IDE studies.

Additional cage placement pitfalls were observed that deserve mention. In one patient, cages were found to be undersized. Fig. 33-1 shows a lateral radiograph of this patient. We believe that this problem was caused by incorrect identification of the disc space. Related to this problem, there were four cases referred to as "false channel" or "malpositioned broach." Fig. 33-2 shows a case in which the broach cut deeply into the verte-

**Box 33-4 Complications of Clinical Study Group**

| Device-Related Complications: | 26 of 425 (6.02%) |
| Cage Complications |  |
| Cage migration: 3 (0.71%) |  |
| Broken cage: 1 (0.23%) |  |
| False channel: 4 (1.00%) |  |
| Anterior placement: 3 (0.71%) |  |
| Undersized cage: 1 (0.24%) |  |
| Anterior vertebral fracture: 1 (0.24%) |  |

| Pedicle Screw Complications |  |
| Broken screw: 2 (0.47%) |  |
| Loose screw: 10 (1.18%) |  |
| Malpositioned screw: 1 (0.24%) |  |

| Non-Device-Related Complications: | 19 of 425 (4.2%) |
| Reoperation to repair CSF leak: 7 (1.82%) |  |
| Infection: 6 (1.56%) |  |
| Epidural hematoma: 1 (0.24%) |  |
| Foot drop: 2 (0.48%) |  |
| Flat back: 1 (0.24%) |  |
| Major medical: 1 (0.24%) |  |
| Seroma: 1 (0.24%) |  |
TABLE 33-1

COMPLICATIONS COMPARED WITH IDE STUDY

<table>
<thead>
<tr>
<th></th>
<th>Cage IDE (%)</th>
<th>Current Study (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reoperation for dural tear</td>
<td>1.80</td>
<td>1.82</td>
</tr>
<tr>
<td>Deep infection</td>
<td>2.71</td>
<td>1.56</td>
</tr>
<tr>
<td>Major medical complication</td>
<td>0.45</td>
<td>0.24</td>
</tr>
<tr>
<td>RSD</td>
<td>1.36</td>
<td>0</td>
</tr>
<tr>
<td>Device complication</td>
<td>9.00</td>
<td>6.02</td>
</tr>
<tr>
<td>Surgical death</td>
<td>0.90</td>
<td>0</td>
</tr>
<tr>
<td>Nerve root injury</td>
<td>1.35</td>
<td>0.47</td>
</tr>
<tr>
<td>Epidural hematoma</td>
<td>0</td>
<td>0.26</td>
</tr>
</tbody>
</table>

Fig. 33-1 In this case, cages were undersized because of failure to accurately locate the disc space.

Fig. 33-2 Broaches cut deeply into the L5 and S1 bone creating a "false channel" and an improper fit.
bral endplates, resulting in pseudarthrosis. The appropriate technique to use to avoid this problem is illustrated in Chapter 27. A thin reamer or spreader is placed into the disc space and spread. If there is any question of the accuracy of the placement of this instrument, a radiograph should be taken to verify its position. The spreader is used to distract the disc space to normal disc height. "Working plates" are tightened down to hold the distraction. A round reamer prepares a round hole. The goal of reaming and broaching is merely to flatten the endplate, not to cut a deep channel. Therefore for placement of an 11 mm cage, the disc space should be distracted to 11 mm. An 11 mm reamer should be used, followed by 11 mm broaches.

The "guided broach" follows the round channel and makes it square. The "final broach" follows the previous channel and squares the bottommost portion of the channel. The final broach should be held with fingertip force only and allowed to follow the previous channel. A false channel is created if the final broach is placed in a direction different from the guided broach, thus creating an excessively large channel that will predispose to a loose-fitting cage and pseudarthrosis. We recommend that if there is any question of the correct direction of the final broach, the final broach can merely be omitted.

There were three cases of anterior placement of the cage. Fig. 33-3 shows a lateral radiograph of one case. In most cases the cage comes to a firm stop against the anterior anulus fibrosus. In Fig. 33-3, the cage has penetrated through the anulus. Often the defect in the anulus is caused by stretching required for reduction of a spondylolisthesis. All three of our anterior placement problems occurred at L5-S1 and caused no adverse effect. If anterior cage displacement occurs at L4-5 or above, the surgeon should reposition the cage, often a difficult task that may require a separate anterior approach to the spine.

Fig. 33-3 One cage was placed through the anterior anulus. If this occurs at higher levels, it should be removed through an anterior approach, if necessary, to avoid damage to the great vessels.
In one case, an anterior fracture of the vertebral body was observed (Fig. 33-4). This fracture occurred because the prepared channel was not sufficiently deep to contain the cage. When the surgeon hammered the cage deeper, it fractured the corner of the vertebral body. No adverse effect was noted during the healing process. We do not believe that any special precautions need to be taken postoperatively when this occurs.

In three cases, the cages were classified as having migrated. Fig. 33-5 shows posterior migration of one cage, indicated by the position of the marker bead. This patient had four prior lumbar surgeries and developed radicular pain approximately 5 months after cage fusion. The cage was removed through a posterior exposure. Because there was very little motion, the pedicle screws were also removed. Fig. 33-6 shows radiographs 6 months later. Because flexion and extension films showed no motion, the patient's sur-

Fig. 33-4 The anterior lip of L5 was fractured as the result of an attempt to drive the cage deeper than the prepared channel.

Fig. 33-5 Anteroposterior (A) and lateral (B) views of a case in which the cage retropulsed.
geon classified him as a fusion success. We have reclassified this case as a locked pseudarthrosis and a fusion failure. On final follow-up, the patient had very little back pain and no radicular pain, and was considered a clinical success.

Fig. 33-7 shows the final intraoperative radiograph of a patient treated for degenerative spondylolisthesis. The cages appear to be correctly positioned. Three months after surgery, there was a recurrent 14 mm slip (Fig. 33-8). By 5 months after surgery, this slip had increased to 16 mm (Fig. 33-9). Although the patient had no neurologic symptoms and only mild back pain, it was thought that the construct should be revised. The revision surgery was performed entirely posteriorly. The pedicle screws at L4 were found to be loose as a result of osteoporosis. The cages were removed, alignment was restored, larger cages were placed, larger screws were placed at L4, and a second point of proximal fixation was gained at L3. A final radiograph is shown in Fig. 33-10. The patient had
Three months after surgery, there was a 14 mm recurrent forward slip.

At 5 months after surgery, the slip had increased to 16 mm.

After a posterior revision, alignment was restored.
It became immediately apparent that surgical times and blood loss were considerably decreased in this clinical study when compared with the IDE study. In the IDE study, the average patient had two prior failed surgeries at two levels. The average blood loss in the IDE group was 1577 ml. In the first 60 patients in this clinical practice group, the average blood loss for primary procedures was 269 ml for one-level and 569 ml for two-level fusions. In patients with prior surgery, the average blood loss was 378 ml for one-level and 470 ml for two-level procedures. The average surgical time in the IDE study was 297 minutes. In this clinical group, the average surgical time for primary cases was 202 minutes for one-level and 251 minutes for two-level procedures. In patients with prior surgery, the average surgical time was 208 minutes for one-level and 251 minutes for two-level operations. In our cases we always had two senior surgeons participate in each surgery, and we believe there is considerable time saved when compared with one senior surgeon working with a resident or fellow. In more recent cases, our surgical time for one-level primary cases is routinely under 120 minutes.

In the IDE study, there was no effort to limit patients’ use of nonsteroidal antiinflammatory drugs (NSAIDs) before surgery. In this series, we required patients to avoid traditional NSAIDs for 4 weeks before surgery. We restrict NSAID use longer than Dr. Stowell recommends in Chapter 8. COX-2 inhibitors cause no difficulties in this regard. Although it may be anecdotal opinion, we have found that patients who had unexpectedly high surgical blood loss were found to be taking unreported NSAIDs. In addition, we have made a conscious technical effort to control blood loss at every step of the surgery. We believe that time spent on hemostasis lowers blood loss, allows more precise implant placement, and shortens the total surgical time.

In the IDE study, one surgeon routinely had blood loss figures double the average for the other surgeons. In two of this surgeon’s cases, the blood loss exceeded 10,000 ml. Two of this surgeon’s patients died intraoperatively. When a high level of blood loss is tolerated for a lengthy period, the bleeding may suddenly accelerate to an alarming rate as a result of intravascular coagulopathy. Surgeons should be knowledgeable of the principles of transfusion management summarized in Chapter 8.

**Products Used to Control Bleeding**

A number of products are available for use in controlling bleeding during spine surgery. Although most surgeons have working experience with these products, many are unaware of important details in their package inserts.

The Gelfoam sponge is intended for application to bleeding surfaces as a hemostatic agent. It is a water-insoluble, off-white, pliable product prepared from purified pork skin, gelatin, and water. Gelfoam powder is prepared by milling absorbable Gelfoam sponge. The mode of action of Gelfoam in controlling bleeding is mostly mechanical. Gelfoam is
usually completely absorbed within 4 to 6 weeks, and can be used dry or saturated with sterile saline solution. Although most surgeons saturate Gelfoam with topical thrombin, the efficacy of this combination has not been tested by the manufacturer, and the package insert states that this use "cannot be recommended." Gelfoam also may swell on absorbing fluids and therefore should be removed after use in laminectomy procedures. The manufacturer states: "When Gelfoam was used in laminectomy operations, multiple neurologic events were reported, including but not limited to cauda equina syndrome, spinal stenosis, meningitis, arachnoiditis, headache, paresthesia, pain, bladder and bowel dysfunction, and impotence." Although many surgeons use a sheet of Gelfoam on top of the dura as a protective barrier during wound closure, it is probably important to avoid leaving this product in tight, bony spaces such as the spinal canal.

Bone wax is composed of 80% refined white beeswax and 20% isopropyl palmitate. Bone wax achieves local hemostasis of bone by acting as a mechanical barrier. Although it is an absorbable material, it is thought to increase the risk of infection and to persist at the bony site for years. It should be used sparingly, and excess material should be removed from the surgical site.

Avitene is a microfibrillar collagen hemostat used to control blood loss when hemostasis by ligature or other conventional procedures is ineffective or impractical. Avitene is provided in a powder form, in sheets, and as a collagen sponge called Ultrafoam. In a study of bleeding from knife incisions in pig spleens, the manufacturer demonstrated that Ultrafoam without thrombin performed as well as Gelfoam with thrombin. They claimed that the advantage was that one can avoid use of bovine thrombin and the attendant possibility of forming antibodies to bovine thrombin, which could precipitate factor V deficiency and abnormalities of hemostasis on reexposure.

Surgicel is an oxidized, regenerated cellulose in a sheer weave. It is plant based and has no animal or human components. Surgicel conforms to but does not adhere to irregular surfaces. When saturated with blood, it rapidly swells into a gelatinous mass. Surgicel achieves hemostasis because its low pH denatures albumin and globulin. It is usually absorbed without tissue reaction. The manufacturer recommends that Surgicel be removed following use in the spine. There have been at least six reports of paraplegia resulting from Surgicel-related thoracic cord compression.

Floseal is an absorbable hemostatic agent packaged as a kit containing an engineered bovine collagen—derived gelatin matrix component and a thrombin component. A proprietary dispersion needle is provided to mix the components during use. The mixed matrix conforms to irregular bleeding surfaces and swells approximately 20% on contact with blood or fluids. Floseal is hydrophilic and adheres to wet tissue. The particulate nature allows excess material not incorporated into the clot to be removed by gentle irrigation without disturbing the hemostatic seal. Surgeons should be aware that because of the swelling of the gelatin matrix, Floseal is not indicated for use in neurosurgical procedures. It is, however, very effective in stopping bleeding from epidural vessels made troublesome by traditional NSAIDs.
no further displacement over time. The primary surgeon interpreted final radiographs as showing fusion; however, we reviewed this patient's films and listed the result in the database as pseudarthrosis.

Of the 13 patients with cage problems, 10 went on to normal fusion success. Three were counted as fusion failures. One case resulted in a definite pseudarthrosis, one was considered a locked pseudarthrosis, and in one the fusion was uncertain and therefore counted as a fusion failure.

The patient with a malpositioned screw had degenerative disc disease at L4-5 and L5-S1 with left-sided radiculopathy. No previous surgery had been performed. This patient awoke with severe right-sided radiculopathy with no motor weakness and no left leg pain. There was no response to steroid therapy. Three months after surgery, a CT scan (Fig. 33-11) showed that the L5 screw on the right side had penetrated the lateral wall of the vertebral body in an area close to a nerve root anteriorly. Injection of local anesthetic with contrast medium (Fig. 33-12) relieved the radicular pain. Further surgery was done immediately to remove the offending screw. The final clinical result was unsatisfactory. The patient could sit at work most of the day without undue discomfort, but had marked radicular pain with all activities. We believe that an MRI and CT scan should be done immediately postoperatively when a patient experiences new radicular pain after surgery. This was one of only two nerve root injuries that we encountered among the 425 cases in this study. The other nerve root injury is described in Case 3 of Chapter 36.

![Fig. 33-11](image1)

**Fig. 33-11** The L5 screw penetrated the lateral wall of the vertebral body and caused irritation of a nerve root anteriorly.

![Fig. 33-12](image2)

with contrast and bupivacaine, the pain was temporarily blocked. Because of this the screw was removed.
Essel VH Fibrin Sealant is made by mixing two components, delivered through a proprietary, dual-dispersion needle: a concentrated fibrinogen with aprotinin, and thrombin with chloroplatinic chloride. Tisseel forms a solid coagulum within 3 to 5 minutes of delivery and replaces the last stages of natural hemostasis, converting fibrinogen to fibrin strands, watertight seals. Tisseel components are derived from human plasma and ne-derived aprotinin. Tisseel is widely used after durotomy repair in spine surgery to a watertight seal. Most surgeons believe that after dural repair with Tisseel, patients can be ambulated on a normal schedule and do not need 3 days of bed rest, which is ten recommended after dural repair without Tisseel.

FDA routinely divides further surgery into three categories: reoperation, revision, removal surgeries (Box 33-5). Reoperation is defined as a surgical procedure in which the devices were not altered or reconfigured. Revision is defined as surgery in which the devices were reconfigured, extended, or replaced, but some original elements remain. Removal indicates that the cages or pedicle screw devices are removed. Overall, patients (30.6%) had 154 further operations on their lumbar spine.

Reoperation

EPIDURAL HEMATOMA

A patient developed an epidural hematoma. Neurologic function was normal immediately after surgery; however, progressive lower extremity weakness developed within the 24 hours postoperatively. An MRI scan obtained the morning after surgery documented the hematoma. The Hemovac drain appeared to be functioning normally. Surgery was performed that day to drain the hematoma. The compression was found in an area ed off from the drain. Neurologic function improved quickly, and the patient regained strength within a few weeks of the initial procedure. The importance of doing immediate imaging studies in the presence of any new radicular pain or neurologic abnormality cannot be overstressed.

Box 33-5 FURTHER SURGERY-154 OPERATIONS IN 130 PATIENTS

<table>
<thead>
<tr>
<th>Reoperations</th>
<th>Revisions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eoair CSF leak: 8 (1.8%)</td>
<td>Revise pedicle screws: 4 (0.9%)</td>
</tr>
<tr>
<td>Treat infection: 4 (0.9%)</td>
<td>Revise displaced cage: 2 (0.4%)</td>
</tr>
<tr>
<td>ALIF for pseudarthrosis: 2 (0.4%)</td>
<td>Extend fusion: 40 (9.4%)</td>
</tr>
<tr>
<td>Repair pseudarthrosis: 5 (1.1%)</td>
<td>Reinstrumentation: 1 (0.2%)</td>
</tr>
<tr>
<td>Further decompression: 3 (0.6%)</td>
<td>ALIF (remove failed BAK): 1 (0.2%)</td>
</tr>
<tr>
<td>Epidural hematoma: 1 (0.2%)</td>
<td></td>
</tr>
<tr>
<td>Remoals</td>
<td></td>
</tr>
<tr>
<td>Remove pedicle screws: 83 (19.5%)</td>
<td></td>
</tr>
</tbody>
</table>
CSF LEAK

Reformed to repair CSF leaks. Our group wrote a report of six cases of postoperative CSF leak associated with bar spine surgery and generally have no long-term deleterious effect. Although reoperation is inconvenient for everyone involved, none of these patients had any long-term adverse effect. These dural tears all occurred during dissection of scar, not during broaching or cage placement. Scaluto et al. reported in 2003 that placement of cylindrical cages through a PLIF approach had a 52% rate of dural tears, often at the root axilla, with a 20% rate of postoperative weakness or radiculopathy. These complications did not occur in this series, because less nerve root retraction is required for placement of rectangular CFRP cages and because full nerve root mobility was achieved before any PLIF steps were initiated.

TREATMENT OF INFECTION

Five of six cases of infection occurred within a 3-month period in 2002. These infections involved three different hospitals and different organisms. Despite intensive investigation, a cause was never found, and the infections ceased. The overall infection rate of 1.56% is lower than that experienced in the initial IDE study and is within an acceptable range. We routinely used intravenous first-generation cephalosporin preoperatively and for 24 hours after surgery. Factors associated with increased infection include prolonged surgical time, multiple previous surgeries, a draining wound, and chronic infections in the bladder, teeth, or other areas.

We recommend that a Hemovac-type drain be used in all cases. Although postoperative bleeding can usually escape through the edges of the incision, the lack of a functioning drain is associated with increased risk of epidural hematoma, chronic drainage, and increased risk of infection.

In the presence of a chronic draining wound or suspected infection, the patient should be returned to the operating room, the wound opened and irrigated thoroughly, and antibiotic therapy initiated based on initial empiric selection, modified later by culture results. If the implants are stable, they should be left in place. We recommend that the wound be closed over Hemovac drains and the patient be returned to surgery every 3 days until the wound is clean and cultures are sterile. If the wound is initially packed open, it may not be possible to obtain primary closure when the infection is controlled. If the infection re-
CSF LEAK

Six reoperations were performed to repair CSF leaks. Our group wrote a report of six cases of postoperative CSF leak associated with the use of ADCON-L (Gliatech, Inc., Cleveland, OH), an antiadhesive agent. This report was rejected for publication, but a later series of four cases was published, and ADCON-L was subsequently withdrawn from the market. The cases associated with ADCON-L were all performed between August and October 1998. The six cases reported here were not associated with the use of ADCON-L. Since the group began the routine use of Tisseel for any dural repairs, this complication has occurred in one case.

We agree with Wang et al. and Cammisa et al. that dural tears are a routine part of lumbar spine surgery and generally have no long-term deleterious effect. Although reoperation is inconvenient for everyone involved, none of these patients had any long-term adverse effect. These dural tears all occurred during dissection of scar, not during broaching or cage placement. Scaluto et al. reported in 2003 that placement of cylindrical cages through a PLIF approach had a 52% rate of dural tears, often at the root axilla, with a 20% rate of postoperative weakness or radiculopathy. These complications did not occur in this series, because less nerve root retraction is required for placement of rectangular CFRP cages and because full nerve root mobility was achieved before any PLIF steps were initiated.

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wound is clean and cultures are sterile. If the wound is initially packed open, it may be possible to obtain primary closure when the infection is controlled. If the infect-
quires open packing, it is possible to obtain secondary closure using an interconnected latissimus dorsi—gluteus maximus musculocutaneous flap."  

**Revision**  

**CAGES OR PEDICLE SCREWS**

Cage revision cases were described earlier. In an additional case, a patient who had had an L4-5 BAK fusion had undergone revision with bilateral pedicle screws and posterolateral fusion from L3 through S1 with fusion using carbon fiber reinforced polymer (CFRP) cages at L5-S1. The patient later had an anterior procedure to remove the BAK cages and replace them with a stackable CFRP cage. This case is discussed in Chapter 34 (see Case 5).

