INTRODUCTION

Severe axial back pain represents one of the most challenging problems in spine surgery. Seventy to 85% of people have low back pain at some time. It is considered the second most common cause of appointments to physicians in the United States. The social and economic burden incurred by treatment of axial back pain is high and accounts for 2% of the gross domestic product. Surgical options remain controversial in spite of the fact that back pain producing lumbar degenerative disc disease is the most common cause of operative intervention on the spine. Though many treatments are in use, results have been somewhat unsatisfactory, even with aggressive fusion procedures.

The causes of axial back pain are multifaceted and still not well understood although the technologies for diagnosis and treatment have grown significantly in the past 30 years. Among the problems in treating low back pain are a lack of an adequate nomenclature for the differential diagnosis, lack of complete understanding of specific pathophysiologic-based pain generators, the presence of anatomic segmental overlap of sources of pain, its frequency as a source of somatization of psychogenic stressors, and the likely adaptive changes of the pain perception system which alter response to chronic nociceptive stimuli over time. This chapter focuses on the surgical treatment of axial back pain.

PATHOPHYSIOLOGY

Degenerative disc disease (DDD) has been defined as a clinical syndrome characterized by manifestations of disc degeneration and symptoms related to those changes. Disorders of the spinal motion segment are generally accepted to be a source of low back pain. Degenerative changes in components of the motion segment seem to be associated with release of nociceptor stimulating chemical mediators; cytokines, nitric oxide, phospholipase A2 and others have been implicated. Anatomically, there are several sources of nociceptors which include the facet joint capsules, perivascular tissue, periosteum, outer anulus, and major traversing roots and rootlets. In the authors’ experience, and that of others in the literature, the damaged posterior anulus is the most common source of axial back pain syndromes. The dorsal root ganglia, which house the sensory cell bodies, have been identified as a likely modulator of low back pain. Chronic injury has been shown experimentally to increase sensitivity to mechanical stimulation. Upregulation and downregulation of various neuropeptides has been associated with peripheral injury and it seems likely that similar changes occur with chronic peripheral nociceptive stimulation. The better understood in this group of axial back pain causes are disc herniation, radiographic segmental instability, and spinal stenosis. For these causes, there is a general agreement on basic approaches for diagnosis and treatment, though this is better defined when radicular symptoms are present. Less understood anomalies of the intervertebral disc as a source of low back pain include internal disc disruption syndrome, isolated disc resorption, and painful degenerative disc disease. In clinical practice ‘internal disc disruption syndrome’ as originally described by Harry Crock seems to run on a continuum with painful degenerative disc disease, the former being the most extreme manifestation and the latter, when asymptomatic, representing its antithesis. Why a similar-appearing lesion is well tolerated in many and severely disabling in some is not clear and thus the approach to diagnosis and treatment is often controversial.

The number of fusions in the United States continues to rise yearly with over 50% being performed for symptomatic degenerative disc disease, or internal disc disruption syndrome (IDD) without herniation. IDD was first described as a pathological condition of the disc causing low back pain with or without lower extremity radiation with minimal deformation of the disc anatomy. Historically, it was accepted that the intervertebral disc had no nociceptive ability and no innervations. Anatomic research has revealed that the outer layers of the anulus fibrosus and endplates are innervated from the sinuvertebral nerve branches and their rich innervations in the perianular connective tissue. As the disc undergoes degeneration, it loses its ability to convert nucleus compressive loads to tensile anulus loads, resulting in further stresses and degeneration of the endplates, facets, and anulus. In addition, disc degeneration may cause pain at other locations. Collapse of a degenerated disc may increase pressures on the facet joints, thereby leading to facet overload and painful facet arthropathy. A degenerated disc may also extrude nuclear material and irritative chemicals into nociceptive-rich locations such as the posterior lateral spinal canal, resulting in radicular-like pain.

PRESENTATION DIAGNOSIS AND CLINICAL COURSE

Most cases of axial back pain resolve over time with conservative care. There is 70% spontaneous improvement after 5 years in a study of a group suffering from chronic low back pain. Eighty percent of the group that did not improve had other mitigating factors present, such as psychosomatic issues. Although the low back pain from degenerative disc disease usually improves spontaneously, a significant number of patients do not improve, and may even have worsening symptoms and disability. There are currently no reliable diagnostic methods differentiating disabling painful internal disc disruption syndrome from asymptomatic degenerated discs and there is disagreement on indications for fusion when compared to nonsurgical
treatments. Clinical examination is usually characterized by low back pain with or without extremity radiation. The diagnosis of isolated, mechanical (activity and posture related) low back pain should only be made after first excluding less common conditions such as tumors, deformity, infection, ongoing neurologic injury, visceral disease, etc. Flexion postures such as sitting, forward leaning, and bending are typically aggravating due to increases in disc pressure in these positions. For most patients, lying recumbent usually relieves the symptoms. Some patients are intolerant of lumbar flexion to the extent that supine reclining increases pain that is only relieved when lying prone. The group that responds with diminished pain in lumbar hyperextension positions, in the authors' experience, can frequently overcome symptoms by nonsurgical means. Maintenance of static postures is intolerable in many of the more severely afflicted patients. This is presumably related to viscoelastic creep of segmental soft tissues. Degenerative discs may be associated with referred, sclerotomal pain to the buttocks and lower extremity.

