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SPECIALTY UPDATE

What's New in Spine Surgery

By Keith H. Bridwell, MD, Paul A. Anderson, MD, Scott D. Boden, MD, Alexander R. Vaccaro, MD, and Jeffrey C. Wang, MD

What's New in the Treatment of the Cervical Spine

Trends in the treatment of the cervical spine include the evaluation of new technology as well as a focus on the understanding of old concepts and postulates. The results of randomized controlled trials of cervical arthroplasty are now available, and this procedure appears promising.

Anatomy

To safely perform many of the complex surgical procedures that involve the use of screw fixation, an understanding of the surgical anatomy of the cervical spine is essential. Osseous and vascular anomalies in the cervical spine that place the vertebral artery at risk during surgery have been identified. The vertebral artery normally enters the spine at C6 and ascends in the foramen transversarium until C2, where it turns, first laterally and then cranially, and ascends into the C1 foramen transversarium. It then loops medially, lying on the superior surface of the C1 arch. Approximately 15 mm from the midline, it turns anteriorly, enters the spinal canal, and passes through the foramen magnum. In the subaxial spine in a small number of patients, the artery can enter at C7 (or, more commonly, it can become ectatic with age) and can intrude into the vertebral body, placing it at risk during corpectomy. This finding is easily recognized on anteroposterior radiographs or axial computed tomography and magnetic resonance images. The vertebral artery may pass too far rostrally and medially within C2, thinning the pedicle so that C1-C2 transarticular and C2 pedicle screws cannot be placed safely. This occurs in as many as 15% of cases. As an alternative, screw purchase can be obtained in the C2 lamina, thereby avoiding vertebral artery risk. Biomechanical studies

comparing this method with other C2 screw constructs have shown similar fixation strength.

Lateral mass fixation into C1 is gaining popularity. Screw position is critical, as rostrally angled screws can penetrate the atlanto-occipital articulation and screws that extend too far anteriorly may injure the carotid artery. Because the anterior arch of the atlas is 3 to 5 mm more anterior than its lateral masses, screws may easily extend anteriorly even though they appear to be in an appropriate position. The internal branch of the carotid artery can lie directly anterior to the C1 lateral mass and may be damaged. The ponticulus posticus is an osseous bridge over the cranio-lateral aspect of C1 that encloses the vertebral artery. It occurs in as many as 19% of patients. One method of C1 lateral mass screw placement is to place screws into the posterior C1 arch (if large); this should be avoided when a ponticulus posticus is present. Other important anomalies include a fenestrated vertebral artery and a takeoff of the posterior inferior cerebellar artery between C1 and C2, which is present in 0.5% of the Korean population. Many of these anomalies can be predicted on the basis of minor osseous radiographic changes at C1, such as asymmetry, scalloping, or widening of the foramen transversarium. When present, computed tomography angiography or magnetic resonance angiography is recommended prior to screw placement.

Myelopathy

Early physical findings of myelopathy classically include clumsiness and hypesthesia of the hands, ataxic gait, hyperreflexia, and pathologic reflexes such as clonus, the Hoffmann sign, and the Babinski sign. Rhee found that in patients having a successful outcome following decompression for myelopathy that a pathologic finding was present in only 78% of patients preoperatively. Surprisingly, the prevalence of hyperreflexia was no different from the prevalence in individuals without myelopathy. Sustained clonus and Babinski signs were present

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in only one-third of the patients with myelopathy. The Hoffmann sign was the most common finding, occurring in roughly 80% of myelopathic patients, and it was more common with increasing severity of the myelopathy. These findings are difficult to quantify and may be present normally or may result from other diseases. More quantitative means for the assessment of myelopathic patients are the ten-second stepping test (the number of steps that a patient can perform in ten seconds while standing in place) and the finger grip and release test. Normal patients can perform more than twenty repetitions of each test, whereas myelopathic patients perform fewer than fifteen grip and eleven stepping functions.

Disc Arthroplasty

Three cervical disc arthroplasty devices have been approved by the United States Food and Drug Administration (FDA) panel for implantation into patients with single-level radiculopathy or myelopathy who have had a failure of nonoperative management. Exclusion criteria include severe spondylosis, instability, facet joint arthrosis, and congenital spinal stenosis. Approval was gained on the basis of three randomized controlled studies that were designed to show that arthroplasty is equivalent to arthrodesis with use of an allograft and plate. The outcomes were assessed at two years, with the primary outcome variables being improvement in terms of neck disability and overall clinical success. All three studies demonstrated that arthroplasty is equivalent to arthrodesis, with the benefit of maintenance of intervertebral motion. The adverse outcomes were no different from those in controls. Many of the secondary variables showed significantly favorable results in association with arthroplasty, such as earlier return to work, greater improvement in functional outcomes, and lower reoperation rates. Other subgroup analyses have shown the efficacy of both arthrodesis and arthroplasty for the treatment of myelopathy at a single level and in patients receiving Workers' Compensation. The early results of those investigations are reassuring, but long-term follow-up is needed to determine the ultimate role of cervical arthroplasty.

Epidural Steroid Injections

Steroid injections performed by means of either an intralaminar or a transforaminal route are routinely prescribed for patients with radiculopathy and myelopathy. Rare cases of spinal cord infarction and quadriplegia have been reported following cervical steroid injection. The mechanism is thought to be intra-arterial injection into the radicular artery and/or vasospasm. The radicular artery arises from the vertebral artery and is located along the ventral root surface. It gives rise to a medullary artery, which joins the anterior spinal artery and, in some cases, a posterior branch supplying the dorsal root ganglion. Cannulation of this branch is possible and may lead to a direct intramedullary injection of medication. Injectable particulate (Depo-Medrol) and nonparticulate (Decadron) corticosteroids are available. Direct injection of particulate

steroid into the vertebral arteries of pigs resulted in stroke, whereas injection of nonparticulate medication had no effect. These data suggest that cervical injections should be done with radiographic confirmation that intravascular needle positioning has not occurred, and they also suggest that nonparticulate steroids may be safer.

What's New in Biologic Topics Related to the Spine

Spine remains at the forefront of advances in biologics as an application to musculoskeletal disorders. Efforts continue to enhance the process of achieving spine fusion and to eliminate the need for autogenous iliac crest bone graft harvest. Since the FDA's postmarketing approval of rhBMP-2 in 2002 and Humanitarian Device Exemption for rhBMP-7 late in 2004, the use of recombinant bone morphogenetic proteins (BMPs) in spine fusion continues to grow. Given the limited access to recombinant proteins (with only two companies having approved BMPs) as well as their relatively high cost, there has been renewed interest in promoting less expensive and poorly validated alternatives. In addition, while research continues to focus on developing biologic strategies to retard or reverse intervertebral disc degeneration, these treatments remain years away from clinical practice.