**EXTEND FUSION**

Further surgery was performed to extend the fusion in 40 patients who had adjacent-segment degeneration. A number of authors have addressed the problem of adjacent-segment degeneration.* In 1988 Lee' predicted that application of a rigid internal fixation system produced greater stress concentration in the adjacent segment. Kumar et al** studied 28 patients who underwent fusion surgery and a matched group of 28 patients who underwent nonfusion lumbar surgery. Their study lasted 20 years. The incidence of radiographic changes in the adjacent segment was twice as high in the fusion group as in the nonfusion group; however, there were no statistically significant differences between the two groups in outcome measures. Lai et al*** studied 101 patients who had undergone fusion with pedicle screws and found that patients with preserved posterior complex integrity between the fused segment and the adjacent segment developed instability in 6.5% versus 24.3% without preserved posterior complex integrity. Schlegel et al**** studied 58 patients who had undergone lumbar fusion and who had an average symptom-free interval of 13.1 years. At the point of study, these patients developed recurrent severe symptoms. Schlegel's group found that segments adjacent to the adjacent segment were as likely to break down as the adjacent segments. Hambly et al***** agreed that degenerative changes occurred in the second level above the fused levels with frequency equal to those occurring in the first level. Ghiselli et al' studied 215 patients who had undergone posterior lumbar fusion an average of 6.7 years earlier and reported that the rate of symptomatic adjacent-segment degeneration warranting further surgery appeared to be 16.5% at 5 years and 36.1% at 10 years. Our previous report of the 10-year results of patients treated with the Lumbar Interbody Fusion Cage in the IDE study† indicated that 61% of patients had radiographic changes in the adjacent segment, but the changes were clinically significant in only 20%. Of these, 15% had undergone adjacent procedures and the other patient was contemplating surgery.

In the current group, 9.4% of the group as a whole underwent adjacent-segment fusion procedures with variable intervals of follow-up from 1 to 5 years. We recommend that the upper 30% of the lamina be preserved along with the ligamentous structures whenever

*References 12, 13, 16, 17 19, 24.
possible, with the exception that a full laminectomy should be performed if it is necessary to decompress or protect the exiting nerve root. When a portion of the lamina and the posterior ligamentous complex are preserved, a subsequent fusion surgery can often be performed through an interspace having normal tissue with little difficulty from previous scar. It is our impression that patients who have had good initial results after cage fusion can again achieve good results after adjacent-segment procedures. Too few of our patients have sufficient follow-up after the second cage procedure to evaluate this concept statistically.

REMOVALS

Pedicle screws and plates were removed in 83 of 425 patients (19.5%). This is a lower rate than experienced in the IDE study, in which pedicle screws were removed in 35.2% of patients. Indications for removal of pedicle screws are further reviewed in Chapter 34 in a discussion of evaluation and treatment of failed cages. We believe that it is difficult to determine when pedicle screws are a source of pain. Certainly, if a screw is loose, it may be painful. Attempts to administer a diagnostic injection to block the pain may fail to deliver the anesthetic agent to the painful screw tract; therefore a negative injection study may not be meaningful. When pedicle screws are removed, we recommend that the midline incision be opened to the fascial level and skin flaps developed on both sides. We recommend that a bilateral fascial incision be made about 4 cm lateral to the midline and Wiltse-type muscle-splitting approaches be used to remove the screws and plates. This approach is less traumatic than opening the midline exposure, which may be required if a cross-connector was used. The procedure routinely takes less than an hour, the patient requires only a one-night stay, and can usually return to full activities in a week or two. The only problem with this approach is that it creates a potential pocket of dead space above the fascia that can accumulate fluid. The one patient who had a reoperation for seroma had continuous reaccumulation of fluid for 3 months from this source. Tisseel is useful for sealing the pocket should this problem occur.

DECOMPRESSION AT UNFUSED LEVELS

Steffee repeatedly warned that surgeons should never end a fusion at a decompressed vertebral level. Whenever a decompression is needed above a fusion, that level should also be included in the instrumentation and fusion. Certainly this recommendation makes intuitive sense. If removing the posterior ligament complex above the fusion results in higher adjacent-segment failure, as Lai et al have observed, then more extensive destabilization should also result in more frequent mechanical failure of the segment.

Two of the surgeons rejected Steffee’s advice and performed 31 decompressions above fusions. Of these 31 patients, 26 were available for follow-up. Clinical success in this subset was achieved in 19 of 26 (73%). When these results are compared with those of the study group as a whole using the chi square statistic, clinical success rates were not statistically different (chi square = 1.19; p = 0.275). Further surgery was done in 12 of the 26 patients with adjacent decompressions (46.1%). When these results are com-
pared with those of the study group as a whole using the chi square statistic, a statistical difference is approached (chi square = 2.60; p = 0.10). Surgery to extend the fusion to the decompressed level was performed in six patients (23%). When these numbers are compared with those of the study group as a whole, statistical significance is reached (chi square = 3.89; p = 0.485). Therefore Steffee’s recommendation is confirmed by this study group: Do not end a fusion at a level of decompression.

**L1-2 Fusion**

The Brantigan Interbody Fusion Cage was approved by the FDA in February 1999 to treat degenerative disc disease at one or two levels between L2 and the sacrum when two cages are accompanied by bilateral pedicle screw stabilization. L1-2 was excluded from the IDE study because fusion at this level is rarely required, and statistical comparisons are not available. However, occasionally lumbar fusion may be indicated at the L1-2 level because of adjacent-segment degeneration after fusion to L2, major disc herniation with degeneration, failed previous laminectomy or discectomy, degenerative lumbar spondylosis, or other causes.

Twelve patients were identified in the study group who had cage fusion at L1-2. In seven cases, the indication was degeneration above a long fusion. In five cases, the adjacent segments had not been previously fused. Because of increased risk of neurologic injury to the conus medullaris, the surgical procedure was modified. The entire pars interarticularis and inferior articular processes were removed bilaterally, and cages were placed through a transforaminal lumbar interbody fusion (TLIF) approach without retraction of the dura. Seven patients (59%) achieved clinical success. Clinical results included zero excellent, two good, five fair, and five poor as measured by the modified Prolo scale reported previously in Chapter 9. Fusion was successful in seven cases and failed in five.

The Lumbar Interbody Fusion Cage IDE study reported fusion success in 176 of 178 (98.9%). In the larger clinical series from our group, fusion success was achieved in 321 of 326 non—L1-2 patients (98%). When the fusion results of our larger series are compared with the IDE results using the chi square statistic, the fusion rates were not statistically different (chi square = 0.1414; p = 0.7069). When the fusion results of the L1-2 group are compared with the larger clinical series from our group using the chi square statistic, L1-2 fusion rates are significantly lower (chi square = 64.9297; p <0.0001).

The Lumbar Interbody Fusion Cages IDE study reported clinical success in 79 of 91 (86.8%). In the larger clinical series from our group, clinical success was achieved in 285 of 345 (82%) of non—L1-2 patients. When the clinical results of our larger clinical series are compared with the IDE results using the chi square statistic, clinical success rates were not statistically different (chi square = 0.555; p = 0.4563). When the clinical results of the L1-2 group are compared with the larger clinical series from our group using the chi square statistic, clinical success rates at L1-2 are significantly lower than experienced at the lower lumbar levels of PLIF (chi square = 4.588; p = 0.0322).
Fig. 33-13 shows radiographs of a patient who had undergone an L1-2 cage fusion 1 month earlier. The position of the implants appears satisfactory. There is 1 degree of measured kyphosis. Fig. 33-14 shows a lateral film taken 2 months after surgery. The kyphosis has increased to 10 degrees. The kyphosis increased to 12 degrees 2 months later (Fig. 33-15). At 6 months after surgery, the kyphosis had increased to 14 degrees (Fig. 33-16). At 8 months after surgery, the kyphosis seemed to have stabilized at 14 degrees with the use of a TLSO brace (Fig. 33-17). At 10 months after surgery, the kyphosis had increased to 17 degrees (Fig. 33-18) despite the use of the TLSO brace. The patient deferred revision surgery in the hope that the fusion would stabilize. Revision surgery was further delayed by the worker's compensation carrier.

Fig. 33-13 Anteroposterior (A) and lateral (B) views after surgery at L1-2. There is 1 degree of kyphosis.

Fig. 33-14 Two months after surgery, the kyphosis had increased to 10 degrees.
Six months after surgery, the kyphosis had increased to 14 degrees.

Eight months after surgery, the kyphosis stabilized at 14 degrees with the brace.

Ten months after surgery, the kyphosis had increased to 17 degrees. This patient required revision surgery.
Deformity and trauma surgeons have long recommended that a fusion should not end at L1 because of an excessively high rate of mechanical stress and failure at the thoracolumbar junction. Instead, two thoracic levels should be included in the instrumentation and fusion. We had expected that the extra stability afforded by anterior cage placement with pedicle screw fixation would compensate for the added stresses at this level. This expectation was not realized. The failures were not limited to patients having a long fusion ending at L1. Of the five patients who had L1-2 fused with a nonfused adjacent L2-3 segment, two patients had fusion failure and three were unsuccessful clinically, with poor Praia scores. Revision has been recommended in both fusion failures.

Hashimoto and colleagues report in Chapter 16 their favorable experience with anterior one-level fusion at the thoracolumbar junction, which appears to be much more successful. The anterior procedure may be more successful because it avoids removing the stabilizing posterior elements. In any case, it must be noted that CFRP cage fusion with pedicle screw fixation performed through a traditional posterior approach has a higher than expected rate of clinical and fusion failure.

**Use of Single-Cage PLIF**

All mechanical testing of the CFRP cages assumed use of bilateral cage placement and bilateral pedicle screw fixation. The manufacturer is required to state that data do not exist to justify the use of a single cage component or unilateral pedicle screw fixation. Fig. 33-19 shows an anteroposterior radiograph of a case performed elsewhere in which the surgeon placed only a single cage at L5-S1 because the nerve root scarring from prior surgery made safe placement of a second cage questionable. Fig. 33-20 shows a CT image of the same patient. Of course, this is the correct intraoperative decision because a second cage can be placed through an anterior approach later if required. There is clear failure of fusion through this single cage. The surgeon failed to pack extra bone around the cage, and this was not a correct decision.

Molinari et al reported a study in which 19 active-duty military personnel were treated with two CFRP cages and 16 were treated with a single cage. When only a single cage was used, bone graft was inserted from a bilateral approach. Molinari et al reported that the results were generally good and that patients having a single cage had fusion and clinical success equal to those having two cages.

Some patients may require a single-cage fusion because of circumstances found at the time of surgery. The indications may include not enough space for a second cage (because a first cage was placed in the midline), failed previous discectomy with nerve root scarring, and conjoined nerve roots or other root anomalies preventing safe root retraction. In addition, when a three- or four-level interbody fusion is performed, the surgeon may prefer to use single cages at some levels to save time and minimize blood loss. In Fig. 33-21, the first cage was placed in the midline and there was insufficient space for a second cage. This case had copious extra bone grafting and resulted in a solid fusion and clinical success.
Fig. 33-19 Use of a single cage without extra bone graft resulted in fusion failure.

Fig. 33-20 Coronal CT scan demonstrates failed fusion at L5-S1.

Fig. 33-21 Anteroposterior (A) and lateral (B) views of a single cage case in which extra bone was added. This resulted in solid fusion.
In the current study group, 31 patients were identified who had PLIF with a single Lumbar Interbody Fusion Cage and variable screw placement in at least one fusion level. Twenty-six of these patients had clinical success. Fusion was successful in 30 patients (97%). The results for fusion and clinical success using a single cage were statistically no different from the results reported in the IDE study ($p = 0.7069$ for fusion success; $p = 0.4563$ for clinical success). The single failed fusion occurred at L1-2, a level that has been recognized as an independent risk factor for failed fusion. We emphasize that when a fusion is performed with a single cage, it is particularly important for the surgeon to pack additional bone in the disc space around the cage.

**Use of 9 mm Cages**

When the Lumbar Interbody Fusion Cage was first designed, the optimal dimensions were unknown. It appeared that the average width that would allow bilateral cages to be placed was 11 mm. Possible failure modes included subsidence into the vertebral bodies (which argued for maximal width of the struts) and fusion failure (which argued for maximal width of the opening for bone graft surface area). In the design of the 11 mm cage prototypes tested mechanically in cadaver spines the two concerns were given equal weight: the opening was 5.5 mm wide and the strut width was 5.5 mm (or 2.75 mm each). This design performed well in cadaver spines and bore physiologic loads without subsidence.

In the design of larger and smaller cage sizes, the width of the struts was retained at 2.75 mm because of the concern for subsidence if the support area had been reduced. Thus the cage that is 9 mm in width has an opening for bone graft that is 3.5 mm wide, proportionately 18% narrower overall than the 11 mm cage, but 36% smaller in surface area for bone graft. The 9 mm cage has a bone surface area 54% less than the 13 mm cage. Because bone healing was potentially compromised with the 9 mm wide cages by the proportionally greater reduction in bone graft surface area, it is clinically important to study the clinical and fusion success of these narrow cages.

Patients may require a 9 mm wide cage because of circumstances found at the time of surgery. The indications may include not enough space for a larger width or height cage in the disc space, nerve root anomalies that may limit access to the disc space, and limited ability to retract nerve roots because of epidural scarring.

In the current study, 90 patients were identified who had PLIF at one or more levels using one or two 9 mm wide cages. The major statistical difference between the demographics of the 9 mm group and the IDE study is patient gender. In the IDE study 43% of patients were women, and in the 9 mm group 66% were women, a statistical difference ($p = 0.003$). This difference is not surprising because women typically require smaller implants.

In the 9 mm group, clinical success was achieved in 74 patients (82%) and fusion success in 82 (91.1%). If the 9 mm cases are removed from the larger study group, fusion
success was achieved in 96.5% of cases. When the fusion results of the larger series were compared with IDE results using the chi square statistic, the fusion rates were not statistically different (chi square = 0.1414, \( p = 0.7069 \)). When the fusion results of the 9 mm group are compared with the larger study group, the results with the 9 mm cages are statistically lower (chi square = 10.034, \( p = 0.0015 \)). Therefore we conclude that use of 9 mm cages results in lower fusion success of about 5%.

Although it is possible to avoid this problem by performing generous bone grafting in the disc space between, beside, and in front of the cages, the reason for using the 9 mm cages is usually that insufficient space is available for wider cages or for bone graft. The preponderance of women in the 9 mm patient group implies that the smaller cages were appropriately selected. Use of 9 mm cages in large men simply because it is surgically easier will likely result in greater decrease in fusion success.

Two interesting observations must be made. First, it required a study of 425 patients to observe a 5% difference in fusion success. Second, although the FDA allows the sale of numerous devices without clinical data, the FDA would not allow a PMA supplement to approve 9 mm cages whose dimensions are exactly proportional to the 11 mm cages because the dimensions are outside the lower limits of the devices tested clinically.

**Fusion Below Long Scoliosis Fusions**

Traditional deformity surgery with Harrington rod instrumentation often included fusions from T4 to L4. These procedures performed decades ago frequently result in flat-back deformities and degeneration below the fusion. Fig. 33-22 shows AP and lateral radio-

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**Fig. 33-22** Anteroposterior (A) and lateral (B) views of a patient with a T4 to L4 Harrington rod, which resulted in symptomatic degenerative changes at L4-5.
graphs of such a case, with symptomatic degenerative change at L4-5 below the fusion. This case was treated with a wedged Lumbar Interbody Fusion Cage as shown in Fig. 33-23. The old rod can be removed, but this can be an extensive procedure if the rod is completely covered with bone. In this case, the old rod was linked to the new construct. We had eight of these procedures in this series. Three were lost to follow-up. Four of five were clinically successful and achieved fusion. Attempting to fuse L5-S1 when it is the only unfused lumbar segment has a lower success rate.

Satisfactory clinical and fusion results were achieved with the Lumbar Interbody Fusion Cage with pedicle screw fixation in a study of 425 consecutive patients. Although dural tears were common, they had no long-term significance. Two patients experienced nerve root injury in spite of 138 patients having scarring from prior lumbar surgery. Cage fusion with pedicle screw fixation has a higher than expected failure rate at L1-2. Narrower 9 mm cages have 5% lower fusion success compared with larger cages. Interbody fusion using cancellous bone packed inside the cages without additional bone appears to have satisfactory fusion success if appropriately sized cages are used. Surgeons should not end a fusion at a level of decompression. Interbody fusion with a single CFRP rectangular cage appears to have satisfactory fusion success if additional bone graft is packed around the cage filling the disc space.
REFERENCES


Outcomes of L1–L2 posterior lumbar interbody fusion with the Lumbar I/F cage and the variable screw placement system: reporting unexpected poor fusion results at L1–L2

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Abstract

BACKGROUND CONTEXT: Posterior lumbar interbody fusion (PLIF) was introduced 50 years ago. The Lumbar I/F cage (DePuy Spine, Raynham, MA) was designed to enhance PLIF results. PLIF with the Lumbar I/F cage and posterior Variable Screw Placement System (VSP) has increased the success of fusion to nearly 100% at the four lowest lumbar levels, L2–L3 through L5–S1. Less commonly, PLIF is indicated for the L1–L2 level. Clinical-results of Lumbar I/F cage fusion and VSP at L1–L2 have-not been reported.

PURPOSE: The purpose of this study is to report the functional outcomes, fusion rate, and complications related to PLIF with Lumbar I/F cage and VSP of L1–L2

STUDY DESIGN/SETTING: The setting is a retrospective, single-arm cohort study of consecutive PLIF surgical patients at a single center.

PATIENT SAMPLE: A review of 373 of 425 patients who underwent PLIF with Lumbar I/F cage and VSP from 1999 to 2002 identified 12 patients who had PLIF with Lumbar I/F cage and VSP at L1–L2. Mean follow-up was 31 months (range 12–65 months).

OUTCOME MEASURES: Clinical success was determined with a modified Prolo score evaluating pain, function, medication usage and economic status. Fusion success, determined by evaluation of plain radiographs, was defined by continuous bone bridging the fusion area with no lucencies.

METHODS: The 12 patients were evaluated for clinical success and/fusion success at last follow-up. These results were compared with the results of the 373 patients reviewed, and historical groups of the original Investigational Device Exemption study and the 10-year follow-up study.

RESULTS: Previous surgery was reported by 10 of 12 patients, with an average symptom-free period of 3 years after previous fusion and before presentation with severe symptomatology necessitating further surgery at L1–L2. Seven patients had clinical success (59%), and five patients were clinically unsuccessful (41%). This included zero excellent, 2 of 12 (15%) good, 5 of 12 (42%) fair, and 5 of 12 (42%) poor results. Fusion was successful in seven (58%) and failed in five patients (42%). Three failed fusions were associated with L1–L2 subsidence. Two patients required further revision for non-union.

CONCLUSIONS: In 12 patients with L1–L2 fusion, we report an unexpected high rate of failed fusion and poor clinical outcome.

Keywords: PLIF; Interbody fusion orthosis; Cage; Pedicle screw; Degenerative disc diseases; Spinal fusion/instrumentation/methods; Treatment outcome

Introduction

Posterior lumbar interbody fusion (PLIF) was introduced by Cloward [1–4] more than 50 years ago. Limitations of PLIF included inadequate compression strength of allograft bone [5] and low fusion rates [6]. The Lumbar I/F cage (DePuy Spine, Raynham, MA) was designed to enhance posterior lumbar interbody fusion results by
providing the mechanical strength to provide load-sharing during fusion and to allow the best biological healing with autologous bone graft [7].

In an Investigational Device Exemption (IDE) study of the Lumbar I/F cage, fusion success was reported in 176 of 178 patients (98.9%) [8]. Almost half of the study cases were two-level procedures. Less than 10% were three- or four-level procedures. The high fusion success was undiminished over multiple fusion levels including 100% of the three- and four-level fusions. Based on this study, the Lumbar I/F cage was approved by the Food and Drug Administration for treatment of degenerative disc disease at one or two contiguous levels from L2 to the sacrum, accompanied by posterolateral fusion and pedicle screw fixation using the Variable Screw Placement (VSP) Spinal System.

The L1–L2 level was excluded from the study protocol and from the Food and Drug Administration approval because of the low frequency of isolated degenerative disc disease at this level. The approval was limited to two levels because of the small number of three- and four-level procedures in the study. Nevertheless, some patients develop symptomatic degenerative disc disease at the L1–L2 level. The purpose of this retrospective review is to report the functional outcomes, fusion rate, and complications related to PLIF with Lumbar I/F cage and VSP of L1–L2.

Materials and methods

Description of the Lumbar I/F cage

The Lumbar I/F cage is manufactured from poly-ether-ether ketone reinforced with “chopped” or short carbon fibers. The cage is filled with autologous bone and placed in a disc space channel. This allows bone fusion from end plate to end plate across the bone graft within the cage. The cage material is one-tenth the stiffness as compared with metal and minimizes stress shielding of the bone graft [8]. Because the cages are radiolucent, bridging bone can be accurately assessed by plain radiographs.

