

7-1-2009

## What's new in spine surgery

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### Recommended Citation

Bridwell, Keith H.; Anderson, Paul A.; Boden, Scott D.; Vaccaro, Alexander R.; and Wang, Jeffrey C., "What's new in spine surgery." *The Journal of Bone and Joint Surgery*. 91, 7. 1822-1834. (2009).  
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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**

Many controversies still exist with regard to the surgical treatment of cervical spine pathology. The role of allograft, autograft, plate fixation, and bone morphogenetic protein is not entirely clear. There is still debate about the surgical treatment of myelopathy anteriorly as opposed to posteriorly. Clearly, there is substantial anatomic variation in the location of the vertebral artery. Disc arthroplasty for the cervical spine continues to appear to be a viable option for patients with single-level pathology.

**Anterior Cervical Fusion**

Despite interest in motion preservation, cervical fusion remains a common and highly successful surgical approach for the treatment of radiculopathy and myelopathy. Recently reported clinical outcomes following single-level fusion have shown that a substantial reduction in pain and disability occurs in about 90% of cases. Improvement in overall health-related quality of life, as measured with the Short Form-36 (SF-36), was substantial compared with that occurring after total hip or total knee arthroplasty. Multivariable analysis showed that the presence of litigation and narcotic use were negative predictors of success, whereas high levels of preoperative disability and sensory loss were positive predictors. Following allograft and plate fixation of a single level, fusion success occurred in 95% of the patients as reported in three randomized clinical trials. To enhance fusion success, other biologic and reconstructive measures have been utilized. Pulsed electromagnetic field stimulation following anterior fusion showed improved fusion success as compared with controls at six months but no difference at twelve months and showed no improvement in any clinical outcome parameters. Recombinant human bone

morphogenetic protein-2 (rhBMP-2) is an alternative, especially in cases of multilevel fusion, after which the pseudarthrosis rate is known to be increased. The United States Food and Drug Administration (FDA) recently warned against the off-label use of rhBMP-2 in the cervical spine because of severe inflammatory reactions causing dysphagia, hematoma, and airway obstruction requiring secondary surgery. This is of particular concern when used anteriorly in the cervical spine. Dosing may be an important factor, with recommended doses in the cervical spine being 0.4 to 0.7 mg/level. However, the rate of success of anterior cervical fusion with rhBMP-2 after multilevel procedures is lower than desired. Another common method to enhance fusion is immobilization, although no consensus has been reached regarding specific indications. In a study of >550 patients who were managed with a plate and allograft at a single level, the use of an orthosis made no difference in fusion success and was associated with a delayed return to activities, including work.

**Myelopathy**

Myelopathy due to cervical cord compression is expected to increase in frequency with the aging population and is increasingly the focus of research. Assessing the severity of myelopathy is difficult as symptoms are subtle and physical findings are subjective. More quantitative assessment methods are needed so that the effectiveness of various treatments can be measured. Several quantitative methods that have been shown to be reliable and valid include the evaluation of grip strength with use of a standard dynamometer, the ten-second step test, and the ten-second open-and-close hand test. In the latter two tests, normal subjects can perform these movements more than fifteen and twenty times, respectively. Another test is the triangle step test, in which sitting subjects repetitively touch the apices of a 30-cm equilateral triangle for twenty seconds. Normal patients can perform twenty-five touches, whereas myelopathy patients complete fewer than fifteen

*Specialty Update has been developed in collaboration with the Council of Musculoskeletal Specialty Societies (COMSS) of the American Academy of Orthopaedic Surgeons.*

**Disclosure:** The authors did not receive any outside funding or grants in support of their research for or preparation of this work. One or more of the authors, or a member of his or her immediate family, received, in any one year, payments or other benefits of less than \$10,000 or a commitment or agreement to provide such benefits from a commercial entity (DePuy). In addition, one or more of the authors, or a member of his or her immediate family, received, in any one year, payments or other benefits in excess of \$10,000 or a commitment or agreement to provide such benefits from commercial entities (Biomet, Stryker, Seaspine, Medtronic, Aesculap, Zimmer, Osprey, Pioneer, Osteotech).

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touches. The correlation of the triangle test to disability scores is excellent. The most common measure of myelopathy is the Japanese Orthopaedic Assessment (JOA) score (range, 0 to 17) and the modified JOA (mJOA) (adapted for use in Western society). In a large prospective study evaluating the outcomes of cervical myelopathy, the mJOA and the Neck Disability Index (NDI) were tested for responsiveness as compared with the SF-36. Results demonstrated that the NDI correlated better with the SF-36 change, although both had acceptable psychometric properties. In that study, neurologic improvement occurred in 85% of patients, with the absolute improvement in the mJOA averaging 2.7 points.

The surgical treatment of myelopathy has changed over the last decade from the anterior approach to the posterior approach with the widespread use of laminoplasty. One of the major disadvantages of this technique is the higher incidence of C5 motor root paralysis, which occurs in 3% to 10% of patients. Risk factors include the presence of C5 foraminal stenosis and excessive posterior cord shift. A strong association with C5 palsy was seen in patients with a triad of radiographic findings, including C5 foraminal stenosis, a spinal cord anteroposterior diameter at C5 of  $\leq 7$  mm, and a cord-lamina angle  $\geq 30^\circ$ . The latter is formed by intersecting lines along the anterior aspect of the spinal cord and the ipsilateral lamina. The method to prevent this complication in patients with unfavorable anatomy remains elusive, although a simultaneous decompression of the C5 nerve root may be indicated.

### *Vertebral Artery*

The relationship of the vertebral artery to screw placement, especially in the upper cervical spine, continues to receive attention. Osseous anatomic abnormalities strongly correlate with vascular anomalies, with surgical implications. In one study, 6% of all patients who were studied with computed tomographic angiography had vertebral artery anomalies at C1-C2, the majority of which had surgical relevance. In such cases, computed tomography angiography or magnetic resonance angiography is recommended before surgery. Additional studies of the vertebral artery in the subaxial cervical spine also show a higher rate of abnormalities than previously identified. The artery enters the spine at C6 in only 94.6% of cases, whereas anomalous entries occur at C7, C5, and C4 in 1.6%, 3.3%, and 0.3% of cases, respectively. Consistent with the upper cervical spine, a small transverse foramen was associated with absence (and therefore an anomalous position) of the vertebral artery. The significance of these anatomic studies was borne out in one series by the identification of screw misplacement involving the foramen transversarium in as many as 20% of screws placed at C1 and C2. Fortunately, arterial injury and neurologic deficits were rare.

### *Cervical Disc Arthroplasty*

Two recent studies evaluated the twenty-four-month results of two randomized controlled trials in which cervical arthroplasty

was compared with fusion following discectomy for the treatment of single-level radiculopathy or myelopathy. Both studies, along with a previously published investigation, demonstrated equal or greater pain relief and functional outcomes in association with the experimental treatment. Adverse events appeared to be similar, although the rate of reoperations was lower for the arthroplasty group at the time of short-term follow-up. Longer follow-up studies at four years showed excellent maintenance of satisfactory outcomes in both the arthroplasty and fusion groups. Longer follow-up is needed to measure the effectiveness of arthroplasty in reducing adjacent-segment degeneration and the durability of the devices.

### **What's New in Biologic Topics Related to the Spine**

Biologics continued to be a major focus in spine research and the development of new products for patients with spinal disorders in 2008. Most of the current attention remains on bone formation, but research also continues to investigate the role of biologics in retarding or reversing intervertebral disc degeneration. In patients undergoing spine fusion, the choice of bone-graft substitutes remains an emotional rather than scientifically driven decision for many, but the desire to eliminate the need for autogenous iliac crest bone graft harvest is strong. Since the FDA's post-marketing approval of rhBMP-2 in 2002 and its issuance of a Humanitarian Device Exemption for rhBMP-7 late in 2004, differences in the clinical performance of these two proteins have become more striking and local side effects resulting from physician-directed uses have become more evident. While an increasing amount of research continues to be focused on understanding the biology of the intervertebral disc and developing biologic strategies to retard or reverse degeneration, these treatments remain years from routine clinical use.