Recombinant Osteoinductive Proteins

The initial clinical studies of rhBMP-7 (OP-1, Stryker Biotech, Hopkinton, Massachusetts) for posterolateral spine fusion yielded rates of successful radiographic fusion of 50% to 70%, and these modest fusion rates were attributed to the use of a "more challenging" noninstrumented spine fusion model. Data last year on surgical fusion showed a fusion success rate of approximately 50% in association with OP-1 when used for instrumented fusion, still not at a level consistently equal or superior to that associated with autograft. Data from the United States trial on the use of OP-1 for posterolateral fusion remain under review by the FDA for consideration for postmarketing approval. Only one spine study involving the use of OP-1 in addition to iliac crest autograft was published in 2007. The study involved thirty patients with cervical or lumbar pseudarthrosis. The rate of successful fusion on plain radiographs was 80%. With that study design, it was hard to discern whether OP-1 had a greater effect than iliac crest bone graft did.

Although rhBMP-2 (INFUSE; Medtronic Sofamor Danek, Memphis, Tennessee) has been approved by the FDA for anterior lumbar interbody fusion, considerable physician-directed use has occurred in the posterolateral spine. Glassman et al. reported on ninety-one patients who received 12 mg of INFUSE in a sponge wrapped around a bulking agent (local bone, allograft, hydroxyapatite/tricalcium phosphate granules, or demineralized bone matrix). In that series, 93% of the patients had radiographic fusion on thin-slice computed tomography scans. Although the difference was not significant, the local bone or allograft chips appeared to be the better

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bulking agents. In another study, the same authors reported on a higher concentration of rhBMP-2 (2.0 mg/mL), not yet clinically available, and demonstrated that this concentration achieved 100% computed tomography-based fusion success in 95% of a subgroup of patients who were smokers. Those two studies highlight a consistent trend of very high fusion rates in association with rhBMP-2. Perhaps someday the combination of rhBMP-2 with another agent such as the prostaglandin EP4 receptor agonist will allow the use of lower BMP doses. Another potential strategy that has been validated only at the rodent level is combining the natural BMPs found in demineralized bone matrix with a synergistic agent such as Nell-1 to improve the performance of the demineralized bone matrix.

A primary concern associated with the off-label use of recombinant BMPs is related to local adverse events. The three most commonly reported local side effects have been heterotopic bone formation in the surgical approach track, transient bone resorption when used near exposed cancellous bone, and sterile seroma fluid collections and/or local edema. Most of these local side effects are believed to be related to the use of more BMP as a result of either an increased concentration of the growth factor on the sponge or overstuffing of the defect with more sponge than is recommended. In the cervical spine, one report cited a twofold increase in the prevalence of moderate or severe dysphagia following the use of rhBMP-2. The true prevalence of this complication seems technique-related and manageable with systemic steroids.

INFUSE is also being used widely for lumbar transforaminal and posterior interbody fusions. In a pilot investigational device exemption study that was suspended, the authors noted some ectopic bone formation on the ventral aspect of the spinal canal related to cage prominence and reported that the finding did not correlate with an adverse clinical outcome. Wong reported the cases of five such patients who had neurologic impairment resulting from the ectopic bone, challenging the previous position that ectopic bone formation did not result in neurologic findings. Another study demonstrated vertebral osteolysis in five of sixty-eight patients within four months after transforaminal lumbar interbody fusion with rhBMP-2. In all five cases, the osteolysis was transient and symptoms and radiographic findings improved by six months postoperatively. A study by the North American Spine Society demonstrated a higher-than-expected prevalence of radiculitis two years after INFUSE usage, and this side effect will need to be closely monitored to better define its prevalence and to identify preventive strategies that are effective.

While the actual rate of INFUSE-related complications is difficult to pinpoint, fewer than 400 adverse events have been reported to Medtronic after the use of an estimated 500,000 kits of INFUSE since 2002. Certainly, there is likely to be an underreporting phenomenon, especially for the three already known local side effects. Still, the incidence of severe side effects seems to be very low and potentially may be lowered

further by dissemination of techniques for safe use as more physician-directed studies are published.

Other Bone-Graft Substitutes

Although much focus remains on recombinant osteoinductive proteins, their relatively high cost continues to drive research involving other bone-graft solutions with simpler regulatory hurdles. Yet another study demonstrating the failure of platelet concentrates to improve spine fusion healing was published this year. That study adds to a growing body of literature suggesting that platelet gels either inhibit or have no effect on spine fusion healing. While platelet gels may be useful for impaired wound-healing and possibly for diabetic foot surgery bone-grafting, their role in promoting bone formation in the spine remains highly unsubstantiated.

Demineralized bone matrix is now regulated by the FDA, resulting in a small increase in efficacy data for some formulations. However, clinical data are still quite sparse. Schizas, in a pilot clinical study of fifty-nine patients undergoing posterolateral lumbar spine fusion with instrumentation, recently reported that one type of demineralized bone matrix (Accell Connexus; IsoTis OrthoBiologics, Irvine, California) was associated with a radiographic fusion success rate (70%) that was comparable with that of iliac crest bone or local bone alone (77%). The questionable sensitivity of plain radiographs to detect nonunion in the presence of internal fixation is a weakness of that and many similar studies.

Interest in mesenchymal stem cells remains high but, because most of these products are regulated as "minimally manipulated tissues," few outcome data from rigorously designed studies are likely to be available in the near future. The studies that are under way may not include the proper controls to assess whether the stem cells are providing any increased healing in comparison with the allograft alone. These and other minimally manipulated products that are claimed to have bone-healing potential must be carefully evaluated by surgeons as the FDA does not require definitive proof of bone-enhancing capability.