Description of the Variable Screw Placement System (VSP)

The VSP (DePuy Spine, Raynham, MA) includes pedicle screws and plates. The screw has a cancellous thread ending in an integral nut, above which a machine thread with tapered and locking nuts allows the screw to be anchored securely to the plate [8].

Description of the operation

In the standard PLIF operation, the extent of the required laminectomy should expose the entire space between the medial walls of the pedicles. The superior one-third of the lamina should be preserved to maintain continuity of ligament structures above the fusion level. At L1–L2, because of increased risk of neurological injury to the conus medullaris, a more lateral approach was used, essentially a transforaminal lumbar interbody fusion. A spreader is placed in the disc space and used to distract the disc space on each side to normal disc height or to the elastic limit of the annulus. A “working plate” is tightened down over the pedicle screws on one side to hold the distraction. In contrast to PLIF at the lower levels, it is not generally possible to use bilateral working plates. Next, a round reamer is used to prepare a round hole in the disc space on the opposite side. The goal of reaming and broaching is merely to flatten the end plate, not to cut a deep channel. Therefore, for placement of a 9-mm cage, the disc space should be distracted to 9 mm. The 9-mm reamer should be used, followed by the 9-mm broaches. The “guided broach” follows the round channel and makes it square. The “final broach” follows the previous channel and squares the bottom most portion of the channel. The final broach should be held with fingertip force only and allowed to follow the previous channel. A “false channel” is created if the final broach is placed in a different direction than the guided broach, thus creating an excessively large channel that will predispose to a loose-fitting cage and pseudarthrosis. We recommend if there is any question of the correct direction of the final broach that the final broach merely be omitted.

Clinical study design

From February 1999 to October 2003, we performed PLIF using the Lumbar I/F cage with VSP pedicle screw fixation on 425 patients in our practice. During the summer of 2004, we conducted a retrospective chart review of all patients. We had a minimum of 1 year of full clinical and radiographic data on 377 of 425 patients (87%). Although 1 year is not long enough to define an exact rate of clinical success, it is sufficient follow-up to identify complications and failed fusions. From this group we identified 12 patients who had received PLIF at the L1–L2 level. The mean follow-up was 31 months (range 12–65 months). All 425 operated patients had disabling back and/or radicular pain refractory to conservative management with moderate to severe degenerative change, with instability and adjacent segment deterioration based on flexion-extension radiographs, magnetic resonance imaging (MRI), or discogram. In the subset of 12 L1–L2 patients, 10 patients had 25 prior spinal operations (average 2.5). In the previously operated patients, there was an average symptom-free interval of 3 years (1–7 years), followed by onset of significant and severe symptoms correlating with imaging identifying L1–L2 as the source of the new symptoms. At the L1–L2 level, nine had preoperative radiographic adjacent segment degeneration with or without stenosis, and three had herniated degenerative discs causing stenosis in the presence of degenerative flexion-extension or rotational instability.
Of the 12 L1–L2 patients, there were three men and nine women. Average age was 44 years (range 34 to 80). Insurance was workers’ compensation in four and private insurance in eight. Three patients had positive smoking history with an average 21-pack/year histories.

Clinical success was defined according to previous published literature parameters used over many years and modeled after an expanded Prolo Scale [8–11]. The 5-point Likert scales for pain, function, economic status, and medication usage are added to a combined 4- and 20-point scale as used for the IDE study of the Lumbar I/F cage [8]. This study defined a patient’s result as a clinical success when the final rating was excellent (17 to 20 points) or good (13 to 16 points), or fair (9 to 12 points) with a minimum improvement of three points or more in the combined 20-point scale.

Fusion status

Fusion status was recorded for each surgically treated segment at each follow-up interval. Fusion healing was defined by previously published literature parameters [8–10]. Fusion success was defined as radiographic evidence of bone bridging the disc space within the cages, without evidence of lucency across the cage. If lucency was seen to extend across the cage, the level was considered not fused. For patients undergoing multiple-level fusion, all surgically treated segments must be fused for the patient to be considered a fusion success.

Sagittal plane alignment

The sagittal alignment is approximately 5 degrees kyphosis at the thoracolumbar junction [12]. After surgery, progressive kyphosis may impair the final result. The radiographic criteria of proximal junctional kyphosis was adapted from Yang and Chen [13] and defined as greater than 10 degrees progression in the proximal segment kyphotic angle from preoperative to last follow-up radiograph. Proximal segment kyphosis was measured from T11–T12 to L1–L2 disc spaces on the current radiographs. This measurement included two disc spaces and the T12 vertebral body. The angle was measured by the method of Cobb [14]. Measurements were made on the preoperative and last follow-up lateral radiographs. Additional Cobb angle measurement was made of the L1–L2 disc space on preoperative and last follow-up radiographs.

Results

Clinical success

Clinical success was achieved in 7 of 12 patients (59%). This included 2 (17%) Good and 5 (42%) Fair results. Clinical success was not achieved in the other 5 (42%) with

<table>
<thead>
<tr>
<th>Patient</th>
<th>Clinical success</th>
<th>Fusion success</th>
<th>Comment</th>
<th># Prior surgery</th>
<th>Previous operated levels</th>
<th>Further surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Y</td>
<td>Y</td>
<td>Fused radiographically. Continued pain with limitations.</td>
<td>5</td>
<td>L3–S1 PLIF</td>
<td>None</td>
</tr>
<tr>
<td>2</td>
<td>N</td>
<td>Y</td>
<td>Fused radiographically, T12–L1 ASD with instability.</td>
<td>2</td>
<td>L3–L5 PLIF</td>
<td>None</td>
</tr>
<tr>
<td>3</td>
<td>N</td>
<td>Y</td>
<td>Fused radiographically at every level with continued pain.</td>
<td>2</td>
<td>L2–L4 PLIF</td>
<td>L4–S1 PLIF</td>
</tr>
<tr>
<td>4</td>
<td>Y</td>
<td>Y</td>
<td>Healed fusion at time of exploration effusion.</td>
<td>1</td>
<td>L4–L5 PLIF</td>
<td>None</td>
</tr>
<tr>
<td>5</td>
<td>Y</td>
<td>Y</td>
<td>Fused radiographically with mild pain and limitations.</td>
<td>2</td>
<td>L2–L4 PLIF</td>
<td>L.R. L1–L2, L1 screw loose, fusion healed</td>
</tr>
<tr>
<td>6</td>
<td>N</td>
<td>N</td>
<td>Reinjury 6 months post-op. Recurrent pain.</td>
<td>0</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>7</td>
<td>N</td>
<td>N</td>
<td>Fused radiographically ASD T12–L1 continued pain.</td>
<td>5</td>
<td>L2–S1 PLIF</td>
<td>None</td>
</tr>
<tr>
<td>8</td>
<td>Y</td>
<td>N</td>
<td>Pseudarthrosis twice at exploration. Treated with re-instrumentation and BMP; then IR with BMP.</td>
<td>3</td>
<td>L3–S1 PLIF</td>
<td>Revision PLF BMP and screws x1, IR BMP BMP x1</td>
</tr>
<tr>
<td>9</td>
<td>Y</td>
<td>N</td>
<td>Pseudarthrosis at exploration. IR with BMP.</td>
<td>2</td>
<td>L2–L5 PLIF</td>
<td>IR BMP PLF</td>
</tr>
<tr>
<td>10</td>
<td>Y</td>
<td>N</td>
<td>Pseudarthrosis radiographically with L1–L2 subsidence.</td>
<td>2</td>
<td>L4–L5 PLIF</td>
<td>None</td>
</tr>
<tr>
<td>11</td>
<td>N</td>
<td>Y</td>
<td>Fused radiographically with continued pain.</td>
<td>0</td>
<td>None</td>
<td>L2–L4 PLIF</td>
</tr>
<tr>
<td>12</td>
<td>Y</td>
<td>Y</td>
<td>Fused radiographically, with asymptomatic L2–L3 stenosis.</td>
<td>1</td>
<td>L4–L5 PLIF</td>
<td>None</td>
</tr>
</tbody>
</table>

ASD = adjacent segmental degeneration; BMP = bone morphogenic protein; IR = Implant removal of pedicle screws and plates; N = no; PLF = posterolateral fusion; Y = yes.
Poor results. Both patients without previous surgery were clinically unsuccessful. Table 1 lists the clinical status of these patients at final follow-up.

**Fusion success**

Fusion success was achieved in 7 (59%) (Table 1 and Fig. 1), and was unsuccessful in 5 (42%) patients. Fusion was successful in two of the three patients who smoked, and unsuccessful in one. The failures were not limited to patients having a long fusion ending at L1. Of the five patients having L1–L2 fused with a nonfused adjacent L2–L3 segment, two patients had fusion failure and three were unsuccessful clinically with poor Prolo scores. Failed fusion was associated with subsidence in three, pedicle screw loosening in two, and in one 34-year-old woman, a single cage retropulsed 5 mm without clinical neurologic symptoms. This patient had an isolated L1–L2 PLIF, without previous surgery. One of the two cages retropulsed into the spinal canal, causing back pain without neurologic loss. The device failure led to an unsuccessful fusion. The other patient without previous PLIF had L1–L2 and L4–S1 PLIF with successful fusion of both levels (Fig. 1). Table 1 correlates the clinical status with fusion success. Figure 1 is an example of a healed fusion. Figure 2 is an example of a failed fusion with subsidence of the cages causing increased kyphosis and lateral tilt through the disc space. Figure 3 demonstrated computed tomographic (CT) evidence of nonunion above a long fusion. Figure 4 shows CT evidence of nonunion of L1–L2, with the adjacent L2–L3 level never treated.

![Fig. 1](image)
Cages used in L1–L2 fusion

Ten patients had two cages placed at the L1–L2 level. The other two patients had a single cage placed at L1–L2 (9×9×25 mm). The reason given for a single cage was the limited space in the disc space for two cages, and in one report, concern about retraction of the dura with the conus medullaris near-by. In the first single-cage case, Hea-los (Depuy Spine), an osteoconductive matrix, was used to fill the other side of the disc space. In the second case, a trans-foraminal approach was used to place a single cage obliquely across the disc space. In 11 patients, the cages were 9×9×25 mm length. One patient had two 9×11×25 mm cages. A total of 22 interbody cages at L1–L2 were used. All levels were supported with bilateral pedicle screws and VSP plates.

Complications

In one patient, an epidural hematoma with acute cauda equina syndrome occurred immediately after L1–L2 surgery. The hematoma was drained immediately with complete resolution of all symptoms. Another had loosening of the pedicle screw fixation, with subsidence and kyphosis across the L1–L2 segment. This patient is using an electromagnetic bone stimulation device to encourage bone fusion healing.

Further surgery

Five patients had further surgery after the L1–L2 fusion at an average of 18 months (range 14–26 months), as reported in Table 1.

Sagittal plane alignment

There was no preoperative proximal segmental T11–L1 kyphosis above the L1–L2 fusion. There was no proximal segmental T11–L1 kyphosis at last follow-up. Two patients developed L1–L2 segmental kyphosis greater than 8 degrees associated with radiographic subsidence of one or both of the interbody cages through the L2 cephalic end plate. One patient with 3 degrees angulation did not have...
identified subsidence. The three patients with increased Cobb angle measurement across the L1–L2 disc space did have failed fusions.

Discussion

Outcome measures

At the time of the original Brantigan Lumbar I/F cage IDE in 1990, there was little agreement regarding optimum outcome measures in a spinal fusion study. To our knowledge, a thorough examination of the statistical validity of the Prolo Scale has not been undertaken. However, the Prolo Score has been widely accepted and is used in this report to maintain continuity with the original IDE and the 10-year follow-up of the Lumbar I/F cages. We believe the Prolo Scale produces results that may be compared with literature reports of outcomes over many years [8,9].

Previous surgery

Ten of the 12 patients had previous PLIF surgery (average 2.5 surgeries/patient). In these 10 patients, there was a 3-year average symptom-free time before presentation with severe symptoms requiring surgical treatment at the adjacent L1–L2 level. In patients with prior surgery, diagnosis was based on progressive MRI changes over time or by positive concordant pain reproduction on discogram. In patients without adjacent fusion, diagnosis was based on MRI findings with positive discogram. The rate of previous surgery of this group is not significantly different than the original IDE Lumbar I/F cage study wherein there were 326 surgeries in 170 patients reported (average 1.9 surgeries/patient) [8] (chi-square = 0.2662, p = .6059).

Clinical success

The Lumbar I/F cages IDE study reported clinical success in 79 of 91 (86.8%) [8]. In the larger clinical series from our group, clinical success was achieved in 285 of 345 (82%) of non-L1–L2 patients. When the clinical results of our larger clinical series are compared with the IDE results using the chi-square statistic, clinical success rates are not statistically different (chi-square = 0.555, p = .4563). When the clinical results of the L1–L2 group are compared with the larger clinical series from our group using the chi-square statistic, clinical success rates at L1–L2 are one-half of the expected success at the lower lumbar levels of PLIF (chi-square = 4.588, p = .0322).

Fusion success

The Lumbar I/F cage IDE study reported fusion success in 176 of 178 (98.9%) [8]. In the larger clinical series from our group, fusion success was achieved in 321 of 326 non-L1–L2 patients (98%). When the fusion results of our larger series are compared with the IDE results using the chi-square statistic, the fusion rates are not statistically different (chi-square = 0.1414, p = .7069). When the fusion results of the L1–L2 group are compared with the larger clinical series from our group using the chi-square statistic, L1–L2 fusion rates are 60% lower (chi-square = 64.9297, p < .0001).
Sagittal plane alignment

The development of junctional kyphosis above a short segmental fusion for thoracolumbar scoliosis or fracture management is not well understood. An increase in kyphosis may give a displeasing cosmetic result, and may result in revision of the fusion [15–17]. Yang and Chen found in five patients with preoperative junctional kyphosis of more than 10 degrees, four of five developed increased junctional kyphosis [13]. In this series, no junctional kyphosis was identified preoperatively, and no increase in kyphosis was found at last follow-up. Isolated L1–L2 angulation was associated with subsidence of the interbody cages in two failed fusions.

Biomechanics

Deformity and trauma surgeons have long recommended that a fusion should not end at L1 because of an excessively high rate of mechanical stress and failure at the thoracolumbar junction. Instead, two thoracic levels should be included in the instrumentation and fusion. We had expected that the extra stability afforded by anterior cage placement with pedicle screw fixation would compensate for the added stresses at this level. This expectation was not realized. The failures were not limited to patients having a long fusion ending at L1. Of the five patients having L1–L2 fused with a nonfused adjacent L2–L3 segment, two patients had fusion failure, and three were unsuccessful clinically with poor Prolo scores. None of the five has required further surgery, but revision has been recommended in both fusion failures.

Conclusions

In this small group of L1–L2 posterior lumbar interbody cage fusion with VSP patients, there was a high rate of failed fusion, and poor clinical success. The failures were not limited to patients having a long fusion ending at L1. This study reports an unexpectedly high failure rate at L1–L2 but does not provide a solution for those patients requiring treatment at this level.

References

Is One Cage Enough in Posterior Lumbar Interbody Fusion: A Comparison of Unilateral Single Cage Interbody Fusion to Bilateral Cages

Guy R. Fogel, MD, John S. Toohey, MD, Arvo Neidre, MD, and John W. Brantigan, MD

Abstract: Posterior lumbar interbody fusion (PLIF), as recommended with bilateral lumbar interbody cages and pedicle screw fixation, has increased the successful fusion rate to nearly 100%. Presently, a unilateral approach to the disc space with a variant of PLIF, the trans-foraminal interbody fusion is often used. There are few clinical studies of unilateral interbody fusion. The clinical and fusion results of unilateral interbody fusion are important as the usage of trans-foraminal interbody fusion procedure increases. This retrospective study of 26 consecutive patients treated with a unilateral cage asks whether fusion healing and clinical outcome is comparable with that obtained with bilateral cages. In this study, there were no pseudarthroses, instrumentation failures, or significant subsidence at any of the single cage levels. Disc space height and foraminal height were restored by the surgery and maintained at last follow-up. Using Prolo scores, 23/26 patients had clinical success (88%), and 3 were unsuccessful. Fusion was successful at all single cage fusion levels and overall in 23/26 (88%) reviewing all levels of fusion. In conclusion, fusion and clinical success rates were not diminished by the use of a unilateral interbody cage rather than the recommended 2 cages. This retrospective comparative study is a Level III-2 Therapeutic Study investigating the results of unilateral PLIF with a single interbody cage compared with historical series with interbody cages.

Key Words: PLIF, TLIF, interbody fusion orthosis, cage, pedicle screw, degenerative disc disease, intervertebral disk displacement/pathology/radiography/surgery, middle aged, spinal fusion/instrumentation/methods, treatment outcome

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From the South Texas Orthopaedic and Spinal Surgery Associates, 9150 Huebner Road, San Antonio, TX 78240.
Device status: The Lumbar interbody carbon fiber Cage and the VSP Spinal Fixation System are approved by the United States Food and Drug Administration. Dr Brantigan has a financial interest in the Lumbar interbody carbon fiber Cage. No Financial assistance was provided from any source for this study.
Reprints: Dr Guy R. Fogel, MD, South Texas Orthopaedic and Spinal Surgery Associates, 9150 Huebner Road, San Antonio, TX 78240 (e-mail: gfolg@spinetex.com).
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Posterior lumbar interbody fusion (PLIF) was introduced by Cloward1-4 more than 50 years ago. Limitations of early PLIF included inadequate compression strength of allograft bone and low fusion rates.5 Carbon fiber reinforced polymer (CFRP) rectangular cages were introduced to enhance PLIF results by providing the mechanical strength to provide load-sharing during fusion and to allow the best biologic healing with autologous bone graft.6,7 PLIF with CFRP cages also restores disc and neuro-foraminal height,8,9 and segmental alignment including balance and lordosis.10-14

PLIF with insertion of bilateral interbody cages has been a standard treatment to predictably restore segmental alignment and balance, and obtain a successful fusion. However, occasionally only a unilateral cage may be placed because of circumstances found at the time of surgery such as limited size of the disc space, nerve root anomalies that may block access to the disc space, and limited ability to retract nerve roots due to epidural scarring of previous surgery. Because unilateral interbody fusion may be necessary in PLIF for the reasons stated above, the question is raised as to whether this will give acceptable balance, strength, and fusion results.

Recently a variation of the PLIF approach, the trans-foraminal interbody fusion (TLIF) has allowed unilateral placement of interbody cages. The TLIF approach may reduce operative time, blood loss, dural tears, and radiculopathy risks and yet provide comparable mechanical stability to the PLIF. Biomechanical studies of TLIF suggest a single interbody cage positioned in sagittal, coronal or oblique orientation provides excellent stability and stiffness.15-17 Clinical and fusion results reported with TLIF are comparable with PLIF results.18-22 In the TLIF reports, there is variety of type and number of implants, and type and location of bone graft material.20,23-32 The rapid evolution and variety of implant and biologic technologies complicates the assessment of the TLIF technique.

This study asks if unilateral PLIF with a single cage will give acceptable results comparable with bilateral implants and to recent TLIF studies with unilateral interbody fusion. This study reports the clinical and fusion results of patients having PLIF with a unilateral approach to the disc space and compares the outcomes to historical bilateral PLIF series and recent TLIF studies.
MATERIALS AND METHODS

The Lumbar I/F cage (DePuy Spine, Raynham, MA) is a CFRP implant made of poly-ether-ether ketone reinforced with “chopped” or short carbon fibers. The VSP (DePuy Spine, Raynham, MA) includes pedicle screws and plates. The CFRP cage and the VSP System have been previously described. From February 1999 to October 2003, we performed PLIF using the CFRP cages and VSP instrumentation on 425 patients in our practice. Surgical indications included disabling back and/or radicular pain refractory to conservative management with moderate to severe degenerative change, with instability and adjacent segment deterioration based on magnetic resonance imaging or discogram. During the summer of 2004, we conducted a retrospective chart review of all patients. Follow-up was achieved on 377 of 425 patients (87%) including 1-year clinical and radiographic evaluation. Although 1 year is not long enough to define an exact rate of clinical success, it is sufficient follow-up to identify complications and failed fusions.