### *Recombinant Osteoinductive Proteins*

Recombinant human growth and differentiation factor-5 (rhGDF-5; DePuy Biologics, Johnson and Johnson, Raynham, Massachusetts) has yielded inconsistent results in spine fusion clinical trials, and the future use of GDF-5 for spine fusion remains uncertain. Basic-science studies continue to investigate this protein as an anabolic stimulus of disc cartilage metabolism. GDF-5 may reappear as a potential intradiscal biologic therapy in the future.

Most clinical studies involving the use of rhBMP-7 (OP-1; Stryker Biotech, Hopkinton, Massachusetts) for posterolateral spine fusion have yielded fusion success rates of 50% to 70% on the basis of radiographs or of 45% on the basis of surgical exploration. The failure to achieve a  $>90\%$  fusion success rate has been attributed to the use of a "more challenging" model involving spine fusion without instrumentation, although at least one study of fusion with instrumentation showed a success rate of approximately 50% in association with OP-1, which is similar to the outcomes reported for the studies of fusion without instrumentation and

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is still not at a level equal or superior to that associated with the use of autograft. It is believed that data from the United States clinical trial of OP-1 for posterolateral fusion remain under review by the FDA for consideration for post-marketing approval. Several preclinical OP-1 studies are now showing that there may indeed be a dose response, as seen with other BMPs, and that the current clinical formulation (concentration) may be insufficient for posterolateral spine fusion.

Although rhBMP-2 (INFUSE; Medtronic Sofamor Danek, Memphis, Tennessee) has been approved by the FDA for anterior lumbar interbody fusion, several physician-directed studies have evaluated the outcomes of transforaminal and posterior interbody fusion as well as posterolateral spine fusion. One study with a two-year follow-up demonstrated an overall fusion success rate of 95% in association with the use of rhBMP-2 at doses of 10 mg/level without autogenous bone for anterior spinal fusion, 20 mg/level with local bone graft and a ceramic bulking agent for posterolateral spine fusion, and 40 mg/level with a ceramic bulking agent and no local bone for posterolateral spine fusion.

A primary concern associated with physician-directed use of recombinant BMPs relates to local adverse events. The most commonly reported local side effects are heterotopic bone formation in the surgical approach track, transient radiculitis, transient vertebral body 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 surgeon using too much BMP either by increasing the concentration of the growth factor or overstuffing the defect, which can result in a higher local concentration or leakage of BMP into the surrounding tissues. BMP-induced radiculitis typically occurs seven to ten days after surgery and persists for a variable length of time. Sanfilippo et al. reported that nine of thirty-nine patients who were managed with a transforaminal interbody fusion with use of BMP-2 experienced radiculitis lasting at least six months. The mean duration of symptoms was at least 13.4 months, and some patients continued to have pain at the time of the latest follow-up.

There have been several reports of psoas muscle ossification in association with rhBMP-2/absorbable collagen sponge implantation in the posterolateral spine. These cases are quite rare, but there appears to be something unique about the psoas muscle, compared with the other posterior spinal muscles, that may make it more susceptible to BMP-2-induced heterotopic ossification in some individuals. The risk factors that lead to this rare side effect are not known but may involve both patient genetic predisposition as well as surgical violation of the intertransverse membrane providing access to the psoas muscle.

The potential for osteolysis due to osteoclastic stimulation by BMPs remains a concern, especially when the vertebral end plates have been extensively decorticated, providing direct access to the cancellous bone and bone marrow of the vertebral

body. Several authors have reported transient peri-implant resorption, which usually resolves spontaneously after six months and usually does not impact healing. The phenomenon was first observed by Burkus et al. when rhBMP-2 was used inside threaded cortical bone allograft dowels and more recently by Meisel et al. when used inside a polyether-ether-ketone (PEEK) interbody cage. Although those authors did not report adverse clinical outcomes related to the osteolysis, McClellan reported graft subsidence, loss of end plate integrity, and a lack of progression to fusion at segments with bone loss. Among patients with postoperative computed tomography scans following transforaminal interbody fusion with BMP-2, twenty-two (69%) of thirty-two levels demonstrated osteolysis, and, of these, eleven levels demonstrated ongoing failure to progress to fusion.

Several authors have reported severe perioperative swelling in the anterior cervical spine, sometimes when excessive BMP-2 doses were used or when the BMP was placed outside the structural cage/implant. This complication often becomes apparent several days following surgery and has necessitated reintubation or tracheostomy because of the risk of respiratory arrest. On July 1, 2008, the FDA issued a public health notification of life-threatening complications associated with the use of BMPs in the cervical spine. Surgeons who are observing these local side effects with any regularity should carefully examine their technique and should avoid using excessive amounts of BMPs in small spaces or overpacking of the BMP implants. Given the high success rate for anterior cervical fusion in healthy patients with allograft and plating, surgeons must carefully balance any increased risk of side effects associated with the use of BMP with the actual need for the increased healing potential in their specific patient. Although several physician-directed studies in which BMP has been used successfully for anterior cervical fusion have been reported, this use is off-label at the present time.

Other studies have answered three common questions about rhBMP-2. First, repeated exposure to BMP-2 does not seem to impact its effectiveness, suggesting that the transient antibodies that develop in 7% to 10% of patients do not have any effect on clinical bone formation. Also, the use of a postoperative drain does not seem to diminish the effectiveness of BMP-2 when used for posterolateral spine fusion. Finally, the use of rhBMP-2 in the presence of anterior spinal infection was reported to be safe and effective, with none of twenty patients having a persistent or recurrent infection after a mean duration of follow-up of forty months.

### *Other Bone-Graft Substitutes*

Although much focus remains on recombinant osteoinductive proteins, their relatively high cost has continued to encourage research involving other bone-graft solutions. There is continued interest in mesenchymal stem cells for bone and cartilage regeneration. In rodent models, both fat-derived and bone marrow-derived mesenchymal stem cells appear to be

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capable of expressing the BMP-2 gene and producing spine fusion. One preclinical study concluded that delivery of mesenchymal stem cells with rhBMP-2 enabled the use of a much lower dose of BMP than was the case for cell-less delivery strategies. As for strategies that propose to use mesenchymal stem cells alone as an alternative to recombinant BMPs, the number of stem cells present in bone marrow is relatively small, and, without specific signals (e.g., BMP), it is not clear whether sufficient numbers of cells are present to consistently initiate bone formation in challenging environments such as the site of a spine fusion.

### *Biologic Treatments for Disc Degeneration*

Progress toward biologic treatments to prevent or retard disc degeneration continued at a slow pace. Animal evidence of beneficial effects of recombinant BMPs (BMP-7, BMP-2, GDF-5) on disc metabolism has prompted the planning of a clinical trial to investigate the response in humans. One group reported that the delivery of a "cocktail" of anabolic factors to the rabbit disc by means of adenovirus was a more effective strategy than the delivery of single proteins. BMP-7 has been shown to prevent apoptosis of human disc cells in vitro, possibly through the inactivation of caspase-3. Simvastatin has been shown to promote chondrogenesis of rat intervertebral disc cells by upregulating BMP-2. Although the clinical use of biologics to treat disc degeneration is a long way off, it is worth monitoring developments in this area, which could ultimately be an important technology for the treatment and prevention of many degenerative spine disorders.

### **What's New in Spinal Deformity Surgery**

The Scoliosis Research Society (SRS) Annual Meeting was held in Salt Lake City, Utah, September 10 to 13, 2008. The Harrington lecturer was Marc Asher, MD, who spoke on Dr. Paul Harrington's contributions and perspective. Lifetime Achievement awards were given to John E. Hall, MD, and to Jacquelin Perry, MD, DSc, and George Thompson, MD, completed a two-year term as President. SRS globalization efforts have expanded over the last five years. The SRS Global Outreach Program currently represents a service initiative with nine endorsed sites on four continents, and the development of worldwide regional courses has focused on international educational activities and the building of professional relationships.

### *Adolescent Idiopathic Scoliosis*

Work continues on the genetic profiling of teenagers with idiopathic scoliosis. Ward and Ogilvie presented evidence suggesting that it may now be possible to predict which curves will progress into the surgical range and which will be resistant to bracing. This may have a profound impact on the nonoperative treatment of idiopathic scoliosis.