Biologic Treatments for Disc Degeneration

Progress toward biologic treatments to prevent or retard disc degeneration has continued at a slow pace. Continued animal evidence of beneficial effects of recombinant BMPs (BMP-7, BMP-2, GDF-5) on disc metabolism have prompted the planning of a clinical trial to investigate the response in humans. A majority of this preclinical work has been performed with OP-1, which can prevent disc height loss after needle puncture injury or chondroitinase administration. Recent evidence of the presence of skeletal progenitor cells in degenerated human intervertebral disc material suggests that growth factor-driven therapy may not necessarily require the addition of exogenous cells. One study demonstrated preliminary results in association with the use of platelet-rich plasma and biodegradable gelatin hydrogel microspheres to retard injury-

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induced disc degeneration in rabbits. An interim report on a small pilot clinical trial in which autologous disc chondrocytes were injected twelve weeks after lumbar discectomy showed that the patients who had received chondrocyte injections had less low back pain than controls did at two years. These biologic disc solutions, which likely will have complex regulatory hurdles, will need to outperform more simplistic tissue-engineered solutions involving the injection of cross-linked scaffolds and polymers.

What's New in Spinal Deformity Surgery

This past year, attendance records were broken for the Scoliosis Research Society (SRS) annual meeting in Edinburgh, Scotland, and the International Meeting on Advanced Spine Techniques (IMAST) in the Bahamas. We are all still very saddened by the passing of Thomas Lowe, MD, who was to be President of the SRS for 2007 to 2008. His leadership is sorely missed.

Idiopathic Scoliosis

The ideal surgical treatment for false double-major curves continues to evolve. There are data to suggest that treating thoracic curves anteriorly results in more of a true spontaneous correction of the lumbar curve, but there is more morbidity in association with an anterior surgical approach than there is in association with a posterior surgical approach. The outcomes are better if the thoracic spine is selectively fused as opposed to fusing well into the lumbar spine or fusing both curves.

The use of thoracic pedicle screws results in potentially more correction than can be achieved with hooks and wires or with a hybrid construct of hooks and screws. It is debatable whether a 55% or 65% correction is of any clinical importance, but if the pedicle screw technique can allow the surgeon to avoid an anterior operation or save distal fusion segments, there is a substantial benefit. There is still concern that thoracic pedicle screws carry more risk than wires or hooks do, but to date no reports have suggested the thoracic screw technique is associated with a higher rate of neurologic deficit. Another complication unique to pedicle screws is the risk to the great vessels.

The most widely used clinical outcome measure for idiopathic scoliosis is the SRS patient-assessment questionnaire. This is variably used with either twenty-two, twenty-four, or thirty questions. For a high percentage of adolescent patients, the instrument does not demonstrate a substantial improvement. In fact, one study suggested that patients with idiopathic scoliosis reported more pain at five years than at two years after surgical treatment.

Measures to assess the patient's skeletal maturity continue to generate substantial interest. There is increasing interest in the assessment of the triradiate cartilage on a pelvic radiograph and the wrist, fingers, and metacarpals on a hand radiograph, and now there is interest in using the olecranon to

assess the proximity to skeletal maturity and the end of peak growth velocity.

Adult Spinal Deformity

How to reduce the pseudarthrosis rate with a long fusion in the adult patient and how to achieve a solid fusion at L5-S1 continue to generate research. The role of iliac screws or a second pair of sacral screws and anterior column support at L5-S1 is a topic of interest. Also, analysis of the decision of whether to stop a long fusion at L5 or S1 continues to evolve. The answer to stopping at L5 or S1 is difficult to study without prospective multicenter randomization and five to ten years of follow-up.

The use of biologics for the treatment of deformity in adults is becoming more widespread, although very few data have been published. However, difficulties with studying the use of bone morphogenetic proteins for the treatment of spinal deformities in adults include the high expense associated with the use of a substantial dose and the difficulty of assessing a multilevel fusion with use of radiographs.

Improvement and/or maintenance of sagittal balance in an adult patient with a spinal deformity remains a substantial challenge. Predicting the ideal balance is quite difficult. It is somewhat dependent on the thoracic kyphosis, the pelvic incidence, and the number of levels being fused. A percentage of patients who have fusion of only the lumbar curve will subsequently decompensate because of progressive kyphosis of the thoracic spine.

There is evolving evidence that the SRS instrument is quite responsive to change brought on by the operative treatment of deformity in the adult population. This is in distinct contrast to the findings in the adolescent population. However, there are no current data to assess whether or not the instrument is responsive to nonoperative treatment of spinal deformity in the adult patient.

Severe Deformities

The use of pedicle screw implants facilitates the treatment of severe deformity, defined as a scoliosis curve of $>100^\circ$ or a sagittal kyphosis of $>120^\circ$. In addition, halo-gravity and halo-femoral traction may have a role and vertebral column resection is an option for these severe deformities. One report at the recent SRS meeting in Edinburgh suggested that resection procedures could be performed with a more acceptable amount of blood loss with use of an antifibrinolytic, such as aprotinin. Unfortunately, aprotinin is no longer available. Although anterior release has been considered a necessary and helpful ingredient in the correction of large curves, there is currently a strong trend away from it and toward more reliance on posterior release (osteotomy and spinal shortening) techniques.

Congenital Spinal Deformity

Resection of the hemivertebra in cases of failure of formation continues to be regarded as a valuable and safe operation in a

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young patient. Answers to the question of whether resection should be performed through an all-posterior approach, separate anterior and posterior approaches, or perhaps an anterior-only approach continue to evolve. When a patient has a unilateral failure of vertebral segmentation, the prognosis and natural history are not entirely predictable. Patients with multiple failures of formation and segmentation in the thoracic spine are at risk for thoracic insufficiency syndrome. Addressing the deformity with primary spinal or rib-cage lengthening still has no clear answer, although rib-cage lengthening is currently generating more attention.

Neuromuscular Scoliosis

The use of corticosteroid treatment for Duchenne muscular dystrophy has reduced the need for surgical treatment of the associated spinal deformity. The effect of correction of the spinal deformity on respiratory function remains difficult to quantitate. There is evolving evidence that the use of an anti-fibrinolytic agent during neuromuscular scoliosis surgery can significantly decrease operative blood loss. For some of these patients, particularly those with cerebral palsy, spinal cord monitoring is challenging, and there may be a benefit associated with the use of transcranial motors. For a patient with cerebral palsy, it appears that a preexistent baclofen pump will increase the risk of complications if deformity fusion is subsequently performed.

Spondylolisthesis

There is no clear indication for when to reduce a high-grade spondylolisthesis as opposed to performing a fusion with mild correction of the slip angle. Factors associated with ideal sagittal balance and the risk of deformity progression in a young patient are being extensively researched, and a classification system is being studied in a multicenter fashion. Considerations include dysplasia of the L5 lamina, the extent and nature of the remodeling of the sacral dome, and the pelvic incidence.