On physical examination, confirmatory findings are localized near midline tenderness to one or more segments by anterior and posterior palpation, reproduction of symptoms by vibration, and increased pain reproduction with sustained positions of increased disc load such as lumbar flexion. Neurologic examination should be normal. Range of motion is limited in all directions and there may be a Gowers' sign on return from forward lumbar flexion. For surgical consideration, clinical history should include marked disability in sitting, static positioning, lifting, bending, and driving intolerance. Relative and absolute contraindications to surgery include secondary social or economic gain, psychological risk factors such as a history of sexual or psychological abuse, addiction, and dysfunctional family support systems currently or historically. All patients should have demonstrated failure of aggressive nonoperative care for at least 6 months.

Plain films may be interpreted as negative or only show typical age-related disc degenerative changes such as endplate sclerosis, uncinate spurring, loss of disc height, and facet degeneration. Flexion-extension lateral views may reveal segmental instability not apparent on static films. When changes are primarily localized to one segment, there is a high likelihood that the segment is the source of symptoms. Spondylolisthesis or spondylosis may be an incidental finding. It is also not uncommon that the segment above is involved and may be the cause of the back pain. In larger spondylolisthetic slips the discs are under tension instead of compression, and typically do not cause back pain without marked translational instability evident on bending films. Unfortunately, frequently there are multiple degenerative segments or none, which makes identifying the source of back pain more difficult. In evaluating pain due to disc degeneration, magnetic resonance imaging (MRI) is the most commonly employed modality to evaluate lumbar discs as the origin of patients' chronic low back pain. From early use of discography, the meaning of a painful injection has been unclear. It is unknown if a disc that is painful when injected can be reliably designated as the cause of clinically significant low back pain. In an effort to improve the specificity of discography in diagnosing discogenic pain, some investigators have used additional criteria beyond pain reproduction on injection. The primary criteria for a positive disc injection are pain of significant intensity on disc injections and a reported similarity of that pain to the patient's usual, clinical discomfort. Other clinical investigators have held more complex, stringent, and sometimes idiosyncratic criteria for positive injections including: negative control disc, concordant pain, dye penetration on injection, demonstration of pain behavior, maximum pressure on injection, and only one or two positive discs. Most clinicians require that at least one additional 'control' disc be examined. The control injection should ideally be 'negative' to confirm a positive study. It is not clear whether this means an adjacent 'control' disc injection must be 'painless,' or just not significantly painful in intensity. It is also not clear whether a painful but discordant disc satisfies the 'negative control' requirement. Most discographers have required that painful injection be considered negative if the sensation is clearly unfamiliar. On the other hand, it is not clear how exact a reproduction is required for a 'positive test.' Some investigators advocate that only an exact reproduction be accepted while others do not. Some investigators have maintained that dye penetration must extend to or through the outer anulus, scoring a 'true' positive injection in addition to the presence of pain with the injection. Others have indicated that 'behavioral' signs of pain such as guarding, withdrawal, or grimacing must accompany the presence of pain for the test to be considered positive. Finally, some have argued that pain elicited during low-pressure injections be considered positive because of the concern that high-pressure injections may cause deflection of the vertebral endplates or cause rupture of membranes over sealed and presumably asymptomatic fissures. Recent work has revealed a 10% false-positive rate among asymptomatic volunteers, with rates going up to 83% in volunteers with a diagnosis of an unrelated somatization disorder. Another study revealed up to a 40% positive pain reproduction following discography performed in asymptomatic patients who had prior discectomies. In another study, a group of patients without low back pain who had recent posterior iliac crest graft for nonspine-related procedures underwent discography. Fifty percent of patients experienced pain that was similar to or an exact reproduction of pain at the iliac crest bone graft harvest sites. These results question the ability of patient to separate spinal from
nonspinal sources of pain on discography. Provocative discography purports to identify a subgroup of low back pain syndromes in which the primary cause of the patient’s symptoms is the disc itself, apart from any other structural or psychological processes. By this theory, the successful alteration of the offending disc and solid arthrodesis or arthroplasty should result in outcomes equal to those achieved for spinal fusion with known primary structural pain generators such as unstable spondylolisthesis. However, discography studies have shown that discographic pain response can be of significant intensity in discs not actually causing the patient’s primary pain. Also, certain ‘asymptomatic discs’ are more likely to be painful on injection, such as discs with annular fissures or discs after prior surgery. Studies also revealed that individuals with certain psychosocial characteristics are more likely to report higher pain intensity levels with disc injections than others, such as those with psychological stressors, chronic pain states, litigation involvements, and so forth. The failure to achieve consistent clinical success after spinal fusion for presumed discogenic pain is usually attributed to the morbidity of surgery or poor patient selection. Therefore, in the patient with a single arthritic or annular disrupted lumbar segment, without emotional troubles, with a stable family and occupational support, no history of chronic or unexplained pain syndromes and any compensation issues, discography may be helpful in confirming that the disrupted segment does hurt while the adjacent segments do not.\(^1\,17\,20\,29\,30\) We recommend, that discography be performed by those experienced in the technique and surgical ramifications, using strict criteria for interpretation. Furthermore, discography results need to be correlated carefully with the clinical history and physical examination to avoid surgical failures.