Scoliosis surgeons continue to debate the surgical treatment of double-major curves and "false" double-major

curves with regard to fusion of the lumbar curve. A multicenter study by the Harms Study Group concluded that patients with preserved lumbar motion had greater function and satisfaction at two years after surgery in comparison with those who had a lumbar curve that was fused. A group of authors from Turkey concluded that selective thoracic fusion may be considered if the lumbar curve is  $<50^\circ$  and demonstrates  $>50\%$  flexibility.

The topic of thoracic pedicle screws for the treatment of adolescent idiopathic scoliosis remains controversial. One report by the Spinal Deformity Study Group suggested that the correction of a thoracic deformity was related to the number of fixation points rather than which specific type of bone anchor was implemented. Several studies have suggested that sublaminar wires are kyphogenic in the thoracic spine and that thoracic pedicle screws have a lordosing tendency, especially if a direct apical derotation maneuver is performed. Researchers at Cincinnati Children's Hospital documented an 80% increase in surgical costs for idiopathic scoliosis treatment over a seven-year time frame, attributed mostly to the increased use of pedicle screws.

Researchers from Texas Scottish Rite Hospital for Children in Dallas and Washington University in St. Louis independently assessed the benefits of halo traction for the treatment of severe deformities. Both groups of researchers concluded that halo traction had a high benefit-to-risk ratio, with improved overall correction and a reduced risk of neurologic deficit in association with the ultimate surgery.

### *Adult Spinal Deformity*

It is generally accepted that the surgical treatment of adult spinal deformity demands a solid fusion, and a long construct from the thoracic spine to the sacrum is often needed. The annual meeting of the SRS highlighted much of the ongoing research in this difficult treatment group. Contrasting views on the role of anterior surgery in this patient subset were presented. Regardless of which approach is utilized, patient outcomes at a minimum of two years of follow-up were good if a solid fusion was achieved and complications were minimized. The results supported sagittal plane balance (not coronal plane correction/balance) as the primary radiographic factor in determining the outcome. Some of the trends gleaned from recent presentations include decreased use of circumferential fusion; increased use of bilateral pedicle screw fixation and multiple fixation points in the sacropelvic unit, usually with use of iliac screws; and frequent off-label use of BMP to enhance fusion rates in both anterior and posterior fusions. To date, we are not aware of any reports of local or systemic complications related to the use of BMP during adult spinal deformity surgery in contrast to its use during anterior cervical spine fusion. Nonetheless, the use of BMP for the treatment of adult spinal deformity will remain highly controversial until it is approved by the FDA for multilevel posterior fusion and more than one vendor distributes it.

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Complications of adult spinal deformity surgery were the focus of many presentations. Additional data on catastrophic failures of the proximal adjacent segment in pedicle screw constructs were presented. The patients who were found to be at greatest risk were women over the age of sixty years with sagittal imbalance, obesity, osteopenia, and a substantial sagittal plane correction. Alternative methods of fixing the cephalad level with something other than pedicle screw implants are being evaluated.

Age appears to be a primary determinant of complication rates after spinal deformity surgery. Patients over the age of sixty years are more likely to experience complications than those in the forty-to-sixty-year-old age group. Nonetheless, data suggest that the postoperative incremental improvement in outcome according to SRS and Oswestry Disability Index measures is identical for patients in the forty-to-sixty-year-old age group and those in the more-than-sixty-year-old age group. It appears that complications reduce the likelihood of benefit from surgery, but they do not preclude benefit as long as the complications are not catastrophic (major paralysis, blindness, death).

### *Neuromuscular Scoliosis*

There is a strong trend away from performing anterior and posterior surgery for fusions to the sacrum in patients with cerebral palsy. The current preferred method is intraoperative traction and a long posterior procedure extending from the upper thoracic spine to the sacrum and pelvis. In most cases, halo traction and posterior techniques will suffice. The crankshaft phenomenon is a substantial concern for juvenile patients with neuromuscular scoliosis who require a long fusion. One study suggested that anterior surgery did not preclude the crankshaft phenomenon and that those at greater risk were the particularly young patients (eight years of age or younger) and those who did not have a long fusion, defined as one extending from above T5 and down to the sacrum as opposed to stopping at L4 or L5. Pedicle screw fixation may improve the correction, especially in patients with Duchenne muscular dystrophy.

Infections are a substantial problem in juvenile patients with neuromuscular scoliosis. A study from the Shriners Hospital-Chicago demonstrated an 11.2% infection rate in patients with cerebral palsy and a 19.2% rate in patients with a myelomeningocele. The majority of patients with deep infections ultimately required implant removal.

### *Early-Onset Scoliosis*

The term "early onset" refers to scoliosis that presents before the age of six years. Etiologies include congenital, infantile, and early juvenile idiopathic scoliosis; chromosomal syndromes; and genetic connective-tissue disorders. These are all circumstances in which traditional bracing does not control the spinal deformity. There usually is substantial risk of either pulmonary compromise or a neurologic deficit if the disorder is not

treated. Spinal fusion is not a good alternative because there is much growth remaining. Strategies include dual growing rods, the Vertical Expandable Prosthetic Titanium Rib technique, vertebral body stapling, and the use of multiple corrective casts. No one technique is completely effective. Although there is no statistical proof that neuromonitoring reduces the prevalence of neurologic deficit, there is a consensus that it is highly advisable.

### *High-Grade Developmental Spondylolisthesis*

Sacral doming is thought to be an early sign of progressive high-grade spondylolisthesis and "impaired spinopelvic alignment." Thus, this finding is considered by many to signal an indication for early intervention and surgery. The classic high-grade developmental spondylolisthesis, which benefits from a reduction with instrumentation, is one with lumbosacral kyphosis, retroversion of the sacrum and pelvis, compensatory proximal lumbar hyperlordosis, and positive sagittal balance. Surgical treatment should be aimed at reducing the lumbosacral kyphosis and correcting the pelvic retroversion so that the anterior spinal gravity line falls through the sacrum and the lumbar segments above can spontaneously adjust to a more normal segmental sagittal alignment.

### **What's New in Spinal Cord Injury**

A study from the 2008 American Spinal Injury Association (ASIA) meeting reported that, on the basis of the prevalence of 250,000 individuals with spinal cord injury alive in the United States today, the aggregate cost for managing patients who have a spinal cord injury is \$22.16 billion per year. Managing patients who have a spinal cord injury is a major social issue, particularly in the setting of a national fiscal healthcare crisis. As this population continues to increase, it is imperative that strides are made in the management and evaluation of these patients.

This past year was particularly exciting for surgeons and scientists in the field of spinal cord injury. Emphasis was placed on the evaluation of functional outcomes and prognostic indicators of mortality following spinal cord injury. The first stem-cell trial for spinal cord injury was initiated, and preliminary results evaluating the role of early surgical decompression following spinal cord injury were reported.

### *Outcome Measures*

The 2006 National Institute on Disability and Rehabilitation Research (NIDRR) Spinal Cord Injury Measures Meeting continued to generate reports in *The Journal of Spinal Cord Medicine*. Reports from 2008 focused on the evaluation of outcome measures and measures of functional recovery. One study provided guidelines for the evaluation of outcome measures for spinal cord injury, emphasizing the methods and principles important in a systematic review. This study was based on the notion that, despite the fact that many outcome measures are described as "reliable and valid," there are no

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specifications of how reliable or how valid they are or in what set of patients they can be used. The authors devised a 5-point method of grading measures of health, function, and quality of life and applied it to spinal cord injury outcome measures. Another study from the Measures meeting focused on the evaluation of functional status following spinal cord injury as neurologic recovery does not always translate into functional recovery. A multinational work group analyzed four functional outcome scoring methods and concluded that the latest version of the Spinal Cord Independence Measure (SCIM III) should be the primary functional recovery outcome measure for spinal cord injury.