What's New in Spinal Cord Injury

Over the last year, researchers have continued to study the basic science and clinical aspects of spinal cord injury. Of particular note, there has been an increased focus on quality evidence-based research and the development and validation of outcome measures that facilitate evidence-based outcomes research.

Outcome Measures

The availability of quality outcome measures of the various aspects of spinal cord injury is essential to the advancement of this research. With this in mind, the SCI Meeting Measures Group convened in 2006 to discuss outcome measures in several key areas. Select peer-reviewed proceedings from this meeting were published in *The Journal of Spinal Cord Medicine* in 2007. One of these articles was an evidence-based literature review on the use of neuroimaging in the setting of acute spinal

cord injury. The goal of that review was to provide clinicians and researchers with recommendations and guidelines for the use of neuroimaging modalities to assess spinal cord injury. The authors reviewed 2300 published reports on the use of neuroimaging for the evaluation of spinal cord injury, ninety-nine of which were either clinical studies (sixty-nine), pre-clinical studies (twenty-three), or review articles (seven) in which neuroimaging was a key component of the outcome measure (or measures). On the basis of their systematic review of the literature, the authors made a number of recommendations and comments: (1) magnetic resonance imaging remains the test of choice for locating the level of a spinal cord injury and assessing the amount of compression on the spinal cord, (2) the severity of cord injury on magnetic resonance imaging (i.e., evidence of cord edema, contusion, hemorrhage, and disruption) correlates with the degree of motor and sensory impairment and is helpful for determining the prognosis for neurological recovery, (3) diffusion-weighted magnetic resonance imaging can detect axonal integrity and swelling and can be used to quantify the amount of axonal loss following spinal cord injury, (4) functional magnetic resonance imaging can detect motor and sensory activity in the injured spinal cord, and (5) plain radiographs and computed tomography scans should be used to evaluate osseous injury but do not provide useful information regarding the injured spinal cord.

While discussing imaging, it is important to note that a novel classification system for injuries of the subaxial cervical spine, referred to as the Subaxial Injury Classification (SLIC) and Severity Scale, was recently developed by the Spine Trauma Study Group. In this system, injuries are classified according to three main categories: (1) the injury morphology as determined on the basis of plain radiographs, computed tomography, and magnetic resonance imaging; (2) the integrity of the discoligamentous complex, which consists of the intervertebral disc, anterior and posterior longitudinal ligaments, ligamentum flavum, interspinous and supraspinous ligaments, and facet capsules; and (3) the neurological status of the patient. The three main morphologies include compression, distraction, and translation/rotation. The discoligamentous complex is categorized as intact, disrupted, or indeterminate. The integrity of the discoligamentous complex is best assessed by using all available imaging studies to look for evidence of a widened space between the spinous processes, disc-space widening, vertebral subluxation, and subluxation or dislocation of the facet joints. The neurologic status of the patient is described as intact, nerve-root injury, complete, or incomplete. A point system is used to quantify the injury of the cervical spine and to help to guide treatment. This system has been shown to have moderate to substantial intraobserver and interobserver reliability and excellent construct validity (>90%). It is hoped that this classification system will improve communication and facilitate quality research regarding injury of the cervical spine.

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Pain is one of the most common and debilitating problems encountered in patients with a spinal cord injury. A study presented at the 2007 annual American Spinal Injury Association (ASIA) meeting evaluated chronic pain in thirty patients who had sustained a spinal cord injury more than one year previously and highlighted the overwhelming need to improve pain management both during post-injury rehabilitation and after transition into the community. For both clinical and research purposes, therefore, it is important to be able to reliably measure pain in these patients. A recent systematic review of the literature evaluated the reliability and validity of outcomes measures for pain following spinal cord injury. On the basis of their review, the authors found that the numeric rating scale (0 to 10 points) was the most reliable for assessing pain intensity in patients with spinal cord injury. The 7-point Patient Global Assessment of Change (PGAC) scale was the best measure for the evaluation of global improvement in terms of pain. The authors recommended the use of either the International Association for the Study of Pain (IASP) or the Bryce/Ragnarsson SCI pain taxonomies when classifying pain in patients with a spinal cord injury.

Numerous rating scales that address general health, function, and quality of life have been developed and refined over the last several years, with a considerable amount of redundancy. Despite these efforts, no single scale has been widely accepted in spinal cord injury research. Work is currently under way to develop reliable and valid outcome measures of general health, function, and quality of life that are tailored specifically to patients with spinal cord injury.

Clinical Outcome Studies

Many of the clinical outcome studies of patients with spinal cord injury that were presented at the 2007 annual ASIA meeting evaluated psychosocial and quality-of-life issues. In one study, patients who returned to work following a spinal cord injury were compared with those who did not return to work following such an injury. Only 21% of patients returned to work within three years after the post-injury rehabilitation. Most of the patients who returned to work had a college-level education and had worked in a nonmanual labor setting before the injury. That study emphasized the importance of counseling patients who have a lower level of education and/or who worked in a manual labor setting. Another study evaluated long-term life satisfaction among 251 adults who had sustained a spinal cord injury during childhood or adolescence. Satisfaction was significantly higher among women, those who were married, and those who were employed. Satisfaction was significantly lower among those who used illicit drugs, those who had been injured at an older age, those who lived with their parents, and those who had pressure sores during the last year. These findings can be helpful for guiding rehabilitation and counseling strategies for patients who sustain a spinal cord injury at a young age. A similar study evaluated the educational achievements of 350 adults who had sustained a spinal cord

injury at a young age. For individuals with quadriplegia as well as those with paraplegia, a higher level of education was significantly associated with greater employment, income, and community participation. These findings further emphasize the importance of education with regard to quality of life following a spinal cord injury. In a study that evaluated the association of walking and independence with health, participation, and subjective well-being outcomes following spinal cord injury, independence in mobility was surprisingly associated with significantly better outcomes than was the ability to walk.

Emerging Therapies

Post-injury therapy is one of the most important aspects of care for patients who have sustained a spinal cord injury. Various therapy strategies to maintain and potentially regain strength, flexibility, and the ability to walk have been described in the past. Locomotive training (also known as body weight-supported treadmill training or suspended treadmill training) has recently received considerable attention in the literature. This form of therapy involves harness suspension of the patient over a moving treadmill in order to provide the repetitive sensory experience of walking. The theory is that this sensory stimulation can facilitate recovery of motor function that may improve walking ability in patients with an incomplete spinal cord injury. A neural network within the spinal cord, which, in itself, is capable of producing rhythmic motor-patterned outputs (i.e., the human locomotion spinal pattern generator), is thought to be responsible for the improved walking function achieved through locomotive training.