From this large group, 26 consecutive patients were identified who had PLIF at one or more levels with a unilateral CFRP cage. Each of these patients had identical treatment to the large group including iliac crest autograft, posterolateral fusion, and bilateral pedicle screw instrumentation. The only surgical variable was that a unilateral single CFRP cage was used rather than bilateral cages. The minimum follow-up was 24 months (mean 36 mo, range 24 to 65 mo). Demographic data were recorded including age, sex, neurologic function, number and type of prior back surgeries, and diagnosis at each lumbar level. Patients were examined and data recorded before surgery, at surgery, and at postoperative intervals after surgery. Evaluations included ratings of pain, function, economic status, and medication. Patient history, sensory and motor function, tension signs, reflexes, and radiographic findings were recorded at each follow-up interval. Additional clinical data were recorded including surgery levels, operative difficulties, complications, fusion status, and reoperation or revision.

Indications for the surgery were 17 recurrent disc disease (recurrent herniation or disc space collapse with foraminal stenosis and radiculopathy), 3 symptomatic spondylolisthesis refractory to conservative care, and 6 pseudarthroses. Two patients had significant degenerative scoliosis. Fourteen patients were revision cases with 24 prior spinal operations. In the previously operated patients, there was an average interval between the 2 surgeries of 42 months (7 mo to 7 y). There were 10 men and 16 women. The average age was 50 years (range 34 to 80 y). The insurance was workers compensation in 5 and private insurance in 21. Nine patients had a positive smoking history with an average 19-pack/year history.

Clinical success was defined according to previous published literature parameters used over many years and modeled after an expanded Prolo scale. The 5-point Likert scales for pain, function, economic status, and medication usage are added to a combined 4-point and 20-point scale. This study defined a patient’s result as a clinical success when the final rating was excellent (17 to 20 points), or good (13 to 16 points), or fair (9 to 12 points) if the patient achieved a minimum improvement of 3 points or more in the combined 20-point scale.

Fusion success within the interbody space was defined by previous published parameters of radiographic fusion assessment of Brantigan and Steffee. As recommended by Blount et al, 2 observers evaluated the fusion from Ferguson anterior-posterior (parallel to the vertebral endplates), and lateral radiographs. A level was regarded as fused if there was radiographic evidence of bone bridging the disc space without lucency. If lucency was seen to extend across the cage, the level was considered not fused. For patients undergoing multiple-level fusion, all surgically treated segments must be fused for the patient to be considered a fusion success. Figure 1 shows a series of anterior-posterior Ferguson radiographs demonstrating progressive solid fusion. Figure 2 shows the features of a pseudarthrosis with discontinuity in the bone graft and lucency adjacent to the cage.

Statistical analysis was carried out using the \( \chi^2 \) analysis. Demographics, clinical and fusion success were compared with the larger reviewed patient group, the IDE cage study, and the available TLIF studies with a minimum 2-year follow-up using \( \chi^2 \) analysis. Statistical significance was defined as \( P < 0.05 \).

![FIGURE 1. Anterior-posterior Ferguson radiographs of L4-5 taken at interval demonstrate increases in bone density within the single cage and around the cage. The contrasting radiographic densities of bone and carbon cage strut (radiodense dot in the strut) allow a comparison of increased bone density with healing of the fusion. There is no lucency between the bone and the vertebral endplates. There was fusion success at 1 year with maintained maturity through 4 years.](image-url)
RESULTS

A unilateral cage was used for the indications of previous surgery with limited access to one side of the disc space in 12 (46%), not enough space in the disc space for another cage in 11 (42%), and nerve root anomaly with low position of the exiting nerve root in 3 (12%). Unilateral cages were placed at thirty lumbar levels in 26 patients. There were 8 single-level fusions with a unilateral cage; 10 with a unilateral cage at a single level in a multilevel PLIF, and 8 with multilevel unilateral cages in a multilevel PLIF. Nerve root anomalies prevented cage placement at L4-5 and L5-S1 only. Not enough space for a second cage occurred at the higher lumbar levels but not at L5-S1. Previous surgery with adhesions prohibited cage placement most frequently at L3-4 but was significant at every level. Details of the PLIF surgery are shown in Table 1.

Clinical success was achieved in 23 patients (88%). This included 3 excellent (12%), 9 good (35%), and 11 fair (42%) results. Clinical success was not achieved in 3 with poor results (12%). Table 2 correlates the clinical and fusion success of these patients.

A retropulsed cage complication occurred in 1 patient, at the L2-3 level with 2 cages in place. A cage was found to have retropulsed into the canal in the third month postoperatively. This was identified and watched. At 8 months, the patient was complaining of back pain and hip pain on the same side as the mal-positioned cage. The cage was removed and the pedicle screw instrumentation removed, and the posterior-lateral fusion was augmented with bone morphogenic protein. This case was a fusion success at three years follow-up. There were no other complications such as dural tear, infection, or neurologic injury.

At the final radiographic evaluation, fusion success was achieved in all 30 unilateral-cage levels. There were no pseudarthroses, instrumentation failures, or significant subsidence at any of the unilateral cage levels. Disc space height and foraminal height were restored by the surgery and maintained at last follow-up. However, there were 3 patients with single level, 2 cage radiographic pseudarthrosis. Fusion success was then 23/26 (88%) for all

![FIGURE 2. L2-4 fusion, L3-4 single cage progresses to appearance of lucencies implying pseudarthrosis with non-continuous bone across the single cage. This level was found to be healed at time of fusion exploration.](image)

<table>
<thead>
<tr>
<th>TABLE 1. Details of Current Fusion Levels</th>
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</thead>
<tbody>
<tr>
<td>Lumbar Level</td>
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</tr>
<tr>
<td>L2-3</td>
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<tr>
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<td>L4-5</td>
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<td>L5-S1</td>
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<table>
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<th>TABLE 2. Correlation of Clinical to Fusion Success</th>
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</thead>
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<td>Patient No.</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
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ASD indicates adjacent segment deterioration; BMP, bone morphogenic protein; E, excellent; F, fair; G, good; IR, implant removal; P, poor; N, no; Y, yes.
patients. The first pseudarthrosis was the L2-3 retro-pulsed cage removed at 8 months and subsequently fused on radiograph and computed tomography (CT) scan. The second was an L2-3 level persistent pseudarthrosis from an initial L2-S1 pseudarthrosis reconstruction that was explored and treated with pedicle screw implant removal and bone morphogenic protein augmentation of posterolateral fusion and subsequently was healed at last follow-up with x-rays and CT scan. The third patient had a pseudarthrosis level reported at L3-4 on CT in a L1-5 fusion for degenerative scoliosis, and did not agree with fusion exploration, accepting a fair clinical result. Table 2 correlated the clinical status with fusion success.

**DISCUSSION**

The goal of lumbar interbody fusion is to relieve pain caused by neurologic compression and achievement of a stable surgical construct. Compared with posterolateral instrumented fusion, adding an interbody fusion produces a significantly stiffer construct that protects the posterior instrumentation from failure, and provides a circumferential fusion mass with an increased rate of successful fusion.\(^7,23,33\) Both the PLIF and the TLIF approach offer circumferential fusion from a posterior approach.

The patients in this unilateral cage series presented with complex surgical problems that precluded the usage of the recommended bilateral interbody fusion cages. Comparison of this series with the historical investigational device exemption clinical trial (IDE) of Brantigan et al,\(^33\) showed no significant difference in the indications for surgery but there was a significantly higher rate of previous surgery in this group (\(\chi^2 = 6.5202, P\) value = 0.0107). Comparison of the clinical and fusion success showed no significant difference between this series and the IDE study. Despite the complexity of revision surgery, the outcome of the unilateral cage patients was as successful as the IDE series.

With the commonality of unilateral interbody fusion with bilateral pedicle screws and posterolateral graft, the comparison to reported TLIF studies is appropriate. Lowe et al\(^38\) reported 90% fusion rate and 80% clinical success in TLIF with 2 titanium-mesh cages. Hee et al\(^14\) reported 96% fusion rate with the same TLIF procedure augmented with autologous growth factors. McAfee et al\(^19\) in 120 spondylolisthesis patients treated with TLIF with a unilateral CFRP cage reported a 97.5% fusion rate. Potter et al\(^15\) reported 93% fusion rate and 79% clinical success with interbody structural allograft or bioabsorbable spacers. Hackenberg et al\(^20\) reported 89% fusion rate and significant improvement in Oswestry disability index in TLIF with a unilateral CFRP. Molinari reported 19 active-duty military personnel were treated with 2 CFRP cages and 16 with a unilateral cage. When only a single cage was used, bone graft was inserted from a bilateral approach.\(^27\) Molinari et al\(^27\) reported that the results were generally good, and that patients having a unilateral cage had equal fusion and clinical success as those having 2 cages. The fusion and clinical results of TLIF with unilateral interbody support and bone grafting were not significantly different by \(\chi^2\) analysis from this unilateral cage series.

During the design of the CFRP cages, mechanical testing assumed use of bilateral cage placement and bilateral pedicle screw fixation.\(^4,9,14\) Biomechanical fatigue strength of 2 cages had a 2-fold safety factor over the maximal loads of daily living.\(^40\) The single cage fatigue strength had a small or nonexistent safety factor over the maximal loads of daily living.\(^40\) Clooney et al\(^41\) in an in vitro analysis found \(>30\%\) of the vertebral endplate surface was required for load transmission across structural interbody grafts. Recent published mechanical data related to single interbody cage in TLIF found no statistical difference in initial stability and stiffness with a single cage compared with 2 cages.\(^15-17\) Ames et al\(^15\) in human cadavers, found no significant difference in motion between PLIF with 2 allograft bone spacers and TLIF with a single spacer as long as there were bilateral pedicle screws. Chen et al\(^16\) in a porcine model found unilateral cage and unilateral pedicle screws had similar stability to the unilateral cage with bilateral pedicle screws. Kettler et al\(^17\) in a human cadaver found a unilateral cage is as stable as bilateral cages. Position of the graft did not change the stiffness or stability.\(^15,42\) Ames et al\(^15\) varied the position of the unilateral graft between the anterior and middle column without diminution of the stability or stiffness of the construct. Harris et al\(^42\) in a human cadaver study placed an oblique single CFRP cage, and found the addition of bilateral pedicle screws matched the flexibility of an intact motion segment. Heth et al\(^43\) compared anterior and transverse placement of threaded cylindrical cages and found no difference in stability with transverse positioned cages. Wang et al\(^44\) in human cadavers compared sagittal versus oblique placement of cylindrical cages and found any differences between cage position was normalized with bilateral pedicle screw fixation. Several key points are made by these studies. A unilateral cage is as stable and stiff as bilateral cages. Cage position does not decrease the stability of the construct. All constructs are improved by bilateral pedicle screw fixation.

Bone grafting of the available surface area of the disc space is important for fusion success. Prolo\(^36\) found successful fusion filled \(77\%\) of the available disc space with bone. A clinical study using CT scan to demonstrate disc removal showed more than \(56\%\) of the cross-sectional area of the endplate could be cleared from a unilateral TLIF approach.\(^45\) The surface area of exposed bone graft in a single CFRP cage is \(138\text{ mm}^2\) and the surface area of a typical L5 lumbar endplate is \(1259\text{ mm}^2\).\(^7\) A single CFRP cage will fill only \(10\%\) of the endplate.\(^30\) Additional bone grafting to fill all available surface area is recommended. Placement of additional bone graft around the single cage may account for the undiminished high rate of fusion success in this series.
A shortcoming of this study is that a small population will result in poor specificity or underestimation of the actual pseudarthrosis rate. To improve the statistical power of the study would require a large number of patients that may be impractical. This study demonstrates successful fusion and clinical results when the patient selection criteria are expanded to include complex revision surgical problems. The results of this study support the use of a unilateral interbody cage combined with bilateral posterolateral fusion and pedicle screws. A prospective randomized trial comparing unilateral with bilateral CFRP cages is warranted. The authors emphasize that when a fusion is done with an unilateral approach to the disc space, it is particularly important for the surgeon to pack additional bone in the disc space around the cage.

CONCLUSIONS

Fusion and clinical success rates are not diminished by the use of a unilateral CFRP cage rather than the recommended 2 cages. Clinical success with the unilateral single cages was not statistically different from the clinical success rates of the IDE study. Fusion success was achieved in 100% of 30 single cage levels and 23 of 26 patients (89%) at all fusion levels. Mechanical failure did not occur with the single cage. A single cage with bilateral pedicle screws provides adequate alignment, balance, and mechanical stability, and allows the maximal amount of autologous graft to fill the disc space.

REFERENCES


Repair of Pars Interarticularis Defect With a Modified Cable-Screw Construct

Gordon R. Bozarth, MD, Guy R. Fogel, MD, John S. Toohey, MD, and Arvo Neidre, MD

Operative treatment of symptomatic spondylolysis is not common. Multiple surgical techniques have been described for direct repairs of the pars defects. Reported success rates are high, although few reports describe successful return to sports in athletes. The purpose of the study was to assess the outcome after bone grafting and fixation of pars interarticularis defects utilizing a modification of the previously described techniques of Scott and of Songer.

A retrospective single-arm cohort study was performed at a single center. This article reports on three athletes with symptomatic spondylolysis or grade 1 spondylolisthesis unresponsive to conservative management who were treated with bone grafting and a screw-cable repair. The outcome measure was the return to sports activities. A retrospective chart and radiographic analysis was conducted on three athletes. Patients were assessed for return to sports, clinical evidence of return to functional activities, and radiographic evidence of healing of the pars defects. All three patients proceeded to radiographic and clinical success. All patients reported resolution of their preoperative pain and return to sports. One patient did require occasional anti-inflammatory drugs for episodic low back pain. The use of this modified cable-screw technique for symptomatic spondylolysis provided excellent clinical, radiographic, and functional results in this small cohort. (Journal of Surgical Orthopaedic Advances 16(2):0–0, 2007)

Key words: pars defect, spondylolisthesis, spondylolysis

Spondylolysis and grade 1 spondylolisthesis are common defects found in the general population, with a reported incidence of 6% (1). While many remain asymptomatic or heal with bracing or symptomatic management, a small subgroup of these patients will continue to have significant functional limitations related to their sport (2). Symptomatic spondylolysis unresponsive to conservative management may be an indication for operative intervention. While lumbosacral fusion has remained the gold standard, direct repair of the pars defect has been shown to be effective in this subset (1, 3–9). Multiple surgical techniques have been described in an attempt to directly repair the pars defect. Direct repair has the advantage of maintenance of the motion segment and compression across the bone-grafted pars defect. We have modified the Scott technique to pass a cable around a pedicle screw on each side, rather than the transverse process, and modified the Songer technique to pass the cable around the base of the spinous process and not beneath the lamina. We report on this modification for direct repair of symptomatic spondylolysis.

Surgical Technique

The patient was positioned on a flexion frame in the prone position. Posterior laminar dissection was performed over the involved segment and a localization radiograph was obtained. Care was taken not to violate the facet capsule. The defect in the pars was localized bilaterally. Soft tissue and callus was debrided from each defect until bleeding bone was evident. Each pars defect was then bone grafted with iliac crest autograft. Pedicle screws were inserted within the pedicle at the same level...
FIGURE 1 Surgical technique of modified Songer repair.

as the laminar pars defect, utilizing a standard technique. A 1-mm AcroMed Songer cable was then passed around the base of the spinous process and the ipsilateral pedicle screw from both sides at the involved level. The cables were then simultaneously tensioning and finally crimped. Figure 1 is a graphic representation of the procedure.

The surgical technique begins with debridement of the pars defect, then bone grafting of the pars defects with iliac crest autograft. Fixation is established with pedicle screw placement into each L5 pedicle, then a 1-mm cable is woven around the spinous process and both pedicle screws are tensioned to compress the pars defect bone grafts.

Case Reports

Patient 1 was a male 17-year-old soccer player with a 2-year history of back pain. His initial injury occurred while playing soccer. He complained of episodic significant low back pain that would limit his school attendance and he could not play soccer. Running became more painful, and basically any quick motion could be painful. He was treated with bracing, and had several rounds of physical therapy consisting of stretching and truncal strengthening. Physical exam revealed negative straight leg raising and normal neurologic examination of the lower extremities. Plain x-rays, including obliques, showed pars defect of L5 bilaterally. A lumbar MRI scan revealed prominent pars defects with edema of the adjacent bone. A technetium-99 bone scan showed increased uptake at the L5 level. The L5–S1 disc showed moderate dehydration. A discogram was done and was negative at L4–5 and L5–S1. Surgical repair of bilateral L5 pars defects was done. The patient was braced with a lumbar corset for 6 weeks. He returned to jogging at 6 weeks and returned to soccer at 3 months. At 6 months, he continued to play soccer; however, he complained of intermittent stiffness of the low back. CT scan at 6 months after surgery showed one pars to be healed and one incompletely healed. At 1 year, the patient was asymptomatic and performing his usual soccer and conditioning program without limitations. CT scan at 1 year showed healing of both pars defects.

Patient 2 was a male 16-year-old baseball player with bilateral L5 pars defects. He was first diagnosed at age 14. He was treated with a brace and when pain free began gradual return to activities with physical therapy. He improved with conservative treatment and returned to full activity. He played school football, baseball, and other sports. He did return to playing high school baseball for the entire season. And then several weeks before his return visit, he began to have shooting pain to his left buttock following a diving fall to the ground. Physical exam showed mildly restrictive spine motion. Straight leg raising was negative. Leg lengths were equal. Plain x-rays of the lumbar spine showed a right-sided pars defect and the left pars appeared intact. CT scan showed bilateral L5 pars defects. A lumbar MRI scan showed Schmorls nodes of several lumbar segments. Bone scan showed uptake of the left L5 pars defect and not the right. He had bilateral repair of the L5 pars defect. At 6 weeks, he was able to swim and jog. At 12 weeks, x-rays showed definite but incomplete healing of the pars defect bilaterally. He increased the amount and type of his aerobic activity. At 5 months, he was playing basketball and doing some running. Radiographs showed one side completely healed and the other side filling in. He began a full-time running program. At 8 months, he was jogging 1 mile. He continues to have some aching in his back. X-ray showed one pars defect completely healed and the opposite shows progressive healing. At 10 months, he was back to full basketball sports and running without discomfort. Radiograph showed apparent full healing of both of the pars defects.

Discussion

Several surgical techniques have been developed for surgical repair of symptomatic spondylolysis and up to grade 1 spondylolisthesis refractory to conservative management. Multiple wire, screw, screw-wire, pedicle screw-wire, pedicle screw-hook, and pedicle screw-rod constructs have been described with a high rate of good to excellent results (3–5, 7, 9–13). These techniques are technically difficult and some require wire, hook, or cable passage beneath the posterior lamina or the transverse process (2, 4, 12, 14). The Scott technique describes a wiring beneath the transverse process on each side around the spinous process. Songer reported a special fabricated

FIGURE 4  A–C, Six months postoperative CT scan. Coronal (A), axial (B), and sagittal (C) views demonstrating persistent incomplete healing of the pars defects repair.  D–F, CT Scan at 1 year following surgical repair. Much improved healing of the pars defect bilaterally is evident.
pedicle screw with a hole in its head to allow passage of a 1-mm cable. This cable was passed from the pedicle screws around the spinous process and beneath the lamina. In our practice, there has been occasional loss of fixation with broken Scott wires. There is some hypothetical increased risk of nerve injury during blind passage of wires beneath the transverse process. Sublaminar passage of a cable may not be necessary. Our modification of previous techniques arose from a need for a stronger material with less breakage, and lower potential for neurologic complications related to wire passage beneath the transverse process or lamina.

The described modification to the Songer cable-pedicle screw technique does not involve the transverse process and does not require sublaminar cable passage, decreasing the degree of technical difficulty. Although the number of cases is small, all patients reported relief of their symptoms and were able to resume normal athletic activity. This suggests that a well-motivated athlete may return to his sport after a direct repair of pars defects for symptomatic spondylolysis.

References

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Clinical Study

Fusion assessment of posterior lumbar interbody fusion using radiolucent cages: X-ray films and helical computed tomography scans compared with surgical exploration of fusion

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Abstract

BACKGROUND: Plain radiographic assessment of posterolateral fusion has been reported as accurate in only two thirds of patients who were found to be healed at surgical exploration. Plain radiographic techniques for fusion assessment of interbody fusion with radiolucent cages are reported to be accurate. A helical computed tomography (CT) scan shows a high sensitivity for pseudarthrosis compared with plain radiography.

PURPOSE: To determine the accuracy of fusion assessment with plain X-ray films and helical CT scans by comparison to results of surgical exploration of fusion.