Proceedings from the 2008 ASIA meeting focused on mortality following spinal cord injury. One study evaluated the risk of mortality in adults and found that subsequent injuries, amputations, fractures, and depressive symptoms should become the focus of prevention efforts. These conditions serve as indicators of a high risk of mortality and the need for immediate intervention. Another study evaluated whether age at the time of the injury and comorbidity indices are predictors of in-hospital mortality and length of stay in a spinal cord injury-care facility. Clinical outcomes and mortality were significantly associated with age, the Charlson Comorbidity Index (CCI), the number of ICD-9 codes, and the Cumulative Illness Rating Scale. Length of stay in the acute spinal cord injury facility was only directly correlated with the CCI. The same group of investigators also reported on mortality and neurologic outcomes in the geriatric population following spinal cord injury. They found that elderly individuals had significantly greater mortality rates at all time points following spinal cord injury when compared with younger patients. However, among survivors, age was not correlated with motor or sensory recovery or pain scores. This finding provides a rationale for individualizing treatment approaches for elderly patients with spinal cord injury as the opportunity exists for neurologic recovery in this patient subgroup.

### *Evaluation and Surgical Management*

One study that was presented at the 2008 ASIA meeting evaluated the use of magnetic resonance imaging as a predictor of neurologic improvement on the basis of the ASIA impairment scale. Data collected from sixty patients showed a trend for neurologic improvement with the absence of hemorrhage and a smaller length of lesion. Edema, disc herniation, soft-tissue injury, cord compression, and canal compromise did not significantly correlate with neurologic improvement.

Although animal studies have demonstrated increased functional recovery in association with early surgical decompression, the lack of Level-1 clinical data continues to generate debate over whether early surgical decompression following spinal cord injury is beneficial. This led to the creation of the Surgical Treatment for Acute Spinal Cord Injury Study (STASCIS), a multicenter, randomized, prospective trial to evaluate the timing of decompression following spinal cord

injury. Patients are randomized to early decompression (performed less than twenty-four hours after an injury) or late decompression and are evaluated on the basis of radiographic and functional outcomes. The initial results of the STASCIS trial were presented at the 2009 AAOS Federation of Spine Associations Annual Meeting. As of January 2009, there were 276 patients in the database available for analysis. At the six-month time point, there was no significant difference in improvement in the ASIA grade between the two groups. However, at one year of follow-up, there was a significantly greater proportion of patients in the early decompression group who had at least two grades of improvement as compared with the late group. Although not significant, there was also a higher percentage of complications in the late group. Preliminary results showed that early decompression is safe and feasible, with major hurdles being delay in admission, imaging, and operating room availability. We eagerly await the final results of the STASCIS trial, which will provide Level-1 evidence for whether early surgical decompression is beneficial.

### *Neuroprotective Treatments*

Trauma to the spinal cord results in an immediate pathophysiological response characterized by loss of electrolyte homeostasis, local ischemia, free radical formation, and inflammation. The National Acute Spinal Cord Injury Studies (NASCIS) II and III resulted in setting a national trend for using methylprednisolone as a neuroprotective agent when administered within the first eight hours after a spinal cord injury. However, after several published analyses of the literature and a critical review of subgroups of the study population, improvement in functional recovery with the use of methylprednisolone appears not to be clinically important. Despite these reports and the fact that numerous professional societies have concluded that methylprednisolone is not clinically indicated, surgeons continue to use it. A recent analysis of the North American Spine Society membership revealed that 86% of surveyed surgeons reported using the NASCIS protocol when managing patients who have spinal cord injury. The most commonly stated reason is fear of litigation, with only a quarter of respondents indicating that methylprednisolone was given because they believed it to be beneficial. Interestingly, a recent study indicated that 24% of surveyed Canadian surgeons currently prescribe methylprednisolone, whereas 76% prescribed it five years ago. The difference in practice patterns between the United States and Canada may be secondary to the litigious environment of the United States.

Seventy-one thousand fans watched the Buffalo Bills 2007 season opener as Kevin Everett suffered an incomplete spinal cord injury resulting from a cervical fracture-dislocation after tackling an opponent. Systemic hypothermia was initiated during transportation to the hospital, where he subsequently underwent decompression and fusion of the cervical spine. Four months later, he was walking. There continues to be a flurry of public interest associated with the use of hypothermia

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in the setting of spinal cord injury. From a neuroprotective standpoint, hypothermia slows enzymatic activity and reduces energy requirements. A recent review of animal and clinical studies on the use of hypothermia was performed. Animal data on systemic and local hypothermia are mixed, with some studies demonstrating a benefit and others demonstrating no effect. Local hypothermia was actively studied in the 1970s for the treatment of human acute traumatic spinal cord injury, but no case series of this intervention has been published since 1984, to our knowledge. No peer-reviewed clinical literature that describes the application of systemic hypothermia in acute traumatic spinal cord injury could be identified. Therefore, while a rationale may exist for the use of local or systemic hypothermia following spinal cord injury, there are few animal or clinical data to support its use.

### *Emerging Therapies*

The reversal of paralysis after spinal cord injury through cell-based strategies aims to replace oligodendrocytes or neurons lost to injury and to enhance the environment for axonal regeneration. Two therapies of particular interest this year include olfactory ensheathing cells and human embryonic stem cells (hESC).

Olfactory ensheathing cells are a specialized glial cell with the unique ability to facilitate the passage of new axons from the peripheral nervous system to a target neuron in the central nervous system. Human studies of olfactory ensheathing cell transplantation following spinal cord injury have been performed in China, Portugal, and Australia. In 2008, the outcomes of the Australian Phase I/IIa feasibility and safety study were reported. In the six patients who were enrolled in the study, there were no adverse findings three years after autologous transplantation of olfactory ensheathing cells. Magnetic resonance images made at three years showed no change from preoperative magnetic resonance images, and there were no substantial functional changes in any of the patients. The investigators concluded that transplantation of olfactory ensheathing cells into the injured spinal cord is feasible and safe for up to three years after implantation. The results of that study are muted by the small number of patients in which the olfactory ensheathing cells were implanted.

Just days after President Obama's inauguration, the FDA granted clearance for the first-ever Phase-I clinical trial of human embryonic stem cells in patients with acute spinal cord injury. GRNOPC1 (Geron, Menlo Park, California) contains human embryonic stem cell oligodendrocyte progenitor cells that have demonstrated promising results in animal models. Oligodendrocyte progenitor cells that have been injected seven days after a spinal cord injury in rats have been shown to differentiate into oligodendrocytes and ultimately to enhance remyelination and to improve motor function. The ultimate goal is to achieve restoration of function in patients by injecting oligodendrocyte progenitor cells directly into the injured spinal cord. Patients eligible for the Phase-I trial must

have a complete spinal cord injury and must agree to have the drug injected between seven and fourteen days after the injury. As many as seven medical centers will be selected to participate in this landmark trial.

President Obama fulfilled his campaign promise of overturning the previous administration's ban on federal funding of stem-cell research by signing an executive order in March 2009. This will undoubtedly increase the pace of human embryonic stem-cell research. However, caution should be exercised when counseling patients on the merits of stem-cell therapy as patients with spinal cord injury are highly vulnerable to the investment of hope in improvement or cure. A study at the 2008 ASIA meeting evaluated the web sites of twelve commercial entities providing cellular or tissue therapeutics to patients with spinal cord injury. The authors found that only 25% of the entities had reported efficacy and safety data in peer-reviewed journals, with 0% conducting a placebo-controlled study. Two-thirds utilized logos suggesting dramatic recovery or explicitly used the terms "miracle," "cure," or "breakthrough." Until there is Level-1 clinical evidence that demonstrates that human embryonic stem cells lead to improved function, clinicians have an ethical responsibility to present peer-reviewed data to patients that provide a realistic outlook of proposed treatments.

### **What's New in the Treatment of the Lumbar Spine**

Lumbar spine disorders affect a substantial portion of the population, and research into the treatment and pathogenesis of these disorders continues to advance each year. As always, novel technology is of high interest, but better studies evaluating outcomes and results are also gaining interest.

### *Surgical Outcomes*

Outcomes studies were highly regarded this past year, and the results of operative and nonoperative treatment comparisons are showing some advantages for surgical treatment. Data from the Spine Patient Outcomes Research Trial (SPORT) were presented at several meetings. With use of this database, patients with degenerative spondylolisthesis and spinal stenosis were studied specifically with regard to the location of the primary pain being either leg pain or low back pain. Both operative and nonoperative treatments were compared in this group. Operative treatment resulted in better outcomes in comparison with nonoperative treatment for all patients in the study, regardless of the location of the primary pain. However, patients with primary leg pain improved more with surgical treatment in comparison with patients with primary back pain.