Several studies presented at the 2007 annual ASIA meeting evaluated various aspects of locomotive training. A feasibility study of twenty-eight patients who underwent locomotive training following a spinal cord injury demonstrated, on the basis of reimbursement rates and actual costs, that this type of therapy was a fiscally feasible form of treatment despite the personnel and resources required. Studies also demonstrated the clinical success of this type of therapy. A recent case report documented the restoration of walking ability in a four and one-half-year-old child following a severe spinal cord injury that resulted in a C8-level ASIA C injury. After seventy-six sessions of locomotive therapy, the patient was able to walk as many as 2400 steps per day with a rolling walker, despite a persistent inability to voluntarily activate lower extremity movements. That case report supports the presence of a human locomotion spinal pattern generator, which, with appropriate sensory stimulation, can initiate the rhythmic, patterned movement necessary for walking. Twenty-four patients with an incomplete motor spinal cord injury who had the ability to generate a rhythmic stepping pattern were studied. Those patients showed a significant recovery of walking function during six-minute and 10-m walking tests following a standardized locomotive training program.

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Neuroprotective Treatments

Efforts to develop pharmacological, biological, and physiological means to prevent secondary spinal cord injury and to improve the recovery of function following spinal cord injury continue to be evaluated. Although high-dose methylprednisolone continues to be routinely administered at many spinal cord injury centers according to the accepted protocols, its use remains controversial because of the lack of clinical data to support its efficacy and the associated complications that have been reported. Many of the preclinical results of stem-cell and immune-based therapies for spinal cord injury are promising. Large, multicenter clinical trials are necessary, however, to determine the efficacy of these interventions for the treatment of spinal cord injury in humans. Following the spinal cord injury sustained by the Buffalo Bills' tight end Kevin Everett during a National Football League game, therapeutic hypothermia for the treatment of acute spinal cord injury has received much attention in the public media. Theoretically, by giving an intravenous infusion of cold fluid and inducing a moderate hypothermia, this treatment minimizes the swelling and secondary injury of the spinal cord and facilitates functional recovery. There is currently no standardized protocol for this therapy in terms of its induction, the degree of hypothermia, or duration. Although preclinical animal studies of therapeutic hypothermia have shown some evidence of success, clinical data do not support its efficacy, and the clinical application of therapeutic hypothermia is not currently recommended for routine use in patients who have sustained a spinal cord injury.

What's New in the Treatment of the Lumbar Spine

Disorders of the lumbar spine continue to present some of the most common and clinically important problems faced by a large percentage of the population. Recent studies have highlighted research into a better understanding of the pathogenesis of the degenerative process, and novel technologies designed to treat such pathology continue to proliferate. Furthermore, longer-term results have demonstrated the efficacy of some of these approaches.

Outcomes

Lumbar total disc arthroplasty has been a very controversial topic over the past few years, with several studies demonstrating equivalence to spinal fusion. A recent multicenter study examining the Maverick prosthesis showed that lumbar total disc arthroplasty was superior to fusion with regard to key clinical outcomes scores, back pain scores, patient satisfaction, and earlier return to work. Additional studies may need to demonstrate more than equivalence to fusion in terms of patient outcomes scores in order for this procedure to gain more sustained clinical acceptance.

Because of the challenges with defining success after spinal surgery, spine surgeons from Stanford University presented their model for minimum acceptable outcomes after

surgery. That study focused on establishing the validity of patient-determined minimum acceptable outcomes as a criterion of surgical success rather than using the typical arbitrary benchmarks of patient measurement scales, which may not equate to clinical improvement. That study examined and proposed new criteria for assessment following spinal surgery, and it was thought to be more reflective of global success, which may not be measurable by functional improvement, earlier return to work, or a decrease in pain medications. Certainly, that study is making spine practitioners reconsider outcomes measurements.

Growth Factors for Spinal Fusion

The use of growth factors instead of autogenous bone graft for lumbar fusion is increasing, especially the use of BMPs. The off-label usage appears to be increasing, and several studies with longer-term results were presented this past year.

The use of BMP-2 for transforaminal lumbar interbody fusion was shown to be associated with increased postoperative radiculitis. The authors presented the results of a study in which thirty-nine patients who were managed with BMP were compared with a control group of twenty-nine patients who were managed with autogenous iliac crest bone graft. The two groups were very similar, but the prevalence of postoperative radiculitis was significantly greater in the BMP group than in the control group (23% compared with 3%). The average duration of these symptoms was more than thirteen months, which can present some clinically important issues.

Another study from St. Louis examined a group of ninety-two patients who were managed with repeat use of BMP-2 in the spine after having had a previous spinal fusion with BMP-2. There is always a theoretical concern regarding the repeat exposure of patients to BMPs, with the possibility of antibody formation and a hypersensitivity response. In that retrospective study, there was not a clinically important effect of repeated exposure to BMP-2 as compared with the findings in a control group, and there did not appear to be any issue with safety or efficacy, regardless of the timing of the second dose.

A prospective multicenter study investigated the use of BMP-2 with a collagen sponge wrapped around ceramic granules as a bulking agent for lumbar posterolateral fusion compared with a control group with autogenous iliac crest bone graft. For this off-label usage, twenty-five patients were managed with the BMP-2, whereas twenty-one were in the control group. There were no adverse events, and the fusion rate in the BMP-2 group was higher than that in the control group (81% compared with 60%). The outcomes measures all favored the BMP-2 group over the control group.

A group of investigators from Los Angeles reported on the use of a bone morphogenetic binding protein (BBP) combined with BMP-2 for spinal fusion. This protein appears

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to bind and retain the BMP in the surgical site and also potentiates the osteogenic ability of the BMPs. That animal study showed that BBP combined with a low dose of BMP-2 had additive effects and significantly increased the fusion rates in comparison with BMP-2 alone. This may allow the use of decreased BMP-2 dosages in humans in the future and hence potentially decrease side effects.

Complications

Anterior retroperitoneal approaches to the lumbar spine are associated with sexual dysfunction in men. One group studied this problem in women. That study, which included thirty women who were managed with an anterior retroperitoneal approach, demonstrated a 6.7% prevalence of postoperative sexual dysfunction; however, the dysfunction appeared to be well tolerated.