**TREATMENT**

The vast majority of patients with painful degenerative disc disease can be managed nonoperatively. The first task is to optimize the patient’s physiologic status. This involves increasing cardiovascular fitness and placing the patient in a smoking cessation program. Most patients with painful disc disease have exacerbation of symptoms with flexion, so extension exercises as well as low-impact aerobic exercise such as swimming and cycling are helpful if tolerated in a conditioning program. In the authors’ experience, isometric neutral stabilization and hyperextension exercises are commonly effective. Robin McKenzie has pioneered and refined extension-based stabilization. It is the authors’ belief that instruction in minute-by-minute comprehensive daily body mechanic control and posture management can diminish the repetitive stimulation of the damaged section of the disc anulus and facilitate recovery in some patients. Back pain and work loss is less in people who maintain a regular exercise regimen. Hip and hamstring stretching, buttock and abdominal strengthening, and hyperextension exercises to strengthen the gluteus and paravertebral muscles are frequently successful in controlling symptoms.\(^29\,30\)

Nonsteroidal antiinflammatory medication and acetaminophen can provide improved symptoms in some patients. Muscle relaxants may have an effect in treatment of acute flares of low back pain symptoms but are not recommended for chronic use.\(^29\,30\)

In general, operative intervention is only offered to patients where surgery is expected to improve the results of the natural course of the disease (Fig. 97.1). In these patients, disability is great and no indication of nonsurgical recovery is suggested by history. Discectomy has been performed in the past for treatment of patients with incapacitating low back pain from painful degenerative disc disease. Currently, there is no accepted indication to treat degenerative disc disease with isolated discectomy. Discectomy is indicated for a patient with incapacitating radicular symptoms resulting in compressive neuropathy from a herniated nucleus pulposus which is progressive or which has failed a 6-week trial of nonoperative treatment. Symptoms may include incapacitating sciatica (extremity pain) with or without a neurologic deficit. The patient may have low back pain in concert with these symptoms but axial back pain as a primary complaint is a relative contraindication to discectomy, which may or may not relieve back pain. We suspect the larger the protrusion is more likely to have a favorable response for isolated back pain.

There have been a variety of disc debulking procedures described over the years as a less-invasive means to eliminate symptoms resulting from compressive neuropathy without the morbidity known to occur with conventional discectomy procedures. They have not to date been shown to be effective for axial back pain without neural compression. Chemonucleolysis as a treatment for patients with low back pain (primarily from herniated discs) was originated by Thomas, who noted that a proteolytic enzyme called papain had affinity for the ground substance (i.e. proteoglycans) of all cartilage in the body. Many studies in humans during the 1970s led to chymopapain being implanted in over 16,000 patients before FDA approval was granted.\(^31\,32\) However, chemonucleolysis fell out of favor.\(^33\) First, multiple studies demonstrated the superiority of surgery over chymopapain injection.\(^34\) Ziegler reported in 126 patient a 98% success rate for patients undergoing surgical excision versus a 60% success rate for patients receiving chymopapain. Furthermore, chemonucleolysis actually caused recurrent low back pain in 54% of the patients, compared to only 5% receiving surgery.\(^35\) Watters et al. also demonstrated a superior patient satisfaction with surgery. This group reported a
disturbing rate of sequestered disc herniation in the chemonucleolysis group requiring reoperation. The second factor leading to the decline of chemonucleolysis related to the fact that there is no significant alteration of the natural history of a lumbar disc herniation treated conservatively when compared to one following chymopapain injection. In part, this is related to the fact that patients with a large disc herniation have much poorer results than do patients with lumbar disc bulges or protrusions (i.e. disc contained in the anulus). Finally, there were unique complications with chymopapain use, such as anaphylactic responses and unpredictable neurologic deficits. Anaphylactic shock was reported to be as high as 1 in 5000. Agre reviewed the neurologic complications following chymopapain injection and found cerebral hemorrhage, seizures, paraparesis, paraplegia, subarachnoid hemorrhage, and death.

Automated percutaneous lumbar discectomy (APLD) has been used for some time as a minimally invasive variation of open discectomy. The working principle is that removing a portion of the nucleus pulposus relieves the intradiscal pressure, thereby alleviating irritation in the nerve root and the nociceptive fibers in the anulus fibrosus. Even proponents of this procedure recommend that APLD be limited to contained disc protrusions. Relative to the natural history of a herniated disc, APLD in several studies has not provided superior results though morbidity is quite low. Furthermore, there is a lack of well-constructed scientific studies evaluating its effectiveness.