In the same group of patients, radiographic parameters that categorized the grade of listhesis, the disc height, and the amount of mobility of the spondylolisthesis were also studied. The study attempted to define a relationship between these radiographic parameters and the outcomes of operative and nonoperative treatments. Regardless of any radiographic pa-



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rameters, patients managed operatively improved more than those managed nonoperatively. The study demonstrated that patients with higher grades of listhesis (grade II as compared with grade I) and those who were stable with regard to angular and translational motion had greater improvement with operative treatment.

This group also was studied with regard to baseline characteristics (sex, age, and psychological and medical conditions), and the patients with degenerative spondylolisthesis were compared with those with spinal stenosis without spondylolisthesis. The investigators found that the two groups had similar baseline characteristics, but the patients with degenerative spondylolisthesis improved more after surgery when compared with those with only spinal stenosis. As these two groups are often combined in clinical studies, future studies should separate these two distinct pathologies.

### *Psychological Screening*

The outcomes for patients with spinal disorders are often influenced, both operatively and nonoperatively, by psychological disorders and patient distress. A study was performed to study the ability of spine specialists to detect psychological distress. This prospective, blinded study examined 400 patients who presented for an initial examination at a university spine center. Four surgeons and four nonoperative spine specialists participated, and their clinical acumen was tested. Overall, this study demonstrated that the majority of the patients had some degree of psychological distress and that only 37% of the patients had no psychological distress when tested. Perhaps more concerning was the poor ability of the clinicians to detect this psychological distress. Surgeons were correct only 40% of the time, whereas the nonoperative specialists were correct 49% of the time.

### *Surgery in the Elderly Population*

Studies evaluated the higher complication rates that have been observed when surgery is performed in the elderly population. A recent study examined the outcome of lumbar fusion in patients over the age of sixty-five years. Fifty patients undergoing single-level lumbar decompression and posterolateral fusion with autogenous iliac crest bone-grafting as part of a control group for a randomized prospective study were included. This carefully selected group of patients demonstrated substantial benefits from surgical treatment, especially when compared with a control population of younger patients and the literature standards.

### *Novel Technology*

Novel technology continues to attract attention as longer-term follow-up is obtained. As part of an FDA randomized prospective study, a pedicle-based dynamic stabilization system was compared with lumbar posterolateral fusion after two years of follow-up. Two hundred and fifty-three patients who were managed with the dynamic device were compared with 114 patients who were managed with posterolateral fusion.

The results showed that the dynamic stabilization group was comparable with the fusion group, with more favorable results in the dynamic stabilization group with regard to improvement in leg pain and back pain scores. Complication rates were comparable between the two groups; however, the rate of screw loosening was 0.88% in the dynamic stabilization group as compared with 1.65% in the fusion group and the rate of revision surgery was 11.1% in the former group as compared with 9.6% in the latter group.

In a separate study, ninety-two patients who had been managed with implantation of the same device for similar indications were evaluated after as long as two years of follow-up. In this population, 20% of the patients had events necessitating revision surgery. Screw loosening accounted for 39% of the complications; other complications included screw breakage and cephalad spinal stenosis at the adjacent segment, despite normal canal diameters at these levels at the time of the index procedure.

Another study of the same device included thirty-eight patients who were evaluated after two years of follow-up. The patients were evaluated on the basis of radiographic and magnetic resonance imaging parameters. Two-thirds of the patients had implantation of the dynamic device only, and one-third had implantation of the device along with an adjacent-level fusion. The authors found that disc degeneration at the level with the implanted dynamic device and degeneration at the adjacent levels continued following surgery. Degeneration at the adjacent segments appeared in 17% of the patients. The authors concluded that the dynamic stabilization device did not protect against adjacent-segment or index-level degeneration; however, whether this progressive degeneration is due to the surgery or represents the natural history of lumbar degeneration is still up for debate.

### *Adjacent-Segment Degeneration*

A long-term follow-up study with a minimum of five years and an average of eight years of follow-up after lumbar fusion with instrumentation was presented. Of the fifty-five patients, twenty-one (38%) had development of adjacent segment degeneration at the time of final follow-up. The authors found that the restoration of lordosis of  $>10^\circ$  in the fused segment decreased the incidence of adjacent segment degeneration. However, the development of adjacent-segment degeneration was not correlated with a poor clinical result.

### **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, thirty-two level-I articles were identified that were relevant to spine surgery. A list of those titles is

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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-fourth Annual Meeting of the Scoliosis Research Society (SRS) will be held on September 23 through 26, 2009, in San Antonio, Texas. It will be preceded by a one-day course entitled "Complications: Pediatric and Adult" and a half-day course entitled "Primer: Basic Spine Deformity," both to be held on September 22, 2009. Web site: [www.srs.org](http://www.srs.org)

The Thirty-sixth Annual Meeting of the American Spinal Injury Association (ASIA) and the United Spinal Association (USA) will join forces in 2009 to present the "Congress on Spinal Cord Medicine and Rehabilitation." The Congress will be held on September 23 through 26, 2009, in Dallas, Texas. Web site: [www.asia-spinalinjury.org](http://www.asia-spinalinjury.org)

The Twenty-fourth Annual Meeting of the North American Spine Society (NASS) will be held on November 10 through 14, 2009, at the Moscone Convention Center in San Francisco, California. Web site: [www.spine.org](http://www.spine.org)

The Thirty-seventh Annual Meeting of the Cervical Spine Research Society (CSRS) will be held on December 3 through 5, 2009, in Salt Lake City, Utah. Web site: [www.csr.org](http://www.csr.org)

The Federation of Spine Associations will present the spine program at Specialty Day at the Annual Meeting of the American Academy of Orthopaedic Surgeons (AAOS) on Saturday, March 13, 2010, in New Orleans, Louisiana. Web site: [www.aaos.org](http://www.aaos.org)

The Annual Meeting of the International Society for the Study of the Lumbar Spine (ISSLS) will be held on April 12 through 19, 2010, in Auckland, New Zealand. Web site: [www.issls.org](http://www.issls.org)

The Seventeenth Annual International Meeting on Advanced Spine Techniques (IMAST) will be held on July 21 through 24, 2010, at the Sheraton Centre Toronto, Toronto, Ontario, Canada. Web site: [www.imastonline.com](http://www.imastonline.com)

NOTES: The authors thank Drs. Steve Mardjetko, Dan Riew, Harvinder Sandhu, and Brian Su for peer-reviewing the sections of this manuscript.

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### Suggested Reading List

1. Anderson K, Aito S, Atkins M, Biering-Sørensen F, Charlifue S, Curt A, Ditunno J, Glass C, Marino R, Marshall R, Mulcahey MJ, Post M, Savic G, Scivoletto G, Catz A; Functional Recovery Outcome Measures Work Group. Functional recovery measures for spinal cord injury: an evidence-based review for clinical practice and research. *J Spinal Cord Med.* 2008;31:133-44.

2. Anderson PA, Puschak TJ, Sasso RC. Comparison of short-term SF-36 results between total joint arthroplasty and cervical spine decompression and fusion or arthroplasty. *Spine.* 2009;34:176-83.

3. Brower RS, Vickroy NM. A case of psoas ossification from the use of BMP-2 for posterolateral fusion at L4-L5. *Spine.* 2008;33:E653-5.

4. Campbell MJ, Carreon LY, Traynelis V, Anderson PA. Use of cervical collar after single-level anterior cervical fusion with plate: is it necessary? *Spine.* 2009;34:43-8.

5. Foley KT, Mroz TE, Arnold PM, Chandler HC Jr, Dixon RA, Girasole GJ, Renkens KL Jr, Riew KD, Sasso RC, Smith RC, Tung H, Wecht DA, Whiting DM. Randomized, prospective, and controlled clinical trial of pulsed electromagnetic field stimulation for cervical fusion. *Spine J.* 2008;8:436-42.