Another group examined the overall rate of vascular complications following procedures performed with and without the involvement of a vascular access surgeon. Overall, they found that 6% of patients had an intraoperative vascular complication, but there was no significant difference between procedures in which the approach had been performed by a vascular access surgeon and those in which it had been performed by the spine surgeon. The investigators concluded that there was no need to mandate the use of a vascular access surgeon if the spine surgeon was sufficiently trained to perform the approach.

Evidence-Based Orthopaedics

The editorial staff of *The Journal* reviewed a large number of recently published research studies related to the musculoskeletal system that received a Level of Evidence grade of I. Over 100 medical journals were reviewed to identify these articles, all of which have high-quality study design. In addition to articles published previously in this journal or cited already in this Update, nineteen additional level-I articles were identified that were relevant to spine surgery. A list of those titles is appended to this review following the standard bibliography. We have provided a brief commentary about each of the articles to help to guide your further reading, in an evidence-based fashion, in this subspecialty area.

Upcoming Meetings and Events Related to Spine Surgery

The forty-third Annual Meeting of the Scoliosis Research Society (SRS) will be held on September 10 through 13, 2008, at the Grand America Hotel in Salt Lake City, Utah. It will be preceded by a one-day course entitled "Osteobiologics," to be held on September 8, 2008. Web site: www.srs.org

The twenty-third Annual Meeting of the North American Spine Society (NASS) will be held on October 14 through 18, 2008, at the Metro Toronto Convention Centre in Toronto, Ontario, Canada. Web site: www.spine.org

The thirty-sixth Annual Meeting of the Cervical Spine Research Society (CSRS) will be held on December 4 through 6, 2008, at the Renaissance Austin Hotel in Austin, Texas. It will be preceded by an Instructional Course sponsored by the Cervical Spine Research Society, to be held on December 3, 2008, at the Renaissance Austin Hotel in Austin, Texas.

Web site: www.csr.org

The Federation of Spine Associations will present the spine program on Specialty Day at the Annual Meeting of the American Academy of Orthopaedic Surgeons (AAOS), to be held on Saturday, February 28, 2009, in Las Vegas, Nevada.

Web site: www.aaos.org

The Annual Meeting of The International Society for the Study of the Lumbar Spine (ISSLS) will be held on May 4 through 8, 2009, in Miami, Florida. Web site: www.issls.org

The sixteenth Annual International Meeting on Advanced Spine Techniques (IMAST) will be held on July 15 through 18, 2009, in Vienna, Austria. Web site:

www.imastonline.com

The thirty-fifth Annual Meeting of the American Spinal Injury Association (ASIA) and the United Spinal Association (USA) will join forces in 2009 to present "Congress on Spinal Cord Medicine and Rehabilitation." The Congress will be held on September 22 through 26, 2009, in Dallas, Texas. Web site: www.asia-spinalinjury.org

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WHAT'S NEW IN SPINE SURGERY

Suggested Reading List

1. Bracken MB, Shepard MJ, Holford TR, Leo-Summers L, Aldrich EF, Fazl M, Fehlings M, Herr DL, Hitchon PW, Marshall LF, Nockels RP, Pascale V, Perot PL Jr, Piepmeier J, Sonntag VK, Wagner F, Wilberger JE, Winn HR, Young W. Administration of methylprednisolone for 24 or 48 hours or tirilazad mesylate for 48 hours in the treatment of acute spinal cord injury. Results of the Third National Acute Spinal Cord Injury Randomized Controlled Trial. National Acute Spinal Cord Injury Study. *JAMA*. 1997;277:1597-1604.
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3. Bracken MB. Methylprednisolone in the management of acute spinal cord injuries. *Med J Aust*. 1990;153:368.
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9. Everett CR, Patel RK. A systematic literature review of nonsurgical treatment in adult scoliosis. *Spine*. 2007;32(19 Suppl):S130-4.
10. Fisher CG, Wood KB. Introduction to and techniques of evidence-based medicine. *Spine*. 2007;32(19 Suppl):S66-72.
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23. Weinstein JN, Tosteson TD, Lurie JD, Tosteson AN, Hanscom B, Skinner JS, Abdu WA, Hilibrand AS, Boden SD, Deyo RA. Surgical vs nonoperative treatment for lumbar disk herniation: the Spine Patient Outcomes Research Trial (SPORT): a randomized trial. *JAMA*. 2006;296:2441-50.

Evidence-Based Articles
Related to Spine Surgery

Aminmansour B, Khalili HA, Ahmadi J, Nourian M. Effect of high-dose intravenous dexamethasone on postlumbar discectomy pain. *Spine*. 2006;31:2415-7.

Sixty-one patients undergoing lumbar discectomy were randomly assigned to receive 40 mg of dexamethasone intravenously, 80 mg of dexamethasone intravenously, or placebo following the skin incision. Based on a visual analog pain scale one day after surgery, the mean radicular pain score was decreased by 4.26 and 4.15 points in the two dexamethasone groups and by only 2.73 points in the control group ($p = 0.006$). The mean total morphine used was lower in the 80-mg group than in the control group ($p = 0.012$). Thus, intraoperative intravenous dexamethasone can reduce postoperative radicular pain and narcotic usage in the first twenty-four hours after single-level discectomy.

Autio RA, Karppinen J, Niinimäki J, Ojala R, Veeger N, Korhonen T, Hurri H, Tervonen O. The effect of infliximab, a monoclonal antibody against TNF-alpha, on disc herniation resorption: a randomized controlled study. *Spine*. 2006;31:2641-5.

A report was generated with use of data from the FIRST II study (Finnish Infliximab Related Study). In that randomized controlled study, infliximab (a monoclonal antibody against tumor necrosis factor-alpha) was

compared with placebo for the treatment of disc-herniation-induced sciatica in patients who were considered to be candidates for discectomy. Magnetic resonance imaging was performed for twenty-one patients at Weeks 0, 2, 12, and 26 following treatment. Eleven patients received a single infusion (5 mg/kg) of infliximab, and ten received placebo. The authors found that the volume of the herniated disc reduced in both groups over time, with no difference noted between the groups. They concluded that infliximab does not interfere with resorption of disc herniation.

Bernaards CM, Ariens GA, Knol DL, Hildebrandt VH. The effectiveness of a work style intervention and a lifestyle physical activity intervention on the recovery from neck and upper limb symptoms in computer workers. *Pain*. 2007;132:142-53.