Other minimally invasive procedures include percutaneous laser nucleolysis of the intervertebral lumbar disc and percutaneous disc decompression with electrophotothermal nucleoplasty. In the hope of avoiding intraoperative trauma to dura and nerve roots, and preventing intraneural and perineural scar formation when approaching lumbar discs, Nerubay et al. used a carbon dioxide laser to vaporize a protruding nucleus pulposus. After performing an initial trial in dogs to determine the amount of laser energy necessary to vaporize the nucleus pulposus, a prospective study of 50 patients was performed. Good and excellent results were achieved in 74% of the patients, with four patients requiring subsequent operative intervention. Patients with sequestered fragments or bony lateral stenosis did not benefit from the procedure. Four complications of nerve root irritation (three which resolved) were attributed to thermal damage caused by warming of the cannula. The authors, however, were careful to point out that strict patient selection is crucial to the outcome. Proponents of percutaneous nucleoplasty claim that the use of radiofrequency (RF) energy removes nucleus material and creates small channels within the disc. Using this coagulation technology, coagulation and ablation are combined to form channels in the nucleus and theoretically decompress the herniated disc. A recent study on three fresh human cadavers measured intradiscal pressure at three points: before treatment, after each channel was created, and after treatment. The results revealed that intradiscal pressures were markedly reduced in young cadavers, while it changed very little in older specimens. Further studies with animal and prospective human trials are needed before any conclusions can be reached about the clinical efficacy of the technique.

The wide abdominal rectus plication (WARP) is another procedure for axial back pain. The WARP abdominoplasty is based on the theory that contraction of the abdominal muscles via the attachments to the lumbar fascia results in intradiscal pressure and resultant diminished intradiscal pressure. When a ‘stretched out’ or an adynamic segment exists in the anterior abdominal wall (such as with some women following pregnancy), the internal oblique and transverse abdominus are not at physiologic length. This laxity prevents maximum force generation with contraction and thereby weakens abdominal support that is usually present via the attachments to the lumbar fascia.

The surgical procedure involves plicating the right side to the left side of the rectus fascia, thus converting the flat rectus muscle into a tube. This diminishes trunk girth and reduces abdominal cavity size and therefore tightens the anterior abdominal–lumbodorsal fascia muscle complex. In the largest series reported to date, the author reported increased height in the intervertebral space on both the MRI and on lateral spine radiographs postoperatively in all 25 patients. The back pain was reduced postoperatively in all except one patient. The author limited the inclusion criteria to patients with a positive abdominal compression (TAC) test, weak internal oblique-transversus abdominus Cybex muscle test, and to those patients with back pain undergoing elective abdominoplasty. The TAC test involves applying manual pressure to the abdomen, which relieves in some patients. The procedure may be a consideration in patients with abdominal wall insufficiency, relief with abdominal corset or binder, and or a positive TAC. The authors have had some success in a consecutive series of 23 selective patients.

The literature provides success rates varying from 17% to 92% with surgical fusion. Many techniques have been utilized and range from the simple posterior fusion without bone graft to most extensive anterior–posterior fusion with pedicle instrumentation. The goal of the operation is to limit sensory stimuli and tissue inflammation across the segment by stopping mechanical motion. Since the patient population likely have facilitated segmental and/or central nervous system (CNS) nociception, complete obliteration of motion is the goal.

Traditionally, posterolateral fusion has been the standard surgical technique. Success rates have been variable and reported as high as 90% using rate of apparent solid fusion and removal of pain and return to work as criteria. Poor results are associated with pseudoarthrosis, workman’s compensation and being out of work longer than 3 months. Pedicle screw instrumentation has been added to the procedures to decrease nonunion rates (Figs 97.2, 97.3). Recent studies have shown that adding instrumentation increases fusion rates by 20%. Also, proponents of instrumentation feel that these constructs offer immediate stability and allow an expedited postoperative recovery (Fig. 97.4). Current practice for painful degenerated discs among many surgeons is posterolateral fusions augmented with pedicle screw instrumentation.

Anterior lumbar interbody fusion (ALIF) is growing in popularity as a primary procedure for low back pain due to degenerative disc disease or as a salvage procedure for individuals who have failed posterior procedures. Concerns about paraspinous muscle damage, the desire for more complete removal of the disc, restoration of disc height have primarily retained interest in this procedure. Crock considered ALIF the procedure of choice for IDD. Studies suggest that any motion across the disc space (as may persist after posterolateral fusion) may be a source of continued back pain. The advantages of ALIF include: proximity of fixation close to the center of spinal motion, complete excision of the central disc material, placement of fusion graft under compression, availability of a large surface area for fusion, availability of a virgin operative site in patients with prior posterior procedures, and the ability to provide a stable anterior column support to diminish torsional and bending force on supplemental posterior instrumentation. Proponents of ALIF advocate that even after solid posterior fusion, motion may still occur anteriorly thorough the disc, causing continued pain. This is due to the plasticity of bone, the variation in degree of posterolateral fusion confluence and rigidity, and the greater distance to the center of vertebral motion. Increased stability of the ALIF would therefore increase the fusion rate while more completely eliminating motion at the operative disc space since the fusion mass is at the center of motion of the spine. Originally, tricortical iliac crest bone graft was
placed in the disc spaces. This has been replaced over time by femoral ring allografts and threaded cages of various materials in order to remove the morbidity of autogenous bone grafting. Interbody fusion, while providing structural support for the anterior column, indirectly decompresses the foramina and nerve roots via restoration of disc height through distraction. Threaded interbody cages, when used in place of femoral ring allograft, increase surface contact and initial fixation between the bone and bone graft. They can also be implanted through mini-invasive approaches. As an alternative to traditional open retroperitoneal and transperitoneal approaches, laparoscopic transperitoneal and endoscopic-assisted retroperitoneal approaches allow for minimally invasive placement of ALIF devices. Using this technique, Loguidice et al. reported 80% clinical success\textsuperscript{71} while Newman and Grinstead reported 86% success based on rate of fusion, pain relief, and return to work.\textsuperscript{68}