6. Glassman SD, Carreon LY, Campbell MJ, Johnson JR, Puno RM, Djurasovic M, Dimar JR. The perioperative cost of Infuse bone graft in posterolateral lumbar spine fusion. *Spine J.* 2008;8:443-8.

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9. Hawryluk GW, Rowland J, Kwon BK, Fehlings MG. Protection and repair of the injured spinal cord: a review of completed, ongoing, and planned clinical trials for acute spinal cord injury. *Neurosurg Focus.* 2008;25:E14.

10. Heller JG, Sasso RC, Papadopoulos SM, Anderson PA, Fessler RG, Hacker RJ, Coric D, Cauthen JC, Riew DK. Comparison of BRYAN cervical disc arthroplasty with anterior cervical decompression and fusion: clinical and radiographic results of a randomized, controlled, clinical trial. *Spine.* 2009;34:101-7.

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- 13.** Hong JT, Park DK, Lee MJ, Kim SW, An HS. Anatomical variations of the vertebral artery segment in the lower cervical spine: analysis by three-dimensional computed tomography angiography. *Spine*. 2008;33:2422-6.
- 14.** Hsu B, Cree AK, Lagopoulos J, Cummine JL. Transcranial motor-evoked potentials combined with response recording through compound muscle action potential as the sole modality of spinal cord monitoring in spinal deformity surgery. *Spine*. 2008;33:1100-6.
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- 17.** Kim HJ, Lee HM, Kim HS, Moon ES, Park JO, Lee KJ, Moon SH. Life expectancy after lumbar spine surgery: one- to eleven-year follow-up of 1015 patients. *Spine*. 2008;33:2116-23.
- 18.** Kwon BK, Mann C, Sohn HM, Hilibrand AS, Phillips FM, Wang JC, Fehlings MG; NASS Section on Biologics. Hypothermia for spinal cord injury. *Spine J*. 2008;8:859-74.
- 19.** Li G, Patil CG, Lad SP, Ho C, Tian W, Boakye M. Effects of age and comorbidities on complication rates and adverse outcomes after lumbar laminectomy in elderly patients. *Spine*. 2008;33:1250-5.
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- 24.** Murrey D, Janssen M, Delamarter R, Goldstein J, Zigler J, Tay B, Darden B. Results of the prospective, randomized, controlled multicenter Food and Drug Administration investigational device exemption study of the ProDisc-C total disc replacement versus anterior discectomy and fusion for the treatment of 1-level symptomatic cervical disc disease. *Spine J*. 2009;9:275-86.
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- 28.** Weinstein JN, Tosteson TD, Lurie JD, Tosteson AN, Blood E, Hanscom B, Herkowitz H, Cammisia F, Albert T, Boden SD, Hilibrand A, Goldberg H, Berven S, An H; SPORT Investigators. Surgical versus nonsurgical therapy for lumbar spinal stenosis. *N Engl J Med*. 2008;358:794-810.

Annotated Evidence-Based Articles  
Related to Spine Surgery

**Ammendolia C, Furlan AD, Imamura M, Irvin E, van Tulder M.** Evidence-informed management of chronic low back pain with needle acupuncture. *Spine J*. 2008;8:160-72.

This paper summarizes the best available evidence for the use of acupuncture for the treatment of chronic low-back pain. When compared with no treatment, there is evidence that acupuncture is effective for pain relief and functional improvement immediately after a series of treatment sessions and at the time of short-term follow-up. Evidence suggests that, in comparison with other treatments, acupuncture is not more effective for pain relief or functional improvement. The most consistent evidence appears to be for the addition of acupuncture to other therapies, which demonstrated more effective benefit in terms of pain relief and functional improvement than the same therapies without acupuncture.

**Andersen LL, Kjaer M, Søgaard K, Hansen L, Kryger AI, Sjøgaard G.** Effect of two contrasting types of physical exercise on chronic neck muscle pain. *Arthritis Rheum*. 2008;59:84-91.

This randomized controlled trial compared two types of physical exercise for the treatment of chronic neck pain associated with monotonous work-related tasks. Patients were randomized to specific strength training of the painful muscle (i.e., trapezius) or general fitness training without direct involvement of the painful muscle. Specific strength training of the affected muscle led to marked prolonged relief of neck muscle pain.

**Bala MM, Riemsma RP, Nixon J, Kleijnen J.** Systematic review of the (cost-) effectiveness of spinal cord stimulation for people with failed back surgery syndrome. *Clin J Pain*. 2008;24:741-56.

The authors conducted a systematic review to assess the cost effectiveness of spinal cord stimulation in patients with chronic pain due to failed back surgery syndrome. Only three studies met the inclusion criteria in terms

of cost effectiveness and suggested that spinal cord stimulation is both more cost effective and less costly in the long term, but there is an initial high cost associated with device implantation and maintenance.

**Barth M, Weiss C, Thomé C.** Two-year outcome after lumbar microdiscectomy versus microscopic sequestrectomy: part 1: evaluation of clinical outcome. *Spine*. 2008;33:265-272.

In this randomized controlled trial involving eighty-four patients, the two-year outcomes after microdiscectomy were compared with those after microscopic sequestrectomy. The former method involved the insertion of pituitary rongeurs and removal of intradiscal tissue, whereas the latter involved only removal of the fragment outside the disc space. Recurrence rates of 10% and 12%, respectively, were not significantly different, although clinical outcomes were better in the sequestrectomy group. The conclusions of the study support the opinion of many surgeons that a limited discectomy should be performed. However, the authors did not adequately describe how much disc material was removed or whether an annular incision was required. Thus, it is unclear whether removal of free intradiscal material at the annular defect should be performed.

**Barth M, Diepers M, Weiss C, Thomé C.** Two-year outcome after lumbar microdiscectomy versus microscopic sequestrectomy: part 2: radiographic evaluation and correlation with clinical outcome. *Spine*. 2008;33:273-9.

In a companion study, the authors assessed two-year radiographs and magnetic resonance images in order to correlate imaging findings with clinical outcomes. They found that microdiscectomy was associated with a greater loss of disc height, endplate degeneration, and endplate changes as compared with sequestrectomy. These radiographic findings correlated significantly with the presence of low back pain. The conclusion, however, is limited because of the exclusion of patients who did not have both preoperative and postoperative studies and those who had second operations.

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**Bronfort G, Haas M, Evans R, Kawchuk G, Dagenais S.** Evidence-informed management of chronic low back pain with spinal manipulation and mobilization. *Spine J.* 2008;8:213-25.

This paper summarizes the best available evidence regarding the use of spinal manipulation therapy and mobilization for the treatment of chronic low-back pain. There is moderate evidence that spinal manipulation therapy with strengthening exercise is similar in effect to prescription nonsteroidal anti-inflammatory drugs with exercise in both the short term and the long term. There is limited evidence that spinal manipulation therapy is better than physical therapy and home exercise in both the short term and the long term.

**Browder DA, Childs JD, Cleland JA, Fritz JM.** Effectiveness of an extension-oriented treatment approach in a subgroup of subjects with low back pain: a randomized clinical trial. *Phys Ther.* 2007;87:1608-18; discussion 1577-9.

In this multicenter randomized clinical study, the effectiveness of an extension-oriented treatment approach was compared with that of a lumbar spine-strengthening exercise program for a subset of patients with low-back pain and symptoms distal to the buttocks that centralized with extension movements. Subjects in the extension-oriented group experienced greater improvements on the basis of the Oswestry Low Back Pain Disability Questionnaire as compared with subjects who received trunk-strengthening exercises at all time-points up to six months.

**Carroll A, Barnes M, Comiskey C.** A prospective randomized controlled study of the role of botulinum toxin in whiplash-associated disorder. *Clin Rehabil.* 2008;22:513-9.

Botulinum toxin injections have been previously described as a treatment for a variety of muscle injuries, including whiplash disorders. A randomized controlled trial of patients with whiplash who had had symptoms for longer than two months was performed. Thirty-one patients completed the study and were managed with either botulinum toxin injection or saline solution injection into four trigger points. Follow-up at three months showed greater improvements and less chronic disability in the experimental botulinum toxin group. However, the conclusions are limited because of the small number of patients, a 20% rate of loss to follow-up, and the short follow-up interval.