STUDY DESIGN/SETTING: The accuracy and interobserver agreement of plain X-ray films and thin-cut helical CT scans were compared with fusion assessment by surgical exploration in patients with posterior lumbar interbody fusion using a radiolucent carbon fiber reinforced polymer cage (CFRP) and iliac crest bone graft.

PATIENT SAMPLE: A review of 90 patients who had surgical exploration of the lumbar fusion.

OUTCOME MEASURES: All patients had plain X-ray films including Ferguson anteroposterior parallel to the interbody space. Fifty-four patients had thin-section helical CT scans.

METHODS: Fusion assessment by exploration was compared with blinded assessment by plain X-ray films and CT scans.

RESULTS: Ninety patients had surgical exploration of 172 lumbar interbody and posterolateral fusion levels. At the time of exploration, fusion was determined to be successful in 87 of 90 patients and 168 of 172 (97%) fusion levels. X-ray assessment showed healed interbody fusions in 87% and posterolateral fusion healed in 75%. CT grading of the interbody fusion found healed interbody fusion in 77%, and the posterolateral fusion was fused in 68%. Plain X-ray films and CT scans had a sensitivity of 100% for pseudarthrosis and a negative predictive value of 100% for healed fusion. Specificity was almost 90% and was not significantly different between X-ray films and CT scans.

CONCLUSIONS: Fusion assessment with plain X-ray films and helical CT scans showed equal accuracy after posterior lumbar interbody fusion confirmed by surgical exploration. Our results indicate that when plain X-ray films show strong evidence of fusion or pseudarthrosis, the helical CT is unlikely to provide useful new information.

Introduction

Modern techniques combining posterolateral fusion (PLF) with interbody fusion (PLIF) using radiolucent interbody cages have increased the fusion rate to nearly 100% by plain radiographic assessment [1–5]. Nevertheless, 10% to 15% of patients may remain symptomatic. Accurate radiographic assessment of fusion success is important to
identify patients who might benefit from further surgery. Physicians have continued to struggle with the correct interpretation of radiographic methods. To date, the “gold standard” of fusion determination has been surgical exploration [6–8]. Comparison of plain radiographic assessment of posterolateral fusion does not correlate with surgical exploration in a third or more of patients [6,9,10]. Plain radiographic techniques for fusion assessment of PLIF with radiolucent cages have been compared with surgical exploration and have been reported to be accurate [1,2].

Improvement in computed tomography (CT) scanning has increased accuracy in fusion assessment. Early studies used only axial images, and, when compared with surgical exploration, they showed noncorrelation in up to 43% of cases [6]. More recently, thin-section 1 mm axial helical CT scans with sagittal and coronal reconstructions provide high-quality images with exquisite bone detail. Several helical CT studies have shown a high specificity for detection of pseudarthrosis compared with plain radiography particularly in evaluation of the interbody fusion [11–16].

From a single surgical cohort, we have performed a retrospective chart and radiographic review of 90 consecutive patients who had surgical exploration of the fusion after posterior lumbar interbody fusion at one or more levels. Our purpose was to show the accuracy of plain X-ray films and helical CT scans in fusion assessment. To our knowledge, a comparison of plain X-ray films and helical CT scans to surgical exploration in evaluation of PLIF with radiolucent cages has not been previously reported.

Materials and methods

Clinical study design

From February 1999 to October 2003, we performed PLIF using the Lumbar I/F Cage (DePuy Spine, Raynham, MA) with pedicle screw and plate fixation in our practice. Iliac crest bone autograft was used for the interbody fusion and local bone for the posterolateral fusion. Inclusion criteria included patients with disabling back pain because of degenerative disc disease at one or more lumbar levels and included patients with primary degenerative disc disease, failed discectomy, spondylolisthesis, failed fusion, and degenerative spondylolisthesis. During the spring of 2005, we conducted a retrospective chart review of all patients. From this group, 90 patients were identified who had surgical exploration of the lumbar fusion. There were 48 men and 42 women. The average age was 43 years (range, 27-70). The average time from the index fusion operation was 27.2 months (range, 12-65 months). The indications for exploration of the fusion were persistent nonspecific low back pain in 63, adjacent-level operation for indications of instability or stenosis in 18, and radiographic pseudarthrosis in 10. The minimum follow-up after the index fusion operation was 24 months (mean, 38 months [median, 35 months; range, 24-68 months]).

Radiographic assessment of fusion

All patients underwent X-ray assessment of 172 levels of fusion before the surgical exploration using plain static X-ray films including anterior-posterior, lateral, and individual Ferguson views of each interbody fusion level. The Ferguson view is an anterior-posterior X-ray directed parallel to the end plates of the vertebral body designed to visualize the interbody fusion. Two of the authors (GRF and JST), blinded to the names of the patients and the results of the surgical exploration, independently graded the X-ray films for evidence of interbody and posterolateral fusion.

Fifty-four patients with 109 levels of fusion had thin-section helical CT scans with sagittal and coronal reconstructions before the exploration of fusion at an average of 30 months (range, 10-60 months) after the index surgery. These patients underwent 1-mm thin-section helical CT scanning of the involved lumbar segments performed on a high-speed helical scanner (Sensation 4; Siemens). Reconstructed images were generated in sagittal plane and coronal planes exactly perpendicular to the plane of each cage. Each helical CT scan was interpreted by one of three radiologists who were blinded with regard to the clinical history and the plain radiographic findings.

The interbody and posterolateral fusion were graded by two methods. Each level and each side was judged individually. Interbody fusion was graded by the method of Brantigan and Steffee [17] as modified to describe the Fraser definition of locked pseudarthrosis (BSF scale) [14] outlined in Table 1. The posterolateral fusion was graded by the method of Lenke et al. [18] outlined in Table 2.

Surgical exploration of fusion

At the time of exploration, the pedicle screws were removed. All soft tissue was removed from the fusion mass. The fusion mass, facet joints, and intertransverse areas

<table>
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<th>Table 1</th>
<th>Classification of interbody fusion success: Brantigan, Steffee, Fraser (BSF)</th>
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<td>BSF-1: Radiographical pseudarthrosis is indicated by collapse of the construct, loss of disc height, vertebral slip, broken screws, displacement of the carbon cage, or significant resorption of the bone graft, or lucency visible around the periphery of the graft or cage.</td>
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<td>BSF-2: Radiographical locked pseudarthrosis is indicated by lucency visible in the middle of the cages with solid bone growing into the cage from each vertebral endplate.</td>
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<td>BSF-3: Radiographical fusion: bone bridges at least half of the fusion area with at least the density originally achieved at surgery. Radiographical fusion through one cage (half of the fusion area) is considered to be mechanically solid fusion even if there is lucency on the opposite side.</td>
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were carefully explored. Motion was evaluated by one or more methods. Where significant portions of the adjacent spinous processes remained, a Kocher clamp was used to apply distraction or compression; direct compression was placed on the fusion mass and facets with a large punch. Long pedicle probes were placed in each pedicle screw hole and used to apply compression and distraction. A solid posterolateral fusion was indicated by observation of a solid bridge of cortical bone bridging the posterolateral area. Posterolateral pseudarthrosis was indicated by either an observed defect in the bridging bone or by visible motion in the posterolateral fusion area. Each side of the posterolateral fusion was graded separately. Solid interbody fusion was indicated by total rigidity and lack of motion between the manipulated pedicle probes. Interbody pseudarthrosis was indicated by any relative motion between the manipulated pedicle probes.

Statistical methods

The sensitivity, specificity, positive predictive value, and negative predictive value for detecting pseudarthrosis were calculated for all plain X-ray films and the helical CT scans by comparing the results of the independent interpretations of those studies with the results of surgical exploration. The threshold for fusion was set at interbody radiographic fusion BSF-3 (Table 1) and posterolateral fusion at Lenke-A (Table 2). The values for the plain X-ray films were compared with those values for the helical CT scan, with use of the normal distribution to approximate the difference between any two percentages. Interobserver agreement for X-ray film interpretation was assessed with the chi square test, Fischer exact test, and the McNemar’s test. Statistical analysis was performed by using SPSS 6.1.3 (SPSS Inc, Chicago, IL).

Results

Ninety patients had surgical exploration of 172 lumbar interbody and posterolateral fusion levels (Table 3). At the time of exploration, fusion was determined to be successful in 87 of 90 patients and 168 of 172 (97%) fusion levels (Fig. 1). Surgical exploration revealed four pseudarthroses (4/172, 2.3%). Two of the four pseudarthroses occurred at L5–S1, one at L4–5, and one at L1–2. Because all pseudarthrosis levels were relatively stable, the pedicle screws were left out and augmentation of the posterolateral fusion was performed with a combination of supplemental local bone chips, demineralized bone graft, and/or bone morphogenic protein. The patient with L1–2 pseudarthrosis had two revision procedures. The first included removal of pedicle screws and augmentation of the posterior-lateral grafting. The second included reinstrumentation with pedicle screw fixation and augmentation of the posterior-lateral bone grafting (Fig. 2).

X-ray assessment showed healed interbody fusions in 87%, and the posterolateral fusion was healed bilaterally in 75% (Table 3). Interobserver agreement for X-ray interpretation was not significantly different comparing

Table 2
Lenke classification of posterolateral fusion success

<table>
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<tr>
<th>Grade</th>
<th>Description</th>
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<tbody>
<tr>
<td>A</td>
<td>Definitely solid with bilateral trabeculated stout fusion masses present</td>
</tr>
<tr>
<td>B</td>
<td>Possibly solid with a unilateral large fusion mass and a contralateral small fusion mass</td>
</tr>
<tr>
<td>C</td>
<td>Probably not solid with a small fusion mass bilaterally</td>
</tr>
<tr>
<td>D</td>
<td>Definitely not solid with bone graft resorption or obvious pseudarthrosis bilaterally</td>
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Table 3
Fusion assessment of interbody fusion (BSF) and posterolateral fusion (Lenke)

<table>
<thead>
<tr>
<th>Explored</th>
<th>L5–S1 # (%)</th>
<th>L4–5 # (%)</th>
<th>L3–4 # (%)</th>
<th>L2–3 # (%)</th>
<th>L1–2 # (%)</th>
<th>Total levels (%)</th>
<th>Matched XR to CT (%)</th>
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</thead>
<tbody>
<tr>
<td>Pseuadarthrosis</td>
<td>69 (40)</td>
<td>69 (40)</td>
<td>23 (13)</td>
<td>9 (5)</td>
<td>2 (1)</td>
<td>172</td>
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<td>Levels with CT</td>
<td>38</td>
<td>45</td>
<td>16</td>
<td>8</td>
<td>2</td>
<td>109</td>
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<tr>
<td>BSF-3 XR</td>
<td>58 (84)</td>
<td>61 (88)</td>
<td>21 (91)</td>
<td>8 (89)</td>
<td>1 (50)</td>
<td>149 (87)</td>
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<td>CT</td>
<td>28 (74)</td>
<td>39 (87)</td>
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<td>7 (88)</td>
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<td>86 (96)</td>
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<td>1 (50)</td>
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<tr>
<td>Lenke-A XR</td>
<td>57 (83)</td>
<td>48 (70)</td>
<td>17 (74)</td>
<td>6 (67)</td>
<td>1 (50)</td>
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<td>26 (58)</td>
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<td>10 (22)</td>
<td>2 (13)</td>
<td>0</td>
<td>3 (13)</td>
<td>13 (12)</td>
<td>6 (46)</td>
</tr>
<tr>
<td>Lenke-C/D XR</td>
<td>5 (7)</td>
<td>7 (10)</td>
<td>3 (13)</td>
<td>1 (11)</td>
<td>1 (50)</td>
<td>17 (9)</td>
<td></td>
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<tr>
<td>CT</td>
<td>9 (24)</td>
<td>9 (20)</td>
<td>1 (6)</td>
<td>2 (25)</td>
<td>1 (50)</td>
<td>22 (25)</td>
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There were 172 levels explored. Four of 172 were pseudarthroses at surgical exploration. All levels had X-ray films, and 109 levels had helical CT scans. The image grading is reported as the number of levels with that grade and a percentage of levels with X-ray film or CT scan. Matching image grading is reported as number of X-ray films to CT scan matches as a percentage of levels with CT scans.
interbody and posterolateral fusion level by level and overall (chi-square test=0.5595, p=.455, Fischer exact test=.046, and McNemar’s=5.400, p=.02). The proportion of overall agreement between observers was 98.6%.

CT grading of the interbody fusion found solidly healed interbody fusion in 77%, and the posterolateral fusion was solidly fused bilaterally in 68% (Table 3). When the CT scan showed a healed interbody or posterolateral fusion, the X-ray film was also healed in 96%. If the CT scan showed a healed posterolateral fusion, the X-ray film was also healed in 85% (Table 3).

Table 4 presents the data to calculate the sensitivity, specificity, positive and negative predictive values for plain X-ray films, and CT fusion assessment confirmed at exploration. The incidence of pseudarthrosis at the time of surgical exploration was 4/172 levels or 2.3%. Sensitivity refers to how good a radiographic test is at correctly identifying fusion levels with pseudarthrosis. When calculating sensitivity, we are therefore interested in only the fusion levels with pseudarthrosis. The sensitivity of both CT and plain X-ray films was 100% in correctly identifying pseudarthrosis. Specificity, on the other hand, is concerned with how good the radiographic test is at correctly identifying fusion levels that are healed and do not have a pseudarthrosis. Specificity was almost 9 of 10 and was not significantly different between X-ray film and CT scan at the chosen threshold for fusion. The positive predictive value refers to the chance that a positive radiographic test for pseudarthrosis will be correct (ie, the chance was less than one in four that there was a pseudarthrosis at exploration when the X-ray films were interpreted as below the threshold for fusion). The negative predictive value is concerned only with the radiographic tests negative for pseudarthrosis. When the radiographic test was solidly healed (negative for pseudarthrosis), 100% of the levels were healed at exploration.

The plain X-ray findings of the CT group were compared with that of those patients who did not have a CT scan. The incidence of solid fusion was not significantly different in the two groups. However, the incidence of pseudarthrosis was significantly greater in the CT group. All of the patients with obvious plain radiographic pseudarthrosis did have adjunctive CT scanning. All cases of surgical pseudarthrosis had both plain X-ray and helical CT studies.

Discussion

The accuracy of distinguishing posterolateral fusion success from PLIF fusion success by surgical exploration is based on observations made over many years. Numerous authors have noted that a solid posterolateral fusion has flexibility of motion up to 4° or 5° [19–22]. Unlike a posterolateral fusion, a successful interbody fusion creates a totally rigid motion segment [23–25]. Luk et al. [24] evaluated 52 cases of anterior lumbar interbody fusion 5 years after surgery and noted there was an average of 1° of motion measured in the fused segment and 12° to 15° in the adjacent nonfused segments. The authors attributed the 1° of motion to artifact and rotational and measurement variations.

The possible errors in each surgical determination should be considered individually. Failed PLIF and failed PLF should be the easiest and most accurate category to evaluate surgically because there is a definite gap in the posterolateral fusion mass. Axial compression and distraction shows definite motion in the posterolateral area, and flexion forces on the pedicle probes show motion in the interbody area. With healed PLIF and failed PLF, the pedicle probes show no motion on flexion or extension forces; however, there is a visible discontinuity in the posterolateral fusion mass. With failed PLIF and healed PLF, there will be a solid bridge of bone bridging the posterolateral fusion area. Axial distraction or compression produces no motion in the posterolateral area, but flexion forces on the pedicle probes produce a slight motion or “springiness.” Admittedly, this category provides the greatest possibility of misinterpretation. With experience, healed PLIF and healed PLF category can be accurately determined because there is solid bridging posterolateral bone with no motion on either axial or flexion forces. A locked pseudarthrosis should appear to be a healed PLIF because, by definition, this type of segment is stable. Although this result is correctly described as “pseudarthrosis,” it should not be considered a noncorrelation in the two-by-two analysis or surgical exploration.

In this study, both the helical CT scans and plain radiography were found to be highly accurate with high sensitivity for pseudarthrosis and high negative predictive value for healed fusion. Helical CT scans did not miss a single pseudarthrosis. Plain X-ray films missed one pseudarthrosis at L5–S1 that was diagnosed with a helical CT scan. The negative predictive value was the most important measure of accuracy. For both X-ray films and CT scans, the negative predictive value was 100% when either the interbody fusion or the posterolateral fusion was solidly healed. The only difference between X-ray films and CT scans was the number of false-positive readings for pseudarthrosis, reflected by the positive predictive value. The X-ray films

Fig. 1. True-negative healed fusion at L4–S1 graded 3A on plain X-ray films and 3B on CT scan and confirmed to be healed by exploration. (A) An anteroposterior view parallel to L4–5 end plates shows a single interbody cage with bridging bone at L4–5 (BSF-3) and bridging bone bilateral in posterolateral fusion (Lenke “A”). (B) A lateral view with bridging bone across the L4–5 interspace. (C) A CT coronal view through posterolateral graft bridging bone across transverse processes bilaterally (Lenke “A”). (D) A CT coronal view through interspace (BSF-3). (E) A CT sagittal view through interbody spaces showing bridging bone (BSF-3”).
falsely predicted pseudarthrosis in 6% and the CT scans in 8%. The false-positive test result was not significantly different between the two modalities in assessment of either interbody fusion (chi-square test = .4624, p = .4965) or posterolateral fusion (chi-square test = .012, p = .9609).

The plain radiographic diagnosis of a successful interbody arthrodesis was enhanced by a radiolucent implant filled with cancellous iliac crest graft and standardized radiographic technique including the Ferguson view of the interbody space. In other studies, accuracy in determining fusion was diminished because of the metallic posterior and anterior interbody instrumentation obscuring the bone graft. Metallic implants obscure the bone graft within, making it difficult to see remodeling or trabeculations that have formed across the interspace between the end plates. When cortical bone chips or synthetic filler is mixed with the cancellous bone graft, the graft is more radio-opaque and remodeling or resorption must be interpreted to assess the progress of bone fusion. Plain X-ray films are dependent on obtaining a true lateral and a true Ferguson parallel view of the interbody end plates. Suboptimal films when seen should be repeated.

A helical CT scan with sagittal and coronal reconstructions has become the preferred imaging to assess both posterolateral and interbody fusion [12,14,26,27]. CT coronal reconstructions are particularly helpful in evaluating the continuity of the posterolateral fusion. With the fine detail of bone trabeculations within the interspace, a helical CT scan would seem to be the ideal adjunct imaging for evaluation of suspected pseudarthrosis. However, a helical CT scan may overestimate the significance of lucencies in the interbody space and may not correctly predict fusion at exploration. Comparison of true positives and true negatives for X-ray films (Table 4) found no significant difference between the imaging modalities (chi-square test = 1.172, p = .2789). The accuracy of plain x-ray films and helical thin-cut CT scans methods was not statistically different when compared with the results of surgical exploration.

One point of concern with this study is that surgical exploration of a lumbar fusion is not commonly indicated today. Indications for late re-exploration of a lumbar fusion (more than 1 year after initial fusion) are commonly radiographic pseudarthrosis, persistent pain or recurrent symptoms, instrumentation failure, or progressive degeneration at another spine level [6,8–10,28–31]. Martin et al. [31] found the rate of late reoperation was 21.5% after lumbar fusion. The indications for late reoperation more than year after fusion are not significantly different than the Brantigan FDA-IDE series in 2000 and 10-year follow-up in 2004 [1,2]. A statistical problem of this study is the small incidence of pseudarthrosis. A larger sample size would clarify our results [32]. Another concern is that this study may have been better if all patients had both CT and plain radiographic studies. However, statistical comparison of patients with and without CT studies showed no significant differences in fusion grades. In practical clinical use for our study group, admittedly without statistical support of efficacy, helical CT scans were more often performed in patients in whom the plain films showed indeterminate evidence of fusion. With these results, the additional cost and increased radiation exposure with helical CT scanning may not be justified. Our results indicate that when the plain films show strong evidence either of fusion or pseudarthrosis, the helical CT is unlikely to provide useful new information.

**Conclusion**

In a study of surgical exploration after PLIF and posterolateral fusion using a radiolucent interbody fusion device, X-ray and CT methods performed very similarly in evaluating lumbar fusion success with no significant differences in accuracy between the two methods. Both x-ray and helical CT scans predicted pseudarthrosis with 100% sensitivity and interbody and posterolateral fusion success with a 100% negative predictive value. Our results indicate that when plain films show strong evidence of fusion or pseudarthrosis the helical CT is unlikely to provide useful new information.