Anterior/posterior combined (360 degree) fusions have historically been used for multilevel fusions and deformity (Fig. 97.5). Recent advances in mini-invasive approaches (resulting in less patient morbidity) and the surgeon’s desire to completely obliterate motion across the disc have made this technique more common for axial back pain. Lower nonunion rates and greater ease in the ability to control lordosis are among the reasons cited by authors to put the patient through this more invasive procedure. Authors have reported up to 88% fusion rates using this technique but only a 63% clinical success, showing those two factors are not mutually inclusive.\textsuperscript{72–75}

Cloward, in 1945, introduced the posterior lumbar interbody fusion (PLIF) as a method of achieving an anterior arthrodesis with a posterior surgical approach.\textsuperscript{45} A wide posterior decompression is performed, allowing retraction of the dural sleeve and nerve roots for complete disc excision and anterior column fusion. This approach allows for a more complete disc excision, restoration of disc height and reproduction of lumbar lordosis, root decompression, solid mechanical arthrodesis, immediate load sharing and structural support, large surface area for fusion between the endplates
and avoidance of a second anterior approach. One report with average 18-month follow-up revealed a greater than 90% fusion rate with an 89% success rate based on pain relief, return to work, and outcome scoring scales. Disadvantages include possible graft displacement, pseudoarthrosis, increased bleeding, dural tears, nerve root injury, and risk of epidural fibrosis due to nerve retraction. PLIF is contraindicated in patients with preexisting, significant epidural fibrosis and those with osteopenic bone. Damage to the nerve roots is a principal concern with PLIF procedures. Steffee et al. reported that a failed PLIF has a worse outcome than failure of any other fusion procedure. The upper (exiting) nerve root, when performing a PLIF, traverses the interspace just out of direct view in the lateral recess and can be damaged when grafts are inserted into the disc space. Exploration of patients with a post-PLIF radiculopathy reveals epidural fibrosis for which there is no good solution. Revision options are limited following a PLIF. A noninstrumented PLIF may be converted to an instrumented PLIF and an instrumented PLIF may be revised to an anterior fusion but this is difficult and fraught with complications.

Concerns about nerve root damage and epidural fibrosis led Harms et al. to popularize a variant of the PLIF called a transforminal lumbar interbody fusion (TLIF). Using a more lateral posterolateral approach than with a PLIF, unilateral excision of the facets allows increased exposure of the disc space without putting undue tension to the dura and the nerve roots. Unlike with PLIF where transpedicular instrumentation is optional, with the TLIF it is mandatory. Also, a TLIF is well suited for a muscle-splitting Wiltse approach, thereby preserving the posterior ligamentous complex and decreasing problems associated with retraction and muscle damage. Pedicle fixation adds stability and the capacity for early mobility following surgery and is advantageous to return to optimal function.

Lumbar fusion has been offered as a solution to treat low back pain when nonsurgical treatment fails. It has been reported that the rate of lumbar fusions in the United States rose 100% between 1980 and 1990. However, fusion for low back pain continues to be controversial. Some researchers feel that low back pain is a multifactorial entity and fusion is hastily undertaken without accurately determining whether the patient’s symptoms would actually be improved without fusion. Reported success rates of fusion range from 5% to 92%. Reports can be criticized for being mostly retrospective and uncontrolled without uniform criteria on how to measure a successful outcome. Three recent trials merit discussion. Lee et al. reported 89% success for fusion on a 62-patient group suffering from chronic low back pain. The study had stringent criteria for inclusion and the author claimed a 92% return to work rate in patients who had been out of work for longer than 4 months. However, the results did not include the success of nonsurgical treatment in the group of patients and the report was retrospective in nature. The study by Fritzell et al., as part of the Swedish Lumbar Spine Study Group, was a randomized controlled multicenter study followed with a 2-year follow-up by an independent observer. The goal was to determine whether fusion was superior to nonsurgical treatments in treatment of patients with resistant low back pain. The authors reported a significant difference in reduction of low back pain, decrease in the Oswestry scores, and reduction of depressive symptoms using the Zung scale. Seventy-five percent of the surgical group, at the conclusion of the trial, would go through the treatment again without knowing the result. But not many of the patients would consider themselves ‘cured’ using the above-mentioned criteria. Butterm et al. compared the results of lumbar fusion surgery in groups of patients with multiple diagnoses. Success rates varied from 69% to 100% depending on the group. Along with the retrospective nature of the study, once again, the outcome scale suffered from a lack of stringency.