**Cohen SP, Hurley RW, Buckenmaier CC 3rd, Kurihara C, Morlando B, Dragovich A.** Randomized placebo-controlled study evaluating lateral branch radiofrequency denervation for sacroiliac joint pain. *Anesthesiology.* 2008;109:279-88.

Denervation of the posterior sacroiliac innervation has been considered to be a possible method to treat nonresponsive back pain. Ninety patients were screened, of whom twenty-eight were randomized to sacroiliac joint radiofrequency ablation or placebo (L4-L5 medial branch ablation). Despite the small number of patients, pain relief and disability were significantly improved in the sacroiliac joint denervation group. This study is limited by the small number of patients and the potential bias of investigators toward this procedure; however, additional study of this approach should be forthcoming.

**Dagenais S, Mayer J, Haldeman S, Borg-Stein J.** Evidence-informed management of chronic low-back pain with prolotherapy. *Spine J.* 2008;8:203-12.

This paper summarizes the best available evidence regarding the use of prolotherapy for the treatment of chronic low-back pain. Prolotherapy has a prolonged history of use, a reasonable but not proven theoretical basis, a low complication rate, and conflicting evidence of efficacy. The authors concluded that, at this time, there is no evidence supporting the efficacy of prolotherapy injections alone without cointerventions. Studies are needed to establish the safety of common prolotherapy solutions and to determine the optimum dose and number of injection sessions required.

**Fernández-Fairen M, Sala P, Dufou M Jr, Ballester J, Murcia A, Merzthal L.** Anterior cervical fusion with tantalum implant: a prospective randomized controlled study. *Spine.* 2008;33:465-72.

In this prospective randomized study, the use of a tantalum implant was compared with the use of iliac bone graft and plating after one-level anterior discectomy. The early results associated with the tantalum implant were equivalent to or slightly better than those associated with iliac bone-grafting and an anterior plate. At twenty-four months, the outcomes for the two groups were identical. It is hoped that the authors will follow these patients for a minimum of five years.

**Gay RE, Brault JS.** Evidence-informed management of chronic low back pain with traction therapy. *Spine J.* 2008;8:234-42.

This paper summarizes the best available evidence regarding the use of traction therapy for the treatment of chronic low-back pain. The preponderance of evidence indicates that sustained traction is ineffective for the treatment of low-back pain with or without leg pain. Although proprietary traction machines theoretically allow the spine to be distracted without reactive muscle contraction, allowing better separation of the vertebrae, there is little evidence that the result truly differs from that associated with simple intermittent axial traction.

**Glassman SD, Carreon LY, Djurasovic M, Campbell MJ, Puno RM, Johnson JR, Dimar JR.** rhBMP-2 versus iliac crest bone graft for lumbar spine fusion: a randomized, controlled trial in patients over sixty years of age. *Spine.* 2008;33:2843-9.

The authors report the results of a prospective randomized controlled trial in which rhBMP-2 on an absorbable collagen sponge (ACS) was compared with iliac crest bone graft for lumbar spine fusion in 102 patients over the age of sixty years. The mean fusion grade on a computed tomography scan was significantly better in the rhBMP-2/ACS group. The total cost of care over two years was \$2000 greater in the iliac crest bone graft group. This was a physician-directed study of an off-label use that appears to have better outcomes at a comparable or slightly lower cost. There was one nonunion in the rhBMP-2 group, compared with five nonunions in the iliac crest bone graft group. Time and additional studies will define the appropriate and safe use of such biologics. In the meantime, care must be exercised with the off-label use of BMP to minimize the risk of inconsistent bone formation or local side effects.

**Graham N, Gross A, Goldsmith CH, Klaber Moffett J, Haines T, Burnie SJ, Peloso PM.** Mechanical traction for neck pain with or without radiculopathy. *Cochrane Database Syst Rev.* 2008;3:CD006408.

The authors performed a systematic review with use of the Cochrane method and could not find any evidence that supports or refutes the use of cervical traction for patients with neck pain or radiculopathy. Although many studies have shown improvement in association with this modality, the presence of potential bias, poor reporting of methods, and inadequate outcome measures precluded their use in this review.

**Henschke N, Maher CG, Refshauge KM.** A systematic review identifies five "red flags" to screen for vertebral fracture in patients with low back pain. *J Clin Epidemiol.* 2008;61:110-8.

A systematic review of the literature on the diagnosis of vertebral body fractures in patients with low-back pain was performed. Twelve studies were reviewed that characterized fifty-one clinical features to assess the accuracy of diagnosis. Five clinical features were found to be useful to increase or decrease the probability of the presence of a fracture: an age of more than fifty years, female sex, the presence of major trauma, pain and tenderness, and a distracting painful injury. These five clinical features may be useful for screening patients with low-back pain for the presence of a vertebral body fracture.

**Imamura M, Furlan AD, Dryden T, Irvin E.** Evidence-informed management of chronic low back pain (CLBP) with massage. *Spine J.* 2008;8:121-33.

This paper summarizes the best available evidence for the use of massage for chronic low-back pain, and there is strong evidence that massage is effective. Massage is beneficial for patients with chronic-low back pain in terms of improving symptoms and function. Although massage therapy may appear costly, it may save money by reducing health-care provider visits, the use of

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pain medications, and the costs of back-care services. However, there is a paucity of high-quality studies that assess the cost-effectiveness of massage therapy.

**Jirattanaphochai K, Thienthong S, Sriraj W, Jung S, Pulnitiporn A, Lertsinudom S, Foocharoen T.** Effect of parecoxib on postoperative pain after lumbar spine surgery: a bicenter, randomized, double-blinded, placebo-controlled trial. *Spine*. 2008;33:132-9.

A prospective randomized trial of the effect of parecoxib on postoperative pain after lumbar fusion, discectomy, or decompression was performed on 120 patients. Forty patients in each surgical group were randomized to receive either placebo or multidoses of parecoxib, and the use of morphine administered by means of patient-controlled anesthesia was monitored. The overall effects in patients receiving parecoxib and morphine were comparable with those in patients receiving morphine alone. The patients receiving parecoxib had significantly improved postoperative pain control with a reduction in opioid requirement, lower pain scores, and a higher subjective rating of the medication.

**Marshall P, Murphy B.** Self-report measures best explain changes in disability compared with physical measures after exercise rehabilitation for chronic low back pain. *Spine*. 2008;33:326-38.

This study examined sixty individuals with chronic low-back pain who, after receiving four weeks of manipulative or nonmanipulative treatment, were assigned to receive either a supervised Swiss ball exercise program or advice alone. Greater improvement in terms of self-rated disability after the treatment period was noted for the individuals who received supervised exercise as compared with those who received advice alone. The authors concluded that use of supervised exercise is more successful than advice therapy and that these differences are primarily in psychological self-reported measures rather than actual physical measurements.

**Martimo KP, Verbeek J, Karppinen J, Furlan AD, Takala EP, Kuijjer PP, Jauhainen M, Viikari-Juntura E.** Effect of training and lifting equipment for preventing back pain in lifting and handling: systematic review. *BMJ*. 2008;336:429-31.

This study, performed in Finland, concluded that there is no evidence to support the use of advice or training in working techniques for preventing back pain or consequent disability. The methods were good, and the results were disappointing.

**Mayer J, Mooney V, Dagenais S.** Evidence-informed management of chronic low back pain with lumbar extensor strengthening exercises. *Spine J*. 2008;8:96-113.

This study specifically examined the evidence regarding the treatment of chronic low-back pain with lumbar extensor strengthening exercises. The authors found that, in the short-term, lumbar extensor strengthening exercise administered alone or with cointerventions is more effective than no treatment and most passive modalities for achieving improvements in terms of pain, disability, and other patient-reported outcomes in patients with chronic low-back pain.

**Novak S, Nemeth WC.** The basis for recommending repeating epidural steroid injections for radicular low back pain: a literature review. *Arch Phys Med Rehabil*. 2008;89:543-52.

A systematic review was performed to determine the efficacy of repeat epidural steroid injections for the treatment of radicular low-back pain. The study objectives failed because of the lack of available quality studies. The authors concluded correctly that no evidence exists to support the use of additional injections, and they recommended additional, more rigorous, investigations.