Bernaards et al. performed a randomized controlled study of the effectiveness of work style intervention and physical activity on recovery from neck and upper extremity pain in computer workers. Four hundred and sixty-eight patients were randomized into three groups: (1) the work style group, (2) the work style and physical therapy group, and (3) the usual care group. The results were conflicting. The patients in the work style alone group had better relief of symptoms in comparison with those in the other two groups; however, no difference was noted in terms of physical activities. Therefore, this study showed the limited effectiveness of work style and exercise on recovery from neck pain.

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Braun J, Zochling J, Baraliakos X, Alten R, Burmester G, Grasedyck K, Brandt J, Haibel H, Hammer M, Krause A, Mielke F, Tony HP, Ebner W, Gömör B, Hermann J, Zeidler H, Beck E, Baumgaertner M, Sieper J. Efficacy of sulfasalazine in patients with inflammatory back pain due to undifferentiated spondyloarthritis and early ankylosing spondylitis: a multicentre randomized controlled trial. *Ann Rheum Dis.* 2006;65:1147-53.

Patients with inflammatory back pain due to active undifferentiated spondyloarthritis or ankylosing spondylitis were randomly assigned to twenty-four weeks of treatment with sulfasalazine (2 g/day) or placebo. Peripheral arthritis was present in 47% of the subjects. No noticeable difference in treatment outcome was observed between the groups overall. However, in the subset of patients with inflammatory back pain and no peripheral arthritis, sulfasalazine was more effective than placebo.

Chow RT, Heller GZ, Barnsley L. The effect of 300 mW, 830 nm laser on chronic neck pain: a double-blind, randomized, placebo-controlled study. *Pain.* 2006;124:201-10.

Ninety subjects with chronic neck pain were randomized to receive a course of fourteen treatments over seven weeks with either active or sham laser to tender areas of the neck. The mean visual analog pain scores improved by 2.7 in the low-level laser treatment group and worsened by 0.3 in the control group. There was no difference between the groups in terms of SF-36 scores. The optimal design of this study suggests that this treatment warrants additional study.

Clarke JA, van Tulder MW, Blomberg SE, de Vet HC, van der Heijden GJ, Bronfort G, Bouter LM. Traction for low-back pain with or without sciatica. *Cochrane Database Syst Rev.* 2007;2:CD003010.

This systematic review of the literature was performed to determine the effectiveness of traction as compared with sham, placebo, reference treatments, or no treatments for patients with low back pain. The authors concluded that traction as a single treatment is not likely to be effective for patients with acute, subacute, and chronic low back pain and that traction cannot be judged as effective for patients with sciatica on the basis of the currently available evidence.

Djavid GE, Mehrdad R, Ghasemi M, Hasan-Zadeh H, Sotoodeh-Manesh A, Pouryaghoob G. In chronic low back pain, low level laser therapy combined with exercise is more beneficial than exercise alone in the long term: a randomized trial. *Aust J Physiother.* 2007;53:155-60. Erratum in: *Aust J Physiother.* 2007;53:216.

Low-level laser therapy is thought to relieve musculoskeletal pain by means of an anti-inflammatory effect, reduction of interstitial swelling, and stimulation of ligament healing. In this study, the authors performed a randomized controlled trial to compare low-level laser treatment, low-level laser treatment combined with exercise, and placebo laser combined with exercise for patients who had had isolated low back pain for twelve weeks. Laser treatment combined with exercise had a small but significant benefit compared with exercise or placebo only. The effect size was small, but the study did provide justification for future investigation of low-level laser treatment.

Eisenberg DM, Post DE, Davis RB, Connelly MT, Legedza AT, Hrbek AL, Prosser LA, Buring JE, Inui TS, Cherkin DC. Addition of choice of complementary therapies to usual care for acute low back pain: a randomized controlled trial. *Spine.* 2007;32:151-8.

In this prospective randomized study, the usual conservative treatment of low back pain was compared with a treatment plan that gives patients with back pain a choice of either acupuncture, chiropractic, or massage therapy in addition to the usual treatment. The authors found that there was no difference between the groups at five weeks in terms of symptoms and functional status. The group of patients who had a choice in treatment had greater satisfaction but also had an increased cost of treatment.

Ferreira ML, Ferreira PH, Latimer J, Herbert RD, Hodges PW, Jennings MD, Maher CG, Refshauge KM. Comparison of general exercise, motor

control exercise and spinal manipulative therapy for chronic low back pain: a randomized trial. *Pain.* 2007;131:31-7.

The authors performed a randomized controlled study comparing general exercise, motor core control exercise of paraspinal muscles, and manipulative therapy in patients with chronic low back pain. The motor core control exercise and manipulative therapy had a very small positive effect at eight weeks, but there was no difference among the groups at six and twelve months. Similar to the findings of other studies targeting specific muscle groups or spinal regions, there does not appear to be a benefit over general exercise in patients with chronic low back pain.

Hancock MJ, Maher CG, Latimer J, McLachlan AJ, Cooper CW, Day RO, Spindler MF, McAuley JH. Assessment of diclofenac or spinal manipulative therapy, or both, in addition to recommended first-line treatment for acute low back pain: a randomised controlled trial. *Lancet.* 2007;370:1638-43.

Hancock et al. performed a randomized controlled study of patients with acute low back pain to compare four different treatment groups: diclofenac plus spinal manipulation, diclofenac plus placebo manipulation, spinal manipulation plus placebo, and double placebo. No group experienced an improved outcome compared with the others. Thus, it does not appear that spinal manipulation or diclofenac resulted in faster recovery over placebo in patients with acute low back pain.

Kumar K, Taylor RS, Jacques L, Eldabe S, Meglio M, Molet J, Thomson S, O'Callaghan J, Eisenberg E, Milbouw G, Buchser E, Fortini G, Richardson J, North RB. Spinal cord stimulation versus conventional medical management for neuropathic pain: a multicentre randomised controlled trial in patients with failed back surgery syndrome. *Pain.* 2007;132:179-88.

The effectiveness of spinal cord stimulation in patients with failed back surgery syndrome who have ongoing neuropathic pain was assessed. One hundred patients were randomized to spinal cord stimulation combined with conventional medical management or conventional medical management alone. At six months, 48% of patients who had been managed with spinal cord stimulation achieved the goal of >50% pain reduction, compared with only 9% of those who had received conventional management. The authors justifiably concluded that in selected patients with failed back surgery syndrome, spinal cord stimulation provides better pain relief and improved quality of life and functional capacity compared with standard medical management.