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Table 4

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CT Scan

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<th>Posterolateral fusion</th>
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<td>31</td>
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<tr>
<td></td>
<td>90</td>
<td>74</td>
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**TP** = True-positive represents pseudarthrosis at exploration and by radiographical criteria. **FN** = False-negative or pseudarthrosis at exploration and **FP** = False-positive is healed fusion at exploration and less than **BSF-3** by radiographical criteria. **TN** = True negative is healed fusion at exploration and **BSF-3** by X-ray film criteria.
References


Abstract: Background Context
Posterior lumbar interbody fusion (PLIF) with the Lumbar I/F Cage and posterior Variable Screw Placement System (VSP) has increased the successful fusion rate to nearly 100% at the four lowest levels, L2-3 through L5-S1. In the design of the cage, only the surface area of the opening for bone graft contact with the endplates varied with the size of the cage. The 11mm cage was the optimal design allowing 5.5mm of bone graft opening or twice the width of each strut. The 9mm cage has only 3.5mm width for bone grafting or proportionately 36% less surface area than the 11mm cages and 54% less than the 13mm cages. In the narrow cage, the bone healing potentially is compromised by the smaller surface area. For this reason, it is clinically important to study the clinical and fusion success of these narrow cages. In some instances, when
space is limited, only 9mm width cages may be used at a fusion level. Clinical results of 9mm Lumbar I/F cage fusion and VSP have not been reported.

Purpose

The purpose is to report the functional outcomes, fusion rate, and complications related to PLIF when more narrow 9mm interbody cages are used.

Study Design/Setting

The setting is a retrospective single-arm cohort study of consecutive PLIF surgical patients at a single center.

Patient Sample

A review of 373 of 425 patients who underwent PLIF with lumbar I/F cage and VSP from 1999 to 2002 identified 90 patients who had PLIF with 9mm Lumbar I/F cages and VSP at a fusion level. Minimum follow-up was 24 months (Mean 36 months (median 33 months, range 24-65 months).

Methods

The 90 patients were evaluated for Clinical success and Fusion success at last follow-up. The results were compared to the results of the 373 patients reviewed, and historical groups of the original IDE study and the 10-year follow-up study.

Outcome Measures

Clinical success was determined with a modified Prolo score evaluating pain, function, medication usage and economic status. Fusion success, determined by evaluation of plain radiographs and helical cut CT scans, was defined by continuous bone bridging the fusion area with no lucency.

Results

Prolo scores were Excellent in 33 (37%), Good in 34 (38%), Fair in 20 (22%), and Poor in 3 (3%). 74 patients (82%) had clinical success, and 16 (18%) were clinically unsuccessful. Fusion was successful in 87 (97%) and failed in three patients (3%). Two failed fusions at the L1-2 level, were revised and failed fusion again, and the third was complicated by infection and was never explored.

Conclusions

PLIF with 9mm width Lumbar I/F Cage and VSP had 97% fusion success. There is no statistical difference to the fusion success with PLIF and two 11 or 13 mm width Lumbar I/F cages and VSP. Mechanical failure did not occur with 9mm cage usage. Authors recommend routine use of bilaterally placed Lumbar I/F cages of maximal width allowable. These results show clinical and fusion success was not diminished by use of 9mm width cages.
Outcomes of Posterior Lumbar Interbody Fusion with 9mm Width Lumbar I/F Cage and the Variable Screw Placement System

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Device status: The Lumbar I/F Cage and the VSP Spinal Fixation System are approved by the United States Food and Drug Administration. Dr. Brantigan has a financial interest in the Lumbar interbody carbon fiber Cage. No Financial assistance was provided from any source for this study.
Posterior lumbar interbody fusion (PLIF) was introduced by Cloward [1-4] more than fifty years ago. Limitations of PLIF included inadequate compression strength of allograft bone[5] and low fusion rates[6]. The Lumbar I/F cage (DePuy Spine, Raynham, MA) was designed to enhance posterior lumbar interbody fusion results by providing the mechanical strength to provide load-sharing during fusion and to allow the best biological healing with autologous bone graft[7, 8].

In an Investigational Device Exemption (IDE) study of the Lumbar I/F Cage, fusion success was reported in 176 of 178 patients (98.9%)[9]. In the 10-year follow-up of the IDE study, Fusion success was reported in 29 of 30 (96.7%) at 10 years[10]. Based on this study, the Lumbar I/F Cage was approved by the FDA for treatment of degenerative disc disease at one or two contiguous levels from L2 to the sacrum, accompanied by posterior-lateral fusion and pedicle screw fixation using the VSP Spinal System. Since the release of the lumbar I/F cages in 1999, favorable results have been reported in Japan [11, 12], United States clinical studies[10, 13], in a active military population[14], and in Europe [15.]

When the Lumbar I/F Cage was first designed, the optimal dimensions were unknown. The 11 mm cage prototypes had the opening of 5.5 mm width and the combined strut width of 5.5 mm (or 2.75 mm each)[16]. In the design of the 9 mm cage size the strut width was retained because of the concern for subsidence if the strut was weakened. This made the opening for bone graft 36% less than the standard 11 mm width cage. Because bone healing was potentially compromised with the 9 mm width cages by the proportionally greater reduction in bone graft surface area, it is clinically important to study the clinical and fusion success of these narrow cages.

In a single surgical practice, we have reviewed 373 of 425 patients who underwent PLIF with the Lumbar I/F Cage and VSP pedicle screw fixation from 1999 to 2002. Of these, 90 were identified who had PLIF at one or more levels using one or two 9 mm wide cages. The purpose of this retrospective review is to report the results of the 9 mm cages and VSP.
Materials and Methods

Description of the Lumbar I/F cage

The Lumbar I/F cage is manufactured from poly-ether-ether ketone reinforced with “chopped” or short carbon fibers. The cage is filled with autologous bone and placed in a disc space channel. This allows bone fusion from endplate to endplate across the bone graft within the cage. The cage material has approximately the same modulus of elasticity as cortical bone and is one-tenth the stiffness as compared with metals. This flexibility minimizes stress shielding of the bone graft and potentially decreases motion between the graft and the endplates during healing[9]. Because the cages are radiolucent, bridging bone can be accurately assessed by plain radiographs.

The width and height of the Lumbar I/F cage are 9mm, 11mm, or 13mm. The lengths are 21 and 25mm. There are 9X9, 9X11, 9X13, 11X11, 11X13, and 13X13mm. The two cage lengths are 21 and 25mm lengths. The 13X13 is only available in 25mm in length. The implant has an open architecture for packing of autologous bone, allowing a large surface area of bone contact (Figure 1).

Description of the Variable Screw Placement System (VSP)

The VSP (DePuy Spine, Raynham, MA) includes pedicle screws and plates. The screw has a cancellous thread ending in an integral nut, above which a machine thread with tapered and locking nuts allows the screw to be anchored securely to the plate. The lumbar I/F cage and the VSP have been previously described [9].

Clinical study design

From February 1999 to October 2003, we performed PLIF using the Lumbar I/F Cage with VSP pedicle screw fixation on 425 patients in our practice. During the summer of 2004, we conducted a retrospective chart review of all patients. We had a minimum of one year of full clinical and radiographic data on 377 of 425 patients (87%). While one year is not long enough to define an exact rate of clinical success, it is sufficient follow-up to identify complications and failed fusions. The current study group is comprised of consecutive 9mm cage patients with a minimum of two years follow-up. All 425 patients had disabling back and/or radicular pain refractory to conservative management with moderate to severe degenerative change, with instability and adjacent segment deterioration based on magnetic resonance imaging (MRI) or discogram. 49 patients (54%) had 75 prior lumbar surgeries (average 1.5 surgeries/patient). In the previously operated patients, there was an average interval of 5 years (range 1-18 years) from the most recent surgery to the current surgery.
Demographic data was recorded including age, gender, neurologic function, number and type of prior back surgeries, and diagnosis at each lumbar level. Patients were examined and data recorded before surgery, at surgery, and at post-operative intervals after surgery. Evaluations included ratings of pain, function, economic status, and medication. Patient satisfaction, sensory and motor function, tension signs, reflexes, and radiographic findings were recorded at each follow-up interval. The mean follow-up was 36 months (range 24-65 months).

Clinical success was defined according to previous published literature parameters used over many years and modeled after an expanded Prolo scale[9, 10, 13, 17]. The 5-point Likert scales for pain, function, economic status, and medication usage are added to a combined 4- and 20-point scale as used for the IDE study of the Lumbar I/F Cage [8]. This study defined a patient’s result as a clinical success when the final rating was excellent (17 to 20 points) or good (13 to 16 points), or fair (9 to 12 points) if the patient achieved a minimum improvement of three points or more in the combined 20 point scale.

Fusion status was recorded for each surgically treated segment at each follow-up interval. All patients had two year follow-up plain static radiographs including Anterior-posterior, lateral, and Ferguson views. Figure 1 shows a typical serial AP Ferguson radiographs demonstrating a solid fusion. Figure 2 shows the features of a pseudarthrosis with discontinuity in the bone graft and lucency adjacent to the cage.

48 patients had thin cut helical CT scanning of the involved lumbar segments at an average 26 mos. (range 8-48mos) following the index PLIF operation. The CT scans were examined by a radiologist who was blinded with regard to the clinical history and plain radiograph findings. The most common type of pseudarthrosis was the locked pseudarthrosis. Locked pseudarthrosis is a lucency in the mid portion of the graft within the cage with boney continuity from the endplate to the graft. Figures 3 and 4 shows typical Helical CT findings for fused and non-healed levels.

Fusion success was defined by previous published parameters[9, 10, 13]. A level was regarded as fused if there was radiographic evidence of bone bridging the disc space without lucency. If a lucency was seen to extend across the cage, the level was considered not fused. For patients undergoing multiple-level fusion, all surgically treated segments must be fused for the patient to be considered a fusion success.

Statistical Methods
Demographics, clinical and fusion success were compared to the larger reviewed patient group, the IDE study[9], and the ten year follow-up study[10] using chi square analysis.

Results

Of the 90 9mm cage patients, there were 31 men and 59 women. Average age was 54 (range 34 to 79). Insurance was workers compensation in 18 and private insurance in 68. 22 patients had a positive smoking history with an average 21-pack/year histories. There were 75 prior surgeries in 49 patients at an average interval of 5 years (range 1-18years) for an average 1.5 prior lumbar surgeries per patient.

Clinical Success

Clinical success was achieved in 74 of 90 patients (82%). This included 33 (37%) Excellent, 34 (38%) Good, and 20 (22%) Fair results. Clinical success was not achieved in three (3%) with Poor results.

Fusion Success

At the final radiographic evaluation, fusion success was achieved in 87 patients of 90(97%) (194 of 197 levels) and unsuccessful in two patients at the L1-2 level and one patient complicated by infection that never had radiographic or surgical exploration proof of healed fusion.

Indications for 9mm Width Lumbar I/F Cage

The primary indication for the use of the 9mm I/F Cage was inadequate width exposure of the disc space to accommodate a larger cage. From the operative note, access was limited by previous surgery to one or both side of the disc space in twenty-six, and nerve root anomaly with low position of the exiting nerve root in five. Of 197 PLIF levels, 116 levels had 9mm wide I/F cages. All disc levels could be accessed. Eleven levels received one 9mm wide cage. Six of these had a single 9mm cage at that level and five were accompanied by a wider cage (11X11) on the contralateral side. 104 levels received two 9mm cages. From Table 1, the 9mm cages were used in approximately 50% of the levels where PLIF was used.

Complications

Two patients had retropulsion of a cage that required revision. In one patient, a lumbar I/F cage at L2-3 level with two cages, retropulsed into the canal in the third month post-operatively. This was identified and watched. At six months, the patient was complaining of back pain and hip pain on the same side as the mal-positioned cage. The cage was removed and the pedicle screw instrumentation removed, and the posterior-lateral fusion was augmented with BMP. A second patient
had a 9mm cage retropulsed at L4-5 with radiculopathy and was quickly repositioned two weeks after
the index surgery. Both patients with retropulsion went on to heal the fusion.

Two patients with a CSF leak and one with an epidural hematoma had a second procedure to
correct the problem. Two had infection requiring debridement. Two patients had screw loosening
requiring revision with BMP augmentation of the posterior-lateral fusion. There was one patient with
persistent post-operative foot drop without cause on extensive diagnostic evaluation.

Further Surgery

49 (54%) patients had 69 further surgeries at an average interval of 2 years (range 1 month to
5 years). Twenty-four had posterior implant removal and exploration of fusion with findings of
complete fusion healing. Sixteen had additional PLIF level surgery.

Helical Cut CT Scans to evaluate fusion

48 patients had Helical CT scans in the course of their care after fusion. Fusion success on the
helical CT scan occurred in 37 of 48 patients (186 of 197 levels). Eleven patients had a single level
reported as a non-healed fusion. Three of the eleven levels involved at least one 9mm cage. Both of
the L1-2 levels with helical CT non-union had two 9mm cages. The third case was an L5-S1 with one
9mm cage and an 11mm cage. Eight of the eleven non-unions were of the locked pseudarthrosis
type. One at L1-2 showed lucency between the graft within the cages and the endplates. The last
two were single level fusions complicated by infection that was associated with subsidence of the
cages through the endplate. One of the infected cases explored 21 months after the index procedure
was found to be a healed fusion. The other was not explored and later died without evidence of
complete healing of the involved L5-S1 level. There were four CT scans interpreted as delayed union
with 2-3mm subsidence and complete boney union around the cages. Seven of the eleven with non-
healed levels on CT were explored within 6 months and found to have a healed fusion. One L1-2 non-
union was explored and found to have very little motion, and was treated with pedicle screw implant
removal and BMP augmentation of posteriolateral fusion. This did not heal and recently the patient
was revised with pedicle screw instrumentation and BMP augmentation of posteriolateral fusion. The
second L1-2 non-union was revised once with pedicle screw instrumentation and BMP augmentation
of posteriolateral fusion, then subsequently with pedicle screw implant removal and BMP
augmentation of posteriolateral fusion. Figure 5 is a Helical CT scan assessed as non-healing fusion
L1-2.
The helical CT evaluation before re-exploration was compared with the findings at fusion exploration. Thirteen patients had Helical CT scan within six months of fusion exploration. Four of thirteen patients had a non-healed fusion level on CT. At exploration, one patient had a retropulsed non-healed cage removed and BMP added to the posterolateral fusion. The other twelve of the scanned patients (26 levels) were considered fused by exploration. Of all 35 patients explored (68 levels) with VSP implant removal, 61 levels (90%) were considered fused.

**Discussion**

**Outcome measures**

At the time of the original Brantigan carbon fiber cage IDE in 1990, there was little agreement regarding optimum outcome measures in a spinal fusion study. To our knowledge, the Prolo Scale has not had a thorough examination of its statistical validity. However, the Prolo Score has been widely accepted for study of interbody fusion cages and is used in this report to maintain continuity with the original IDE and the 10 year follow-up of the Lumbar I/F Cage. We believe the Prolo Scale produces results that may be compared with literature reports of outcomes over many years [9, 10].

**Demographic profile**

This cohort had a variety of socioeconomical and etiological backgrounds similar to the IDE study for the Lumbar I/F Cages. In the IDE study there were 326 prior surgeries in 170 patients (average 1.9 surgeries per patient). Statistical analysis indicated that the following factors had no effect on clinical or fusion success: gender, numbers of levels treated surgically, previous surgery, smoking history, and obesity [9]. The rate of previous surgery of the current 9 mm cage group was significantly less than the original IDE cage study (chi square 24.7616, p= 0.0001). The demographic profile should not adversely bias our conclusions regarding clinical and fusion success.

**Biomechanics**

When the Lumbar I/F Cage was first designed, the optimal dimensions were unknown. It appeared that the average width that would allow bilateral cages to be placed was 11 mm. Possible failure modes included subsidence into the vertebral bodies (which argued for maximal width of the struts) and fusion failure (which argued for maximal width of the opening for bone graft surface area). In the design of the 11 mm cage prototypes tested mechanically in cadaver spines the two concerns were given equal weight: the opening was 5.5 mm wide and the strut width was 5.5 mm (or 2.75 mm each) \[15\]. This design performed well in cadaver spines and bore physiologic loads without subsidence.
In the design of larger and smaller cage sizes, the width of the struts was retained at 2.75 mm because of the concern for subsidence if the support area had been reduced. Thus the cage 9 mm in width has an opening for bone graft of 3.5 mm wide, proportionately 18% narrower overall than the 11 mm cage but 36% smaller in surface area for bone graft. The 9 mm cage has a bone surface area 54% less than the 13 mm cage. Because bone healing was potentially compromised with the 9 mm side cages by the proportionally greater reduction in bone graft surface area, it is clinically important to study the clinical and fusion success of these narrow cages.

Biomechanical studies of the Lumbar I/F cages demonstrated several differences between the 9mm and the 13mm cages [16]. In static compression, the larger cages appeared stronger. With a 45-degree compressive shear force, the 9 mm cages were stronger. In fatigue tests, the 9 mm cages were stronger. Fatigue strength is defined as the load that the cages can bear to 5 million loading cycles without failure. Using two cages, the fatigue strength has a two-fold safety factor compared with maximum loads of daily living. Using a single cage, the fatigue strength safety factor is non-existent over the maximum loads of daily living. The results of this 9mm cage study are important because the narrow cages do not have a negative clinical effect on bone healing judged by fusion success.

A second major finding of this study is mechanical failure did not occur with 9mm cage usage. Two fusion failures at the L1-2 level occurred with two 9mm cages. Our previous study showed an unexpectedly low fusion success of 7 of 12 cases (59%) at L1-2, making this level an independent risk factor for failure [18].

Clinical success

The IDE study for the Lumbar I/F Cage reported clinical success in 79 of 91 (86.8%). This included 52% excellent, 33% good, 15% fair and no poor results [9]. In the ten-year follow-up report, clinical success was maintained in 29 of 33 (87.8%) [10]. When the clinical results of our larger clinical series were compared with the IDE results using the chi-square statistic, clinical success rates were not statistically different (chi-square = 0.555, p=0.4563). Clinical success in the current 9 mm cage series was not statistically different at 81% from the IDE study (chi-square = 0.4518, p=0.5015). The 9mm cohort includes fewer Excellent and more Fair results than the IDE study.

Fusion success

Santos et al. reported that helical CT scans of carbon fiber cage anterior fusions identified twice as many fusion failures as seen on plain radiographs [19]. These were anterior fusions without
posterior instrumentation and the results do not directly relate to the PLIF and VSP construct used in this cohort. The authors have found the Helical CT scan to be as valuable as the plain radiographs in detecting non-union. In our practice, helical CT scanning was used in clinically symptomatic patients at an appropriate interval following surgery, to further evaluate questionable lucencies through the fusion cage seen on plain radiographs.

Overall, comparisons of Helical Ct scans with the fusion results at exploration indicated a sensitivity of 89.9%, specificity of 100%, a positive predictive value of fusion of 100%, and an overall accuracy of 95%. The Helical CT scan correctly confirmed the radiographic identification of the three patients with non-union. Comparison of radiographs including the Ferguson views of each fused level with exploration yielded a sensitivity of 92.6%, a specificity of 100% and a positive predictive value of fusion of 100%. These results indicate that the radiologic fusion interpretation as defined in this study is sufficiently accurate to be used for the assessment of fusion status. Although this study had independent review of CT scan results, it did not include an independent review of the plain radiographs. These were reviewed by the authors. The accuracy of our radiographic observations was confirmed by surgical exploration.

In the IDE study of the Lumbar I/F Cage, fusion success was achieved in 91 of 91 (100%) of the degenerative disc disease cases and 176 of 178 (98.9%) of the entire study group [9]. In the 10-year follow-up of the IDE study, Fusion success was reported in 37 of 37 patients (100%) at 24 months and in 29 of 30 (96.7%) at 10 years [10]. When the fusion results of our larger series are compared with the IDE results using the chi-square statistic, the fusion rates were not statistically different (chi-square=0.1414, p=0.7069). When the fusion results of the 9mm group are compared with our larger clinical series(Chi-square=0.847, p=0.5358), the IDE study (chi-square=1.5942, p=0.2067), and the 10 year follow-up (chi-square=0, p=1.000), the fusion rates were not statistically different.