**Poitras S, Brosseau L.** Evidence-informed management of chronic low back pain with transcutaneous electrical nerve stimulation, interferential current, electrical muscle stimulation, ultrasound, and thermotherapy. *Spine J*. 2008;8:226-33.

This study specifically examined the evidence on the treatment of chronic low-back pain with transcutaneous electrical nerve stimulation, interferential current, electrical muscle stimulation, ultrasound, and thermotherapy. The authors found that there are few studies to support the use of these methods for the treatment of chronic low-back pain. Many of the studies were of poor quality, and many had differing results. Studies both for and against these treatments were found.

**Rasmussen S, Krum-Møller DS, Lauridsen LR, Jensen SE, Mandøe H, Gerlif C, Kehlet H.** Epidural steroid following discectomy for herniated lumbar disc reduces neurological impairment and enhances recovery: a randomized study with two-year follow-up. *Spine*. 2008;33:2028-33.

Two hundred patients who had been managed with lumbar discectomy were randomized to treatment with or without an epidural steroid and were followed for two years. No infections were registered. The authors concluded that epidural methylprednisolone enhanced recovery after discectomy for the treatment of a herniated disc, without apparent side effects. The main conclusion was that the hospital stay was reduced from eight to six days. In North America, the usual hospital stay after an unremarkable discectomy is typically only one or two days.

**Roelofs PD, Deyo RA, Koes BW, Scholten RJ, van Tulder MW.** Non-steroidal anti-inflammatory drugs for low back pain. *Cochrane Database Syst Rev*. 2008;1:CD000396.

The authors performed a meta-analysis on twenty-eight high-quality trials comparing nonsteroidal anti-inflammatory drugs that are used for the treatment of acute and chronic back pain. They found significant pain reduction at one week in association with nonsteroidal anti-inflammatory drugs as compared with placebo, at the expense of a higher rate of adverse events. COX2 nonsteroidal anti-inflammatory drugs were equally effective but had fewer side effects. However, the effect size of the nonsteroidal anti-inflammatory drugs was small and was unlikely to be greater than that of acetaminophen, physical therapy, or manipulation.

**Sidiropoulos PI, Hatemi G, Song IH, Avouac J, Collantes E, Hamuryudan V, Herold M, Kvien TK, Mielants H, Mendoza JM, Olivieri I, Østergaard M, Schachna L, Sieper J, Boumpas DT, Dougados M.** Evidence-based recommendations for the management of ankylosing spondylitis: systematic literature search of the 3E Initiative in Rheumatology involving a broad panel of experts and practising rheumatologists. *Rheumatology (Oxford)*. 2008;47:355-61.

This was a ten-country discussion of the evidence regarding treatment recommendations for ankylosing spondylitis. An international panel of experts analyzed 467 reports and developed twelve key recommendations for treatment, stratified into three general diagnostic recommendations, three recommendations concerning monitoring of disease activity, and six recommendations concerning pharmacological treatment. The agreement of these experts ranged from 72% to 93%. This is a unique method of combining opinions of practicing rheumatologists to develop guidelines with a high degree of agreement and could be expanded to even larger groups of clinicians.

**Standaert CJ, Weinstein SM, Rumpeltes J.** Evidence-informed management of chronic low back pain with lumbar stabilization exercises. *Spine J*. 2008;8:114-20.

This review specifically examined the evidence on the treatment of chronic low back pain with lumbar stabilization exercises. The studies that were examined typically had a mixed group of patients with nonspecific chronic low-back pain, with or without radicular symptoms, so it is difficult to draw specific conclusions. The authors found that lumbar stabilization exercises are effective for reducing pain and improving function in such heterogeneous groups of patients.

**van den Hout WB, Peul WC, Koes BW, Brand R, Kievit J, Thomeer RT; Leiden-The Hague Spine Intervention Prognostic Study Group.** Prolonged conservative care versus early surgery in patients with sciatica from lumbar disc herniation: cost utility analysis alongside a randomised controlled trial. *BMJ*. 2008;336:1351-4.

## WHAT'S NEW IN SPINE SURGERY

A previously published randomized controlled study in which surgery was compared with prolonged nonoperative care was secondarily examined for cost utility of treatment. The quality-adjusted life years (QALYS) were determined from standard outcome instruments. Costs were determined from health care utilization, patients' diaries, and work productivity. Surgery had higher costs that were offset by earlier return to work and therefore was considered to be cost-effective. These results are reassuring, especially considering the high rate of crossover and the selection bias of patients entering the study, which biased the original randomized controlled trial toward nonoperative care.

**Van der Roer N, van Tulder M, van Mechelen W, de Vet H.** Economic evaluation of an intensive group training protocol compared with usual care physiotherapy in patients with chronic low back pain. *Spine*. 2008;33:445-51.

In this prospective randomized study from The Netherlands, the cost-effectiveness of an intensive group-training protocol was compared with that of standard physical therapy in patients with nonspecific chronic low-back pain. The intensive group-training protocol combines exercise therapy, back school, and behavioral principles. At one year, the direct health-care costs were significantly higher for the protocol group, with small and insignificant differences in outcome between the groups.

**Wai EK, Rodriguez S, Dagenais S, Hall H.** Evidence-informed management of chronic low back pain with physical activity, smoking cessation, and weight loss. *Spine J*. 2008;8:195-202.

This review specifically examined the evidence on the treatment of chronic low-back pain with physical activity, smoking cessation, and weight loss. There were a limited number of articles, many of which were of low quality, but the authors concluded that there was no evidence as to the efficacy of smoking cessation or nonoperative weight loss as treatments for chronic low-back pain. There was moderate evidence that different types of physical activity were more effective than no activity for longer-term reductions in disability and improvements in terms of worst pain, medication usage, work status, and mood.

**Weinstein JN, Tosteson TD, Lurie JD, Tosteson AN, Blood E, Hanscom B, Herkowitz H, Cammisia F, Albert T, Boden SD, Hilibrand A, Goldberg H, Berven S, An H; SPORT Investigators.** Surgical versus nonsurgical therapy for lumbar spinal stenosis. *N Engl J Med*. 2008;358:794-810.

The authors report on one cohort from a large prospective randomized surgery trial evaluating outcomes for patients with a chief complaint of leg pain (neurogenic claudication) resulting from the confirmed diagnosis of lumbar spinal stenosis without spondylolisthesis. Two hundred and eighty-nine patients were randomized to decompression surgery or usual nonsurgical care, and an additional 365 patients were enrolled into an observational cohort. In the combined as-treated analysis, patients who underwent surgery showed significantly more improvement in all primary outcomes than did patients who were managed nonsurgically. The detailed information in this study should help physicians to advise patients about the decision to have surgery and the expected outcomes when leg pain has persisted for at least twelve weeks in the presence of lumbar spinal stenosis.

**Yee AJ, Yoo JU, Marsolais EB, Carlson G, Poe-Kochert C, Bohlman HH, Emery SE.** Use of postoperative lumbar corset after lumbar spinal arthrodesis for degenerative conditions of the spine. A prospective randomized trial. *J Bone Joint Surg Am*. 2008;90:2062-8.

In this prospective randomized trial, the use of a postoperative lumbar corset for eight weeks following a posterior lumbar arthrodesis for the treatment of a degenerative spinal condition was compared with the use of no corset. There was no significant advantage or disadvantage to the use of a postoperative lumbar corset following spinal arthrodesis for the treatment of degenerative conditions of the lumbar spine. Perhaps patient desire and comfort should dictate this decision in the absence of additional data.

**Yuan J, Purepong N, Kerr DP, Park J, Bradbury I, McDonough S.** Effectiveness of acupuncture for low back pain: a systematic review. *Spine*. 2008;33:E887-900.

The authors present a systematic review of randomized controlled trials to explore the evidence on the effectiveness of acupuncture for the treatment of nonspecific low-back pain. Twenty-three studies were included, six of which were of high quality. The authors concluded that acupuncture can be a useful supplement to other forms of conventional therapy for the treatment of nonspecific low-back pain, but the effectiveness of acupuncture compared with other forms of conventional therapies still requires further investigation.