Malmivaara A, Slätis P, Heliövaara M, Sainio P, Kinnunen H, Kankare J, Dalin-Hirvonen N, Seitsalo S, Herno A, Kortekangas P, Niinimäki T, Rönty H, Tallroth K, Turunen V, Knekt P, Härkänen T, Hurri H; Finnish Lumbar Spinal Research Group. Surgical or nonoperative treatment for lumbar spinal stenosis? A randomized controlled trial. *Spine.* 2007;32:1-8.

A randomized controlled trial that compared decompressive surgery (n = 50) with conservative treatment (n = 44) for lumbar spinal stenosis with follow-up at six, twelve, and twenty-four months was conducted. Both groups demonstrated improvement in the Oswestry Disability Index, leg and back pain, and walking ability. Patients undergoing surgery had greater improvement in terms of leg and back pain as well as the Oswestry Disability Index. This improvement diminished over time, but it was still significant at the time of the two-year follow-up.

Parker MJ, Livingstone V, Clifton R, McKee A. Closed suction surgical wound drainage after orthopaedic surgery. *Cochrane Database Syst Rev.* 2007;3:CD001825.

Parker et al. performed a systematic review with use of Cochrane methodology on the effectiveness of closed suction drainage in orthopaedic surgery. They included thirty-six studies with 5464 patients involving a broad spectrum of orthopaedic procedures. No differences were noted between the groups managed with and without drainage. No differences in adverse events such as wound infection, hematoma, dehiscence or reoperations were present; however, blood transfusions were more common when drains were used, and the need for dressing changes was more common when drains were not used.

WHAT'S NEW IN SPINE SURGERY

Peul WC, van Houwelingen HC, van den Hout WB, Brand R, Eekhof JA, Tans JT, Thomeer RT, Koes BW; Leiden-The Hague Spine Intervention Prognostic Study Group. Surgery versus prolonged conservative treatment for sciatica. *N Engl J Med.* 2007;356:2245-56.

In this prospective study, patients with severe sciatica were randomized to either early surgery or prolonged conservative treatment. There were no significant overall differences in disability scores during the first year between patients assigned to early surgery and those assigned to conservative treatment with eventual surgery. However, there was faster relief of leg pain and a faster rate of perceived recovery for patients assigned to early surgery.

Ratcliffe J, Thomas KJ, MacPherson H, Brazier J. A randomised controlled trial of acupuncture care for persistent low back pain: cost effectiveness analysis. *BMJ.* 2006;333:626.

This was a cost-effectiveness analysis of a randomized controlled study of three private acupuncture clinics and eighteen general practices in York, England. The analysis showed a mean incremental health gain from acupuncture at twenty-four months of 0.027 quality-adjusted life years (QALYs) for a base estimate of 4241 pounds sterling (\$8300 in United States dollars) per QALY gained. The authors concluded that a short course of traditional acupuncture for persistent low back pain in primary care confers a modest health benefit for a minor extra cost as compared with usual care. A related investigation involving the same study population showed a small benefit of acupuncture at twenty-four months.

Sasso RC, Smucker JD, Hacker RJ, Heller JG. Artificial disc versus fusion: a prospective, randomized study with 2-year follow-up on 99 patients. *Spine.* 2007;32:2933-42.

This report describes twenty-four-month follow-up of a three-center subset of patients from a larger Food and Drug Administration trial of the Bryan cervical disc replacement. Patients were randomized to receive cervical disc replacement or anterior cervical discectomy and fusion with allograft and a plate. The Bryan group showed small but significantly greater improvement in the Neck Disability Index, neck and arm pain visual analog scores, and the SF-36 physical component score. The two-year data from this limited group of experienced surgeons are positive. The key questions that remain to be answered are whether this success will persist in the hands of less skilled surgeons, whether the small early advantages of Bryan disc replacement will persist at longer time points, and whether or not cervical disc replacement will decrease the frequency of adjacent-level degeneration compared with cervical fusion.

Videbaek TS, Christensen FB, Soegaard R, Hansen ES, Høy K, Helmig P, Niedermann B, Eiskjoer SP, Bünger CE. Circumferential fusion improves outcome in comparison with instrumented posterolateral fusion: long-term results of a randomized clinical trial. *Spine.* 2006;31:2875-80.

In this prospective randomized study, circumferential fusion was compared with posterolateral fusion with instrumentation for the treatment of chronic low back pain. At five to nine years of follow-up, the circumferential fusion group showed significantly better improvement than the posterolateral fusion group in terms of the selected outcome and low back pain scores. There was no difference in the SF-36 mental health component or the leg pain score.

Weinstein JN, Lurie JD, Tosteson TD, Skinner JS, Hanscom B, Tosteson AN, Herkowitz H, Fischgrund J, Cammisa FP, Albert T, Deyo RA. Surgical vs nonoperative treatment for lumbar disk herniation: the Spine Patient Outcomes Research Trial (SPORT) observational cohort. *JAMA.* 2006;296:2451-9.

This paper presents the as-treated analysis of the Spine Patient Outcomes Research Trial (SPORT), a randomized trial comparing operative with nonoperative treatment for lumbar disc herniation. Patients in both groups showed improvement in clinical outcomes. At three months, patients in the operative treatment group had greater improvement in clinical outcomes, including bodily pain, physical function, and the Oswestry Disability Index. These improvements, although still present and greater than in the nonoperative treatment group, were diminished at the time of the two-year follow-up. There was a very high crossover rate among the two treatment groups, and therefore the outcomes are subject to confounding factors.

Weinstein JN, Lurie JD, Tosteson TD, Hanscom B, Tosteson AN, Blood EA, Birkmeyer NJ, Hilibrand AS, Herkowitz H, Cammisa FP, Albert TJ, Emery SE, Lenke LG, Abdu WA, Longley M, Errico TJ, Hu SS. Surgical versus nonsurgical treatment for lumbar degenerative spondylolisthesis. *N Engl J Med.* 2007;356:2257-70.

This was a multicenter study of patients with symptomatic degenerative spondylolisthesis. The patients were enrolled in either a randomized cohort or an observation cohort, and the treatment consisted of either operative care (laminectomy with or without fusion) or nonoperative care. There were a total of 607 patients in the study. The intention-to-treat analysis for the randomized cohort showed no significant effects for the primary outcomes. The as-treated analysis for both cohorts combined showed a significant advantage for surgery at three months, which increased at one year and diminished only slightly at two years. The conclusions for this group of patients were that operative treatment was associated with a substantially greater improvement in terms of pain and function than nonoperative treatment in this two-year period.