**Conclusion**

Fusion success is not diminished by the use of 9 mm width Lumbar I/F Cages. The clinical results may be somewhat diminished. The authors continue to recommend routine use of bilaterally placed Lumbar I/F cages of maximal width allowable. If there is any question about width of exposure or safe retraction of a nerve root, a surgeon should not hesitate to use a 9mm cage at that position.
Figure 1, Serial Ferguson views of two 9mm cages demonstrate progression to excellent fusion at 1 year on radiographs. Arrows demonstrate bridging bone across the interspace through the fusion cage.

Figure 2, Serial Ferguson views of L4-5 show two 9mm cages and a locked pseudarthrosis with lucency through mid-substance of each interbody graft. Arrows point to bridging bone interrupted by lucency at one year post-op. This was a healed fusion at exploration.

Figure 3, Helical CT at 9 months post-op shows bridging bone across interbody space on coronal and sagittal reconstructions at three interspaces.

Figure 4, 4A Helical CT Coronal reconstruction with arrow demonstrates L2-3 bridging bone across interbody space and a single 9mm cage. 4B Sagittal reconstruction: large arrow demonstrating subsidence into the L3 body. There is lucency between graft, cage, and endplate of L2 and L3. A thin arrow points to bridging bone posteriorly across the interspace. This was a healed fusion at exploration. Clinically this was a delayed fusion after subsidence of the 9mm cage into the body of L3.

Figure 5, A 73 year old woman with previous L3-S1 healed fusion has non-union of L1-2. This level was revised with pedicle screws, BMP, and 14 mos. later revised with implant removal and BMP again. 5A Coronal CT reconstruction reveals lucency surrounds both interbody cages at L1-2. 5B Sagittal CT reconstruction: superior arrow demonstrates lucency around the cage and inferior arrow shows subsidence into L2 body. Metallic dot in the disc space is the cage position marker.
References


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<th>Level (PLIF)</th>
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<td>26%</td>
<td>23</td>
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Total Levels fused 197 116

With adjacent Lami 15 13.2%

With IR 7 6.1%

* IR= Implant removal; Lami=Laminectomy; PLIF= posterior Lumbar Interbody Fusion, PLF= posteriolateral fusion.
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Article Type: Clinical Case Series

Section/Category:

Keywords: cervical; discectomy; discogenic; fusion; neck pain; Nicotine/adverse effects; Smoking/*adverse effects; patient outcome

Corresponding Author: Dr. Guy Fogel Houston Spine Surgery

First Author: Guy Fogel, MD

Order of Authors: Guy Fogel, MD; Mark F. McDonnell, MD

Abstract:
Improved Fusion Rates with Anterior and Posterior Fusion in Habitual Tobacco Use Patients Treated for Dominant Axial-Mechanical Cervical Spine Pain

Guy R. Fogel M.D., Mark F. McDonnell M.D.

Houston Spine Surgery 5225 Katy Freeway #600 Houston TX 77007 713-526-8523

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Study Design. An extensive outcome questionnaire was used to evaluate the success of combining anterior and posterior instrumented autograft fusion of multiple cervical levels to enhance the fusion rate in the habitual tobacco use patient.

Objective. To document successful radiographic fusion and evidence of improved patient-perceived clinical outcomes leading to a favorable outcome in the habitual tobacco use patient.

Summary of Background Data. The use of tobacco products is known to increase bone resorption and may double the nonunion rates achieved in the nonsmoker. The addition of posterior lateral mass fusion to anterior cervical interbody fusion with plate instrumentation should improve the fusion rate because this construct is the most stable in all loading conditions.

Methods. 49 habitual tobacco use patients were treated with anterior and posterior combined cervical fusion. All were evaluated initially and at final follow-up with radiographs, pain analog visual scale, and a Modified Oswestry disability index. Additionally at final assessment, the North American Spine Society Satisfaction Questionnaire was administered.

Results. Healing of the surgical fusion occurred in all patients. There was no subsidence or loss of lordosis noted in the fusion. Final assessment was 35 months after the surgery. 84% reported self-perceived excellent or good results of treatment. There was a significant self-perceived 30% improvement of pain. Modified Oswestry score had significant 24% improvement. 78% reported neck pain was improved after surgery.

Conclusions. Combined anterior and posterior fusion in the tobacco use patient attained a 100% fusion rate and a high percentage of change in self-perceived improvement of pain and function. The improvement with the combined treatment is important because the habitual tobacco use patient would expect a less satisfactory outcome with anterior fusion alone, then the non-tobacco use patient. The use of anterior and posterior fusion in this difficult treatment group allows a 100% fusion rate and outcome results similar to those achieved in
previously reported series of treatment of axial neck pain. [Key words: cervical, discectomy, discogenic, fusion, neck pain, Nicotine/adverse effects, Smoking/*adverse effects, patient outcome

**Key Points.**

- Combined Anterior and posterior cervical fusion in the habitual tobacco use patient attained a 100% fusion rate.

Of 49 patients, 84% reported a self-perceived satisfactory outcome, and 91% reported improvement of pain.
Habitual tobacco use complicates the healing of multi-level cervical fusions. A posterior lateral mass fusion added to the anterior cervical fusion with plate instrumentation will attain a 100% fusion rate. This report documents a high percentage of self-perceived improvement of pain and function.
Introduction

Habitual tobacco use (HTU) complicates the course of treatment of multilevel cervical arthrodesis. In general, multilevel cervical spinal arthrodesis is successful treatment of degenerative disorders of the neck. A successful outcome in the multilevel patient using tobacco products may be challenging. Tobacco use is associated with increased rates of surgical nonunion and presents with a persistent painful cervical, scapular and radicular pain syndrome [1-5]. Although not all non-unions are symptomatic, non-union in the tobacco use patient is more often symptomatic [2, 4, 6]. Experimental studies have shown nicotine to have a negative effect on bone fusion[7-13]. Some of the proposed causes are a negative effect on early graft revascularization, vascular endothelial growth factor, bone morphogenetic protein, and cytokines important to osteoblast function[8, 9, 14]. Tobacco enhanced hepatic enzyme metabolism increases narcotic and sedative consumption 30% more than in the non-smoker [15]. The tobacco use patient will have an average 1/2 standard deviation greater physiologic response to pain and disability related to cervical pain[16]. The smoker will have more significant degenerative changes and more spinal levels involved than the non-smoker[17].

The HTU patient most often presented with a primary indication of axial mechanical neck pain, with radicular symptoms, but no myelopathy or major loss of nerve root function. The patient had failed to respond to prolonged non-operative treatment methods. The purpose of the pre operative evaluation was to document findings that when treated surgically would give a predictable result and improve clinical patient perceived outcomes. Provocative cervical discography was used pre-operatively as an objective method to assist the surgeon in selection of operative levels to be included in the fusion.

Anterior and posterior fusion is not a new idea. Anterior and posterior combined fusion has been recommended for fusions of three or more levels, particularly with deficient posterior elements from previous laminectomy[18]. A staged posterior fusion for treatment of anterior surgical nonunion has been recommended [19]. Benefits of simultaneous anterior and posterior fusion are: a decrease in the post-operative complications
such as graft dislodgement, instrumentation failure, and surgical nonunion; and optimal decompression from front and back[20]. Biomechanical strength is better with posterior lateral-mass fusion than with anterior plating alone, and best with combined anterior and posterior fixation [21].

With these cautionary findings regarding tobacco use, and the decreased surgical nonunion rate of combined anterior posterior fusion, our senior author began recommending the addition of posterior instrument fusion combined with the anterior cervical discectomy and fusion in the habitual tobacco use patient. Our purpose in presenting this anterior posterior cervical fusion group is to document a successful radiographic fusion rate and evidence of improved patient-perceived clinical outcomes and surgical results leading to a favorable outcome in the HTU patient.

Materials and Methods

83 patients were identified who underwent anterior cervical decompression and fusions combined with posterior lateral mass fusions with the indication of HTU between January 1998 and December 2000. HTU in this study is defined as smoking at least one pack per day, or use of smokeless products more than twice a day. Of the 83 patients so identified, 49 completed an extensive outcome questionnaire and had a current set of cervical radiographs. Therefore, the 49 patients are the basis of this report. The other 34 patients declined participation or could not be located to participate in the review.

The chief complaint of this patient group was dominant mechanical neck pain defined as neck pain greater than arm pain. Patients with tumor, infection, or fracture-dislocation as an indication for surgery were excluded from the study. The smoking history indicated 35(72%) smoked more than one pack per day, and 14(28%) used smokeless products daily. All patients had failed outpatient treatment including physical therapy, epidural steroid injections, and pain management techniques. All patients had been counseled for smoking
cessation before surgery, and none of these patients could stop their tobacco usage. All patients had an M.R.I. (46/49) or less commonly a CT-myelogram (3/49), to document neurologic compression. The mean follow-up was 35 months ± 13.

Preoperative provocative cervical discography was routinely used to define painful disk levels to be included in the fusion (41/49). Discography was performed by an independent neuro-radiologist. Discography demonstrated complete annular tears, the patient’s response by the intensity of pain, and the pain concordance to the usual symptoms. The classification of discography by Garvey et al was applied to analyze the outcomes[22]. A classic discographic pattern of Garvey et al was defined as a significant concordant reproduction of pain at the affected level with little or no pain at adjacent levels studied. Non-classic discography of Garvey et al was defined as any other pattern, usually with a partial or full annular tear but a low level of concordant pain < 5/10, or non-concordant pain at adjacent segments rated greater than 5/10 [22]. Eight patients did not have discography. The patients without discography had clear-cut levels of gross anatomic abnormalities surrounded by normal levels on the MRI. The most common diagnosis was central stenosis often with foraminal stenosis in 6 of 8 patients without discography.

The outcome instruments used were a visual pain analog scale (PAS), a modified Oswestry disability index (ODI), and the North American Spine Society instrument (NASSQ), evaluating the global effect of neck pain on patient satisfaction. In addition to the patient outcome questionnaires, hospital and office charts, discography films, C.T.-myelograms, the M.R.I. and the preoperative, post operative and final radiographs were reviewed. All patients who responded answered the questionnaire by phone conference, and those we were unable to contact by phone, answered the questionnaire by return mail. Patients when contacted were told that the authors would be blinded to the patient responses.

Statistical results were calculated for the 49 patients who completed the detailed follow-up questionnaire and evaluation. Additionally, the chart review of the 34 patients who could not be contacted at last follow-up
suggested there were no significant differences in terms of charted outcome between these patients and the 49 
patients who completed the final outcome questionnaires.

At surgery, the anterior fusions were plated with PEAK plates (Depuy-AcroMed, Cleveland, OH) and 
posterior fusions with Summit lateral mass fixation (Depuy-AcroMed, Cleveland, OH). All patients were 
operated on a Jackson Table (OSI). The table allowed turning the patient without transferring to another table 
and back again. A Mayfield headrest was used and no additional traction was used. Longitudinal incisions were 
used for more than two levels, and a transverse incision was used for 2 or less levels. An anterior iliac crest 
structural graft of 8 mm width was obtained for each level, and additional cancellous bone is taken for the 
posterior fusion as well. A modified Smith-Robinson technique was used. The patient was then secured in the 
Jackson table and turned to the prone position. The posterior portion of the case was done through a midline 
vertical incision Lateral mass screws were placed by modified technique of Magerl[23]. The patients are 
immobilized in an external orthosis (Philadelphia collar) for 8 weeks.

Plain lateral cervical spine radiographs, with flexion and extension views, obtained in all patients at 3-
month intervals, determined radiographic union. Trabecular bony bridging across the disk space and lack of 
motion on flexion/extension views were the criteria used to determine fusion.

Results

Of the 49 patients there were 30 men (62%), and 19(38%) women. The average age was 45 with a range 
from 25-66 years. The education level was less than High School graduation in 20(40%), Graduated High 
School 23(47%), Some College 5(10%), College or technical degree 1(3%). The type of injury was an 
identifiable injury in 37(76%) and poorly defined injury in 12(24%). There were 20(40%) workplace injuries 
and 17(35%) motor vehicle injuries. 46(94%) were involved with Workers’ compensation or litigation. The 
length of onset from injury to date of surgery was 24 months ± 13. The number of levels fused was an average 
of 3 levels ± 1 (Table 1).
The PAS for all patients improved significantly from a mean 9/10 ± 1 pre-operatively to 5 ± 2 (P<0.001) (table 2). The average ODI improved significantly from a mean of 61 ± 10 to 40 ± 14 (P<0.001) (Table 2). In response to the NASSQ query “If you had to spend the rest of your life with your neck condition as it was before your surgery, how would you feel about it?” 92% would be dissatisfied if the neck condition was as before the surgery (Table 3). The average answer was very “dissatisfied” ± 1. In answer to the question, “How has your pain been affected by the surgery?” 78% reported neck pain was improved after surgery (P=0.01). The average answer was “somewhat improved” ± 1 (Table 4). In answer to the question, “Would you have the same treatment again if you had the same condition?” significantly, 66% would have the same treatment (P<0.0001) (Table 5). In answer to the question, “How would you rate the overall results of your treatment for your neck or arm pain?” 84% were excellent to good, 8% fair, and 8% were poor (P=0.003 (Table 6).

When the surgery is based on a classic pattern of discography, provocative pain at involved levels with little or no pain at surrounding levels is predictive of a better outcome. To compare the patients who had pre-operative discography (classical vs. non-classical), the NASSQ were compared by discography results. 85% of patients with classical concordant discography, regardless of number of levels operated had an excellent or good result (Table 7). 63% of the patients who did not have discography had an excellent or good result. Patients who did not undergo discography showed abnormal levels on the MRI with normal levels above and below on radiographs and MRI.

The final radiographic assessment was a mean of 20 ± 11 months All 49 had solid radiographic fusion of every level. There were no lucent lines seen, no subsidence, and no instability or motion detected on flexion-extension views. Additionally 2 patients had adjacent segment deterioration below the fusion, which required subsequent fusion. Hardware removal with exploration of the fusion allowed the best evaluation of the fusion, and the subsequent radiographs give the best radiographic confirmation of the fusion. Surgical nonunion was not reported in any of the exploration cases.
Ten patients had previous surgery. There were 4 patients with previous laminectomy and 6 patients with previous anterior cervical discectomy and fusion. 21 of the 49 patients had additional operations. There were 4 posterior cervical infections 3 were within a month of the index surgery, and one occurred one year later secondary to hematogenous seeding from an infectious bronchitis. All infections resolved with wound debridement and intravenous antibiotics. One patient had continued lateral femoral cutaneous nerve dysthesias (meralgia paresthetica) at the anterior iliac crest donor site. This patient was treated with multiple cortisone injections, and when outpatient treatment failed, debridement of the iliac crest to resect the lateral femoral cutaneous nerve and its branches. One patient had a subsequent posterior laminotomy for continued right radiculopathy with identified residual foraminal narrowing on CT scan. Two patients had extension of their fusion to an adjacent level. Thirteen patients had removal of anterior and posterior hardware for indications of symptomatic hardware, and evaluation for surgical nonunion No operated patient was found to have a surgical nonunion. Seven of the hardware removal patients had the additional indication of significant dysphagia of solid and liquids. All seven patients improved in their dysphagia after removal of the hardware. Not counting the post-operative debridements for infection, 15 patients underwent a secondary cervical surgery after the index anterior-posterior fusion. At the time of the secondary procedure, each level of fusion was healed. No level of surgical nonunion could be found.

Discussion

All human body tissues are affected adversely by tobacco use. Habitual tobacco users are at increased risk of cardiovascular disease, depression, cancer, pulmonary disease, osteoporosis with related fractures, and disk degeneration[16]. Tobacco products experimentally have been shown interfere with bone metabolism and revascularization of bone and also a suppression of bone formation [7, 9-13, 24-28]. Clinically, the tobacco use patient is more likely to be depressed than the non-smoker and more likely to report chronic depressive symptoms [16, 29, 30]. The smoker reports his symptoms are more severe and long lasting than the non-
Studies of identical twins have shown smoking is associated with an increased rate of degenerative change of the disc on MRI. Self-reported functional outcome studies in patients with spinal disorders are usually 2 standard deviations below the U.S. norms and smokers may report half a standard deviation below the non-smoker. Patients report the need to smoke increases with pain but that smoking does not decrease the perception of pain. Health status reporting after spinal surgery did not show progressive improvement as in the non-smokers. After surgery, wound healing is adversely affected. Post-operative rates of wound infections, and non-union of spinal fusions are substantially higher in tobacco use patients.

Achieving fusion at multiple levels in the cervical spine is more difficult than at a single level. The more levels of fusion the more likely a surgical nonunion will occur. Hilibrand et al. clearly shows an increased rate of 50% surgical nonunion of multilevel cervical interbody fusion in smoking patients. It is more difficult to achieve fusion with allograft bone than with autograft bone in multi-level cervical fusions. Bishop et al. demonstrated that cigarette smoking significantly delays the healing of interbody allograft in the cervical spine. Autograft was used exclusively for the anterior and posterior fusions in this study. Our fusion rate was 100%, confirmed by radiography including flexion-extension films in 49 patients, and surgical exploration in 15 patients. We contend the negative influence of tobacco use on multilevel cervical interbody fusion healing is additive with other factors such as multiple involved levels, and the use of allograft bone.

Anterior cervical plating in multi-level fusions has decreased the rate of non-union. However longer constructs have been shown to be less stable causing increased posterior strain, particularly in flexion or distraction. Anterior plating with locking fixation screws and unicortical fixation is the most recent design and is more stable than the conventional unlocked plate and screws. The anterior plate does restore the normal lordosis and preventing kyphosis in the operated cervical spine. Katsuura, et al. reported the plated cervical spine can maintain cervical lordosis whereas anterior cervical fusion without plating could not.
Posterior lateral mass screws and plating are biomechanically superior in all loading modes to anterior plating with locked fixation screws[18, 21]. This series had interbody grafting and anterior cervical plating to restore and maintain the normal cervical lordosis, and posterior instrumented lateral mass fusion to give the maximal stability to allow the fusion to proceed.

The diagnosis of symptomatic cervical discogenic pain is elusive with radiographs, Computerized tomography, myelography and most recently M.R.I. In fact, a significant number of asymptomatic patients will have false positive abnormalities on these tests. False positive levels preclude using these tests alone as routine selection of involved levels for surgical treatment in the chronic axial cervical pain patient. Provocative cervical discography has been the technique of choice when the history and physical examination suggest the patient may be an operative candidate. This diagnostic workup is as described recently by Garvey et al[22], and Palit et al [47], and is similar to the diagnostic evaluation described by authors over the past 50 years of cervical surgical intervention [48-55]. The use of provocative cervical discography to select involved levels is controversial, but recent studies have demonstrated improved functional outcome results in patients where discography was used in the pre-operative surgical evaluation[22]. Our study group of HTU patients had an average of three levels damaged. Our hypothesis is that the number of involved levels and the damage at each level may be greater in the HTU because of decreased healing potential associated with nicotine. A partial-thickness annular tear that would usually heal in a normal disc may not heal and may continue to deteriorate in the tobacco user. This group may be more prone to have permanent full thickness annular tears develop from small, accumulative trauma. In our patients with a provocative discogram of classical pattern there was an improved patient-perceived outcome after successful fusion. Our improved outcomes are the result of the selection of involved levels with discography. These results are similar to those reported by authors in the past [22, 47].
Our patients reported a significant 84% self-perceived beneficial outcome (P=0.003). There was a significant 30% improvement in PAS (P<0.001). The ODI score significantly improved 24%(P<0.001). Our results in tobacco use patients are similar to authors reporting on the treatment of axial dominant neck pain over the past decades. These improved results are important because the tobacco use patient would expect a less satisfactory outcome with anterior fusion alone. The use of anterior and posterior fusion in this difficult treatment group allows a 100% fusion rate and outcome results similar to those achieved in the previous reported series of treatment of axial neck pain.