Future developments to improve the rate of successful fusions will likely involve stimulation of fusion at the genetic level. The use of biotechnology solutions to stimulate bone growth has led to important discoveries. Recombinant human bone morphogenetic protein-2 (rhBMP-2) is now available for use with a tapered, threaded intervertebral fusion cage (LT cage, Medtronic Sofamor Danek, Minneapolis, MN) for the clinical treatment of degenerative disc disease. The success of an initial pilot trial in 14 patients gave the impetus to pursue a pivotal prospective, randomized trial involving 143 patients implanted with the LT cage filled with rhBMP-2 versus 136 patients implanted with LT cage filled with iliac crest autograft. One hundred percent fusion was achieved in the BMP group and 95.6% fusion in the autograft group. There were no significant differences in the Oswestry scores between the groups, while 32 of the 136 patients receiving the iliac crest bone graft experienced some degree of donor site pain after 2 years following surgery. A prospective, randomized trial of posterior lumbar interbody fusion comparing 36 rhBMP-2 versus 35 cases with autograft showed equal success using Oswestry, leg pain, and back pain scores as criteria. Finally, a recent pilot study investigating the difference between rhBMP-2 and autograft in posterolateral fusions has revealed increased fusion rates and higher scores in back and leg pain scales in the rhBMP-2 group. Early work in Sweden investigating the ability of rhBMP-7 versus autograft to achieve posterolateral fusions has also been promising. The current consensus is that recent trials have demonstrated the ability of rhBMP-2 to achieve a high fusion rate and can substitute for autogenous bone graft in both interbody and intertransverse applications. In addition, serology testing has not demonstrated a significant antibody response to rhBMP-2 following implantation.

Intradiscal electrothermal therapy (IDET) has been developed by Drs. Jeff Saal and Joel Saal as an alternate treatment to spinal fusion for patients incapacitated secondary to discogenic pain. IDET is performed in the operating room where a flexible intradiscal catheter
with a temperature-controlled thermal resistive coil is inserted into the nucleus until it penetrates the inner layers of the anulus fibrosus. As the electrode is advance, the outer layers of the anulus deflects it in a circumferential course toward the affected side. At its resting position, the electrode traverses the posterior midline of the anulus fibrosus. At this point, the thermal coil is heated to 90°C per protocol. After appropriate heating, the catheter is removed and the patient is discharged home with immediate ambulation. The theory of why IDET alleviates symptoms is based on two principles. The first is that previous studies have shown that temperatures above 45°C destroy nociceptors in the anulus. Also, a second hypothesis states that raising the temperature to 60°C induces denaturation and shrinkage of collagen. This shrinkage could potentially stabilize the motion segment at the disc and theoretically remove the pain generator. Lee et al. showed a decrease in motion of the operated spinal segment in all planes of testing after IDET with no significant difference in stability in a study of five cadaver specimens with the posterior elements intact. Studies testing both hypotheses have been conflicting, and it is clear that there is no consensus on the biologic effect of IDET on the intervertebral disc. The success rates in clinical trials have also been variable, ranging from 23% to 71%. To establish IDET as a worthwhile treatment, more research needs to be performed at a basic science level to elucidate the biomechanical and physiological effects on the intervertebral discs. Despite its unproven efficacy, IDET continues to be used to treat LBP, partly because it is a technically easy procedure to perform and has few complications. Until long-term data show the benefit of IDET in altering the course of painful degenerative disc disease, the procedure remains an unproven option.

Clinical studies supporting the effectiveness of chondroitin and glucosamine for the treatment of osteoarthritis were the impetus to a group of clinicians to explore their effectiveness in treating low back pain when injecting these substances into the intervertebral disc. The hypothesis is that injection of these substances would promote a reparative response in the disc. Thirty patients who had lumbar discography used to reproduce low back pain took part in the study. Lumbar intervertebral discs were injected with a solution of glucosamine and chondroitin combined with dimethyl sulfoxide (to enhance diffusion of the substrates throughout the disc), and pre-treatment Roland-Morris disability scores and visual analog scores (VAS) were compared with 1-year follow-up post-test values of these scores. Seventeen of 30 patients (57%) were found to have improved markedly with 72% and 76% improvements in the Roland-Morris and VAS scores, respectively. There were no complications or serious side effects. The authors were the first to admit that the study had a weakness because it was nonprospective in nature and had no control or comparison group. The authors could not give a sound scientific explanation for the biochemical effects of the injections. However, the absence of any severe adverse effects and the fact that there was a large subgroup of patients who were very pleased allowed the authors to justify further studies to look for the effects of these injections. The current hypothesis is that the reduction in pain and disability is due to favorable alterations in the intervertebral disc to promote repair. Further clinical and basic science trials will be needed to prove or disprove this hypothesis.

Because of the concerns with lumbar fusion procedures, there is a significant amount of interest in total disc replacement (TDR). Proponents of TDR state that it would potentially relieve symptoms, prevent long-term issues associated with fusion, and also remove the diseased disc mechanism, the ‘pain generator.’ The other major goal of disc replacement surgery is to maintain and restore normal segmental spinal motion by restoring the disc space height and segmental lordosis. Achieving this goal also allows indirect decompression of foraminal stenosis and protects adjacent levels from iatrogenically accelerated degeneration. From a clinical standpoint according to current pivotal FDA trials, general indications for disc replacement surgery include: patients with back pain greater than leg pain not responsive to appropriate nonsurgical treatment, symptomatic one- or two-level disc changes associated with collapse, symptomatic early stage disc changes identified by MRI and/or discogram in the absence of marked facet arthritis, and patients without prior history of back surgery at the affected level. Contraindications include severe facet joint arthropathy, spinal instability, altered posterior elements secondary to prior surgery, infection, spondylolytic spondylolisthesis, and metabolic bone diseases. There is a paucity of data in the literature today concerning total disc replacement. The Charite disc replacement has the most associated data. The Charite has gone through three generations of modifications since its development in 1984. There have been device failures with earlier designs, but few device failures with the most recent model (Fig. 97.6). Buttner-Janetz et al., in 1989, reviewed the initial clinical experience of 62 patients, and submitted that there were 83% very satisfactory results or results that was ‘better-than-before’ the operation. David, in 1993, reviewed his results with the Charite in 22 patients. He had a minimum of a 1-year follow-up and 65% excellent or good results. He concluded...
that the disc replacement procedure had a very narrow application, and artificial disc replacement, in his opinion, was not a routine procedure. Griffith, in 1994, had the first multicenter, multisurgeon, retrospective review of the Charite.99 There were 93 patients in which the Charite 3 device was inserted. The most common diagnosis was degenerative disc disease, in 52%, and the most common level implanted was the L4–5 level. The follow-up was 11.5 ± 8.4 months. He reported a significant functional and pain improvement, although there was no work status change in the patients evaluated. There was a 6.5% incidence of migration, subsidence, and dislocation. He concluded that prospective, randomized studies were needed to compare artificial disc replacement versus fusion procedures. Cinotti et al., in 1996, also performed a one-surgeon retrospective review of 46 Charite 3 devices. He had a minimum of a 2-year follow-up. The diagnoses were approximately 50% degenerative disc disease and 50% failed disc excision. They had a 69% satisfactory result for one-level procedures, and a 40% satisfactory result with two-level procedures.10 They hypothesized that the poorer results in two-level procedures were because the device was difficult to implant at two levels because of excessive distraction that had to be performed at the second level; additionally, at the second level, a smaller device needed to be inserted, and this device needed to be inserted more anteriorly, very likely contributing to decreased range of motion at that second level. They concluded that, in their hands, success was less than that seen in fusion cases. The Charite, in their opinion, was not suitable for two levels, and they also determined that prospective, randomized studies were needed to evaluate disc replacement versus fusion procedures. The ProDisc total disc prosthesis completed its FDA pivotal trial in 2003. The ProDisc has a modular design with a superior and inferior cobalt–chrome endplate (Fig. 97.7). Additionally, the inferior endplate allows for a polyethylene insert to be snapped into place, utilizing a locking mechanism. The earlier ProDisc results have been evaluated by their inventor, Dr. Marnay. He had an outside organization perform a prospective review of 61 of his cases. Ninety-five percent were available for follow-up at 7–11 years. Thirty-three percent of these procedures were performed at two levels. At follow-up, all of the prostheses were intact and functioning, and there was no evidence of subsidence or migration. Additionally, there were no revisions or removals, and 92.7% of the patients were satisfied or entirely satisfied. They concluded that there was no difference in results in one- or two-level implantations, and there were no device-related safety issues.10 Weichert et al. reported a 6-month follow-up of 16 ProDisc patients where the mean VAS score improved from 7.0 to 1.9 and the Oswestry Pain Score improved from 23.3 to 10.2.100 Bertagnoli and Kumar published results of a 108-patient series with a follow-up period of 3–24 months. They reported that 91% of patients had an excellent outcome, 8% a good outcome, and 1% a fair outcome.101 The obvious drawback was that the specific criteria used to make the classification system were not clearly defined. Postoperative complications commonly associated with lumbar disc replacement procedures include: (1) abdominal wall hematomas, (2) vascular injury, (3) dural tears, (4) nerve injury, (5) retrograde ejaculation in males, and (6) migration of the prosthesis. Total disc replacement is in its infancy. The early studies of Marnay and the ProDisc as well as the Charite trials are encouraging. Two additional prostheses are in pivotal trials at this time (Maverick (Medtronic, Minneapolis, MN and FlexiCore (SpineCore, Summit, NJ) (Figs. 97.8, 97.9). The FlexiCore is prearticulated and inserted as one piece. The FlexiCore and Maverick are both all-metallic disc replacements. These FDA supervised studies are prospective, controlled and randomized, and outcomes are being measured using standard patient-based assessments such as the Oswestry low back pain questionnaire, SF-36 and VAS. As spine surgeons learn more about total disc replacement, proper indications are being developed. It is unclear at this time which of these prostheses, if any, is most efficacious. Our experience with 85 ProDisc and FlexiCore implantations suggests they are associated with less morbidity, less surgery, and shorter healing time than fusions. FDA trial results, soon to be available, will hopefully shed light on these potential advantages.