Conclusions

Combined anterior and posterior fusion in tobacco use patients gave a 100% fusion rate. The patients reported a high percentage of self-perceived improvement of pain and function. This improvement with surgical management in this difficult patient group, as compared with the dissatisfaction before surgery because of their neck pain, documents that this surgical treatment is a reasonable option.
Table 1. Number of Cervical Vertebral Motion levels Fused

<table>
<thead>
<tr>
<th>Levels Fused</th>
<th>N=49</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>10</td>
<td>20%</td>
</tr>
<tr>
<td>3</td>
<td>21</td>
<td>43%</td>
</tr>
<tr>
<td>4</td>
<td>16</td>
<td>33%</td>
</tr>
<tr>
<td>5</td>
<td>2</td>
<td>4%</td>
</tr>
</tbody>
</table>
**Table 2. Pain Analog Scale (PAS)* and Modified Oswestry Disability Index (ODI**

<table>
<thead>
<tr>
<th>Population</th>
<th>PAS Initial</th>
<th>PAS Final</th>
<th>p-value</th>
<th>ODI Initial(median)</th>
<th>ODI Final(median)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>All N=49</td>
<td>9 ± 1</td>
<td>5 ± 2</td>
<td>&lt;0.0001</td>
<td>61 ± 10(64)</td>
<td>40 ± 14(40)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>1-2 Levels n=10</td>
<td>9 ± 1</td>
<td>4 ± 2</td>
<td>&lt;0.0001</td>
<td>60 ± 7(61)</td>
<td>36 ± 13(35)</td>
<td>0.0008</td>
</tr>
<tr>
<td>3 Levels n=21</td>
<td>9 ± 1</td>
<td>5 ± 1</td>
<td>&lt;0.0001</td>
<td>60 ± 12(64)</td>
<td>43 ± 11(40)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>&gt;3 Levels n=18</td>
<td>9 ± 1</td>
<td>5 ± 2</td>
<td>&lt;0.0001</td>
<td>64 ± 8(62)</td>
<td>43 ± 16(43)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

* Values shown reflect patient pain levels on a scale of 0 (no pain) to 10 (pain so severe that it cannot be tolerated for more than a few minutes).

** A paired t-test was performed to gain correlation. The assumption of normality was verified using normality tests and quantile plots.

(±) standard deviation
Table 3. If You Had to Spend the Rest of Your Life With Your Neck Condition as It Was before Your Surgery, How Would You Feel About It?*

<table>
<thead>
<tr>
<th>Population</th>
<th>Dissatisfied %</th>
<th>Satisfied %</th>
</tr>
</thead>
<tbody>
<tr>
<td>All n=49 *</td>
<td>92</td>
<td>8</td>
</tr>
<tr>
<td>&lt;3 Levels n=10</td>
<td>90</td>
<td>10</td>
</tr>
<tr>
<td>3 Levels n=21</td>
<td>95</td>
<td>5</td>
</tr>
<tr>
<td>&gt; 3 Levels n=18</td>
<td>89</td>
<td>11</td>
</tr>
</tbody>
</table>

*Based only on the follow-up questionnaire
Table 4. How Has Your Neck Pain Been Affected by the Surgery?*

<table>
<thead>
<tr>
<th>Population</th>
<th>Improved %</th>
<th>Same %</th>
<th>Worse %</th>
</tr>
</thead>
<tbody>
<tr>
<td>All n=49 *</td>
<td>78</td>
<td>14</td>
<td>8</td>
</tr>
<tr>
<td>&lt;3 Levels n=10</td>
<td>80</td>
<td>20</td>
<td>0</td>
</tr>
<tr>
<td>3 Levels n=21</td>
<td>67</td>
<td>24</td>
<td>9</td>
</tr>
<tr>
<td>&gt; 3 Levels n=18</td>
<td>89</td>
<td>0</td>
<td>11</td>
</tr>
</tbody>
</table>

*Based only on the follow-up questionnaire

*p-value for all population is 0.01. Other p-values are not significant.
<table>
<thead>
<tr>
<th>Population</th>
<th>Yes %</th>
<th>Not Sure %</th>
<th>No %</th>
</tr>
</thead>
<tbody>
<tr>
<td>All n=49 **</td>
<td>66</td>
<td>22</td>
<td>12</td>
</tr>
<tr>
<td>&lt;3 Levels n=10</td>
<td>70</td>
<td>10</td>
<td>20</td>
</tr>
<tr>
<td>3 Levels n=21</td>
<td>58</td>
<td>28</td>
<td>14</td>
</tr>
<tr>
<td>&gt; 3 Levels n=18</td>
<td>72</td>
<td>22</td>
<td>6</td>
</tr>
</tbody>
</table>

*Based only on the follow-up questionnaire

**p-value for all population is <0.001. Other p-values are not significant. A nonparametric sign test (Wilcoxon signed rank test) using paired data was performed.
Table 6. How Would You Rate the Overall Results of Your Treatment for Your Neck or Arm pain?*

<table>
<thead>
<tr>
<th>Population</th>
<th>Excellent/Good %</th>
<th>Fair %</th>
<th>Poor %</th>
</tr>
</thead>
<tbody>
<tr>
<td>All n=49 **</td>
<td>84</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td>&lt;3 Levels n=10</td>
<td>90</td>
<td>0</td>
<td>10</td>
</tr>
<tr>
<td>3 Levels n=21</td>
<td>82</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td>&gt; 3 Levels n=18</td>
<td>83</td>
<td>11</td>
<td>6</td>
</tr>
</tbody>
</table>

*Based only on the follow-up questionnaire.

**p-value for all population is 0.003. Other p-values are not significant. A nonparametric sign test (Wilcoxon signed rank test) using paired data was performed.
Table 7. Results related to Discography*

<table>
<thead>
<tr>
<th>Population</th>
<th>Excellent/Good %</th>
<th>Fair %</th>
<th>Poor %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classic n=34</td>
<td>85</td>
<td>3</td>
<td>12</td>
</tr>
<tr>
<td>Non-Classic n=7</td>
<td>100</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Not Done n=8</td>
<td>63</td>
<td>37</td>
<td>0</td>
</tr>
</tbody>
</table>

*Based only on the follow-up questionnaire.
References


OUTCOMES OF SURGICAL TREATMENT OF ADJACENT SEGMENT DISEASE AFTER LUMBAR FUSION WITH LUMBAR I/F CAGES AND THE VARIABLE SCREW PLACEMENT SYSTEM

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Device status: The Lumbar Interbody carbon fiber Cage and the VSP Spinal Fixation System are approved by the United States Food and Drug Administration.

* DePuy Spine sponsored spine surgery fellowship.

**Corresponding author: Dr. Guy R. Fogel

No financial assistance was provided from any source for this study.
Abstract

BACKGROUND CONTEXT: Radiographic changes of adjacent segment deterioration after lumbar fusion have commonly been reported in the literature. Symptomatic adjacent segment disease (ASD) requiring surgical treatment is less common. Clinical management of ASD is difficult, and in some cases surgery is indicated. The surgical treatment of adjacent segment stenosis or instability after lumbar fusion has been seldom addressed. In this study, posterior lumbar interbody fusion (PLIF) is applied as surgical treatment for symptomatic lumbar ASD.

PURPOSE: To report functional outcomes, radiographic fusion rates, further need for re-operation in the surgical treatment of ASD.

STUDY DESIGN/SETTING: This retrospective, single-arm cohort study of a community surgical practice evaluates ASD patients treated with PLIF.

PATIENT SAMPLE: Between 1999 and 2002, 44 patients underwent PLIF at an adjacent segment following a previous lumbar fusion. At more than three years, 34(77%) were available for follow-up.

OUTCOME MEASURES: Clinical outcomes were based on the modified Prolo score, evaluating pain, economic status, function and medication usage. Fusion success, on plain radiographs, was defined by continuous bone bridging the interbody and posterior-lateral fusion level, with no interrupting lucencies, on plain radiographs. The worst remaining adjacent level at the time of the index surgery was graded and compared to last follow-up. Lumbar lordosis, sagittal and coronal alignment was measured.

METHODS: Forty-four patients with previous lumbar fusion underwent second lumbar spine surgery for adjacent instability. All were treated with autogenous interbody and posterior-lateral arthrodesis and pedicle screw fixation in addition to decompressive laminectomy. Medical records and radiographs were reviewed, and final Prolo scores were obtained.

RESULTS: The clinical success was 88.2% with 55% rated as fair. Radiographic fusion success was 91.2%. After augmentation of the posterior-lateral fusion in three patients the fusion rate ultimately was 100%. One had revision of a displaced interbody cage. 18% had extension of fusion to adjacent levels. 43% had pedicle screw removal. 9% had non-device related complication including dural tear in one, post-operative seroma in two and one deep infection. The UCLA grades identified the worst adjacent degenerative level before the index adjacent level fusion averaged 1.3 and at last follow-up
was average 2.4 with an average change of 1. The lumbar lordosis averaged 45 degrees (18-78 degrees). There were 14 (32%) with final lordosis below 40 degrees (average 30 degrees (18-39 degrees). The sagittal alignment was mildly abnormal in three (1.5 cm off plumb) and greater than 20 degrees scoliosis angulation from L1-S1 in two patients.

CONCLUSIONS: Adjacent segment disease may require surgical treatment when indicated for severe symptoms and loss of daily functional activities. Symptomatic ASD may be best treated with PLIF. When compared to previous series of treatment for ASD, PLIF gives comparable rates of clinical success and fusion success. When compared to our previous experience clinical success has more fair and poor results in ASD, and there is a statistically significant lower rate of fusion success in ASD.

Key words

PLIF (Posterior Lumbar Interbody Fusion)
PLF (Posterior-lateral Fusion)
Interbody fusion orthosis
Cage
Brantigan cage
Pedicle screw
Steffee plate
Adjacent segment degeneration
Adjacent segment disease
Intervertebral Disk/pathology/surgery
Lumbar Vertebrae/pathology/radiography/surgery
Postoperative Complications
Spinal Fusion/*instrumentation/*methods
Transitional Disease
Treatment Outcome
Introduction
Adjacent segment deterioration is commonly described after lumbar fusion. Adjacent segment deterioration includes the adjacent or second adjacent motion segment. The more common findings include disc degeneration, hypertrophic changes, multifactorial spinal stenosis; and instability. Adjacent segment disease (ASD) is the clinical syndrome characterized by Hillibrand as the development of new clinical symptoms correlating to the radiographic adjacent segment deterioration\textsuperscript{20}. Although the development of adjacent segment deterioration is be a part of the normal aging process, this process may be accelerated by the altered mechanics that occur with lumbar fusion. Long-term studies of scoliosis and more limited lumbar fusion have suggested fusion increases degenerative changes at adjacent motion segments\textsuperscript{13,16,20,26,28,30,35,38}. This radiographic deterioration may not be symptomatic\textsuperscript{13,21,32}. In fact, in most series functional outcomes are largely unaffected by radiographic adjacent segment deterioration\textsuperscript{2,13,14,16,23,28,30,32}.

Surgical treatment of adjacent segment disease is not often required. Surgery is considered in ASD patients with radiographic deterioration and symptoms of back pain usually accompanied by radicular leg pain, not relieved by conservative measures. Surgical treatment of ASD is a form of revision spine surgery. The overall clinical success of revision spine surgery ranges from 60-80\%\textsuperscript{12,22}. The rate of fusion success in revision surgery is also less than primary results. This report identified 44 patients who had posterior lumbar interbody fusion (PLIF) at adjacent levels to a previous lumbar fusion for the indication of ASD. The purpose of this retrospective review is to report the clinical success, fusion success, need for further surgery, and complications of the surgical treatment of ASD.

Materials and Methods
In a single surgical practice from 1999 to 2002, 44 patients were identified by chart review as having undergone PLIF specifically for treatment of ASD. All had disabling back and/or radicular pain refractory to conservative management associated with adjacent segment deterioration on imaging. Demographic data were recorded, including age, gender, number and type of prior back surgeries, diagnosis, surgical levels, complications, re-operations including revisions. The Lumbar I/F cage and the Variable Screw Placement System have been previously described \textsuperscript{7}. The surgical technique features autograft filled interbody cages and posterior-lateral fusion with pedicle screw fixation\textsuperscript{6,7}. Exploration of adjacent previous fusion was done and if stable, hardware was removed.
Standard biplanar x-rays of the spine with flexion and extension views were reviewed of the pre-operative and last visit for each patient. The lateral x-ray was measured for inter-vertebral disc height, the anterior-posterior translation and angular motion of the vertebral bodies. Sagittal balance and lumbar lordosis were recorded. Radiographic evidence of instability was defined, as described by Wiltse and Winter, as >4 mm of translation or >10° of angular motion between adjacent end plates on lateral flexion and extension radiographs when compared with the adjacent cephalic and caudal levels. A degenerative grade was assigned at each lumbar disc level at the pre-operative and last visit. The amount of lumbar degeneration was classified according to the University of California at Los Angeles grading scale as described by Ghiselli et al (Table 1). The worst adjacent segment was identified before the index surgery and followed to the last available radiograph.

Clinical success was defined according to previous published literature parameters used over many years and modeled after an expanded Prolo scale. The 5-point Likert scales for pain, function, economic status, and medication usage are added to a combined 4- and 20-point scale. This study defined a patient’s result as a clinical success when the final rating was excellent (17 to 20 points) or good (13 to 16 points), or fair (9 to 12 points) if the patient achieved a minimum improvement of three points or more in the combined 20-point scale. Interviews of the patients by telephone were done, in order to obtain their final Prolo scores. At the time of the original Brantigan carbon fiber cage report in 1990, there was little agreement regarding optimum outcome measures in a spinal fusion study. To our knowledge, the Prolo Scale has not had a thorough examination of its statistical validity. In the original IDE and the ten-year follow-up, it has been shown that the Prolo Scale produces results that can be compared with literature reports over many years.

Fusion success within the interbody space was defined by previous published parameters of radiographic fusion assessment of Brantigan and Steffee. Two observers evaluated the fusion from Ferguson anterior-posterior (AP) (parallel to the vertebral endplates), and lateral radiographs. A level was regarded as fused if there was radiographic evidence of bone bridging the disc space without lucency. If lucency was seen to extend across the cage, the level was considered not fused. The posterior-lateral fusion was graded by the method of Lenke et al. Each level and each side was judged individually. Continuous bridging fusion mass on at least one side was considered fusion success at that level. For patients undergoing multiple-level fusion, all surgically treated segments must be fused for the patient to be considered a fusion success.
Results
The 44 patients in this study included 21 men (47.4%), age 39-78, mean 57, and 23 women (52.3%), age 51-83, mean 67. Of 44 patients, four were deceased and six could not be found. The remaining 34 (77%) included 15 men (71.4%) and 19 women (82.6%). The interval from previous surgery to the index ASD surgery was 79 months (7-377 months). The length of follow-up from the index ASD surgery was 77 months (36-112 months). The number of levels fused at the index ASD surgery was 1 level in 13, 2 levels in 19, and multiple levels in 12.

Clinical Outcomes.
30 of 34 (88%) patients achieved clinical success. Excellent scores (17-20) were achieved in 5 (15%), good scores (13-16) in 6 (18%), fair scores in 19 (56%) and poor in 4 (12%). The four patients with poor scores did not achieve clinical success. One required two augmentations of the posterior-lateral fusion.

Fusion Outcomes.
Initially after the index surgery and before additional surgical augmentation of the PLF, fusion success graded radiographically was 91% and pseudarthrosis was seen in 3/34 9%. The fusion success rate was ultimately 100%. The three pseudarthrosis patients required PLF augmentations in order to heal.

Radiologic Review.
The UCLA grades identified the worst adjacent degenerative level before the index adjacent level fusion averaged 1.3 (range 1-3) and at last follow-up was average 2.4 (range 1-4) with an average change of 1 (range 0-2). There were 3 grade 4 patients that had progressed from grade 1 or 2 to grade 4 by last follow-up. The lumbar lordosis averaged 45 degrees (18-78 degrees). There were 14 (32%) with final lordosis below 40 degrees (average 30 degrees (18-39 degrees). The sagittal alignment was mildly abnormal in three (1.5 cm off plumb) and greater than 20 degrees angulation from L1-S1 in 2 patients.

Further Surgery
Of 44 patients, there were 22 further operations in 20 patients (38%). One early revision for a displaced cage was required. 11 (18%) had extension of fusion to adjacent level and 19 (43%) had removal of pedicle screws.

Complications
One device related complication required removal of a retropulsed cage. There were no pedicle screw complications. Non-device related complications included one dural tear, two seromas that
were culture negative, each requiring one debridement and primary closure, and one definite infection that required multiple debridements, long term antibiotics, and was reported to have hematogenously seeded the patient’s hip, resulting in a girdlestone procedure.

**Discussion**

**Incidence**

Adjacent segment deterioration after lumbar fusion is of great concern and it accounts for a substantial amount of revision spine surgery. Although some of the progression of degeneration may be attributed to natural processes of aging, this process is influenced by the abnormal stresses that occur following lumbar fusion\(^3,11,13,14,48,50\). Natural deterioration risk factors for segment degeneration have been well described, including laminar inclination, facet sagittalization and tropism, increased age, osteoporosis, female gender and post-menopausal state\(^5,13,19,33,51\). Several studies have found no statistical relationship to the length of fusion or the presence of degeneration of the adjacent segment prior to the surgery\(^14,35,36\). Park concluded radiographic asymptomatic adjacent segment disease is common but does not predict poor outcomes\(^36\). Others have related increased incidence of ASD with complete laminectomy, multiple fusion levels, severe degenerative spondylosis, facet trophism or violation by pedicle screw, failure of restoration of sagittal balance and lordosis, and extension of fusion to the sacrum\(^15,17,24,25,43\). At 5-10 years following lumbar fusion radiographic adjacent segment deterioration is commonly 30-60% and clinically symptomatic adjacent segment disease is 10-20%\(^6,14,30,32\).

**Biomechanics**

Biomechanical studies have shown that lumbar fusion produces increased motion and increased intradiscal pressure at the adjacent levels\(^9,11,18,27,31,41,44,49,52\). Two clinical radiographic analyses of posterior fusion patients also have shown an increase in mobility of the free segments above a fusion\(^13,46\), while Pellise et al found no change at two adjacent motion segments\(^37\). The importance of sagittal realignment and maintenance of lordosis during fixation have been documented in clinical studies, and clinical experience suggests that lumbar fusion in a nonanatomic sagittal alignment can cause a deleterious effect at the adjacent level\(^1,34\).

**Results of Surgical Treatment**

Whitecloud et al. reported 58% clinical success and 83% fusion success with noninstrumented posterior-lateral fusion\(^53\). Most had only modest improvement in pain with continued need for narcotic medication\(^53\). Schlegel et al. reported 70.3% clinical success, 89.2% fusion success with
noninstrumented posterior-lateral fusion, and 19% required further surgery. Phillips et al. reported 80.8% clinical success, 86.4%, fusion success with non-instrumented posterior-lateral fusion, and 27% re-operation rate. Chen et al. reported successful clinical success in 76.9% and fusion success in 94.9% of instrumented posterior-lateral fusion. Bertagnoli et al. report clinical success at 86% for treatment of ASD with artificial disc.

**Clinical success**

A comparison of clinical success in this ASD group (88.2%) was not statistically different to the Brantigan et al IDE study (85.9%) and 10 year follow-up (87.9%) as well as Chen et al (76.9%), Schlegel et al (70.3%), and Phillips et al (80.8%), although this ASD group had significantly more poor and fair Prolo scores compared to those of both of the Brantigan IDE (chi square = 20.49, p-value = 0.0216) and 10 year follow-up (chi square = 4.276, p-value = 0.0387).

**Fusion Success**

The fusion success was statistically significantly less in the ASD group (91.2%) than in the Brantigan IDE study (98.9%) (chi square = 7.3497, p-value = 0.0067) but was not significantly different compared to the 10 year follow-up (96.7%) (chi square = 0.8199, p-value = 0.3652) or to series from the literature that used non-instrumented fusion and Chen et al (94.9%) who used instrumented fusion.

**Need for further surgery**

Further surgery (38%) was statistically less compared to the Brantigan 10 year follow-up (69%) (chi square = 6.6656, p-value = 0.0098) and significantly greater than Chen et al (5%) (chi square = 12.1952, p-value = 0.0005), but not different than the Brantigan IDE (46%), and Phillips et al. (27.3%).

**Conclusion**

Adjacent segment deterioration should be considered a long term complication of lumbar fusion. Clinical management of symptomatic ASD is difficult. When surgical treatment is elected for ASD, PLIF will result in clinical and fusion success similar to the original lumbar fusion.
Table 1: University of California at Los Angeles Disc degeneration grading scale

<table>
<thead>
<tr>
<th>Grade</th>
<th>Disc-Space Narrowing</th>
<th>Osteophytes</th>
<th>End Plate Sclerosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>II</td>
<td>+</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>III</td>
<td>+</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>IV</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>

*The assigned grade was based on the most severe radiographic finding evident on plain radiographs. These categories are mutually exclusive when used for grading. Patients were rated on the basis of the worst category satisfied. + = present, - = absent, and ± = either present or absent.
References