Investigational prosthetic nucleus replacements purport the same advantages as those provided by total disc replacements. In addition, they may have utility as a postdiscectomy alternative maintaining disc height and possibly preventing recurrence. By replacing the disc nucleus following discectomy, pain related to chemical irritation of neural tissue from extruded products from the native nucleus would be reduced. Two emerging prosthetic nucleus devices use hydrogels. These substances mimic the nucleus by absorbing water to increase in size and fill the disc space. The largest amount of data is available on the PDN (prosthetic disc nucleus; Raymedica, Minneapolis, MN) (Fig. 97.10). The hydrogel core of the device absorbs water and expands to fill the nuclear cavity. The hydrogel is prevented from escaping by the outer jacket. Ray has reported 4-year follow-up results with 90% decrease in Oswestry scores in patients.102 The indications for implantation of the device was back pain with or without...
leg pain, related to painful degenerated discs which were refractory to nonsurgical treatment. Although early reports are hopeful, trials involving PNDs are complicated by device displacement occurring at a relatively high rate (6%). Ray has explanted 10% of the devices from his patients.

It is important to avoid any of the many pitfalls present with surgical treatment of painful degenerative disc disease. Improper patient selection is a common error. Patients with psychosomatic issues, who smoke, have pending litigation claims, are receiving workman’s compensation, and those who have been out of work for an extended period of time often have poorer outcomes with fusions for degenerated discs. Correct identification of the proper level of pain generator is also vital to the success of the surgery and is most challenging in some cases. Novel and new surgical approaches which do not have prospective, controlled long-term studies reported in peer-reviewed journals should be looked at with some skepticism as a treatment for this challenging problem. Thanks to demands of the FDA, we are getting a fair amount of scientific data in regard to total disc replacement procedures.

In the authors’ opinion there is no one best approach or procedure for axial back pain and we perform most of the available procedures in different situations. For example, in a case of collapsed (<2 mm disc height) radiographically stable L5–S1 disc with no need for posterior decompression, an anterior interbody fusion with femoral ring cages with or without BMP has a high fusion success rate greater than 85%. Since the segment is collapsed, not contributing much to motion, and frequently has marked facet joint arthropathy; a simple fusion is usually successful and does not create much additional load transfer to other segments. Arthroplasty is also of low morbidity in our experience, but in this case example the need for restoration of disc height, which can stretch the neural elements if fibrosis is present, and the presence of chronic facet disease, can cause residual symptoms in some patients. Adjacent segment stress transfer of a fused lumbosacral segment is a significant concern but is less than at lower segments, especially if the fusion is at L4–S, which leaves the L5–S1 level between two rigid segments, the sacrum and the L4–5 fusion. All degenerative discs with disc heights approaching 2 cm are best treated with total disc arthroplasty if available, or circumferential fusion with instrumentation. The increased mobility of these segments makes a technically successful fusion more difficult. We have been well satisfied with total disc arthroplasty in this subgroup in 1–2-year follow-up in single and double levels to date. Much less surgical intervention is required than in the circumferential fusion. When fusion is employed in tall discs in lumbar levels above L5–S1, we prefer either a TLIF with pedicle instrumentation or an anterior–posterior combined procedure with pedicle instrumentation placed posteriorly through a percutaneous or paraspinal muscle-splitting approach. The open or percutaneous paraspinal approaches seem to spare early and possibly late morbidity by avoiding extensive muscle retraction required for traditional midline approach. If spinal canal decompression is needed, a midline approach is utilized and usually a TLIF is placed since the exposure for the TLIF becomes part of the decompression for the nerve roots. We rarely consider surgery and even more rarely fuse patients who appear to have significant pain generation from more than two segments without neural compression. Emerging technology such as dynamic posterior stabilization offered by Dynesis (Zimmer, Warsaw, IN) and multilevel total disc replacement, when released by the FDA, may possibly help some in this unfortunate group. The unproven thermal energy and disc debulking techniques discussed earlier have the rationale of not frequently making patients permanently worse. Their success is expectantly low in this patient population but other approaches are still available if, in the future, they fail. One must keep in mind that the desperation of some individuals due to failure of all modes of nonsurgical management and severity of their disability drives them to seek surgical solutions, whether appropriate or not, by surgeons willing to perform these procedures. In many cases, risk factors for failure may make good surgical outcomes so remote that surgery is inappropriate.

**CONCLUSION**

The lower back is a common focus of pain for patients with other structural and supratentorial disorders. The spinal surgeon must develop expertise in selecting good surgical candidates. Reliance on scientific, methodic analysis when available is required for the highest success rate. Recent trends in improved surgical clinical research study design, such as patient-based statistically validated outcomes tools, prospective, randomized trials which are now usually a new technology requirement of the FDA, and insurance payer requirements of peer-reviewed research demonstrating outcome efficacy of surgical treatments are moving us in the right direction as never before. Though objective analysis is currently deficient, there is little doubt from many good clinical outcomes that a portion of the population with severe refractory axial back pain can be helped by surgery. The art and science of doing the most good and the least harm lies in both thorough and rigorous selection criteria, and meticulous diagnostic and surgical execution.

**References**


