What's new in spine surgery

Keith H. Bridwell
Washington University School of Medicine in St. Louis
Paul A. Anderson
University of Wisconsin Hospital
Scott D. Boden
Emory University School of Medicine
Alexander R. Vaccaro
Rothman Institute at Jefferson
Jeffrey C. Wang
University of California - Los Angeles

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What’s New in the Treatment of the Cervical Spine
As is the case with other areas of the spine, advances in the treatment of the cervical spine have been made in the development of new technology such as disc arthroplasty, in the achievement of a better understanding of surgical morbidity, and in attempts to document outcomes of neurologic recovery. These issues were the focus of annual meetings of both the Cervical Spine Research Society and its European counterpart in 2005.

Disc Arthroplasty
Additional evidence establishing the efficacy of cervical arthroplasty has been reported. The short-term results associated with three different cervical disc prostheses have demonstrated equivalency or slight improvement in comparison with the results of fusion in randomized, controlled trials. The indications for arthroplasty in the ongoing United States Food and Drug Administration Investigational Device Exemption investigations are single-level treatment for radiculopathy or myelopathy in patients with a stable spine. Motion ranging from 7° to 12° has been maintained after arthroplasty. Complications have been few; only rare neurologic complications have been reported.

Additional benefits of arthroplasty may include diminished surgical morbidity and earlier return to function. In one study, the reported rate of reoperation was 2.9% after disc replacement compared with 5.4% after fusion. Compared with patients undergoing fusion, patients undergoing arthroplasty were reported to have a lower rate of reoperation at adjacent levels over the same relatively short (sixteen-month) follow-up period. The most common indication for reoperation in patients managed with disc replacement was inadequate foraminal decompression at the index level. This indicates a need for a meticulous wide uncal decompression when performing arthroplasty reconstruction. Presumably because patients do not require immobilization and are not undergoing the process of achieving fusion, return to work is much earlier after arthroplasty. In a cohort of 976 patients, the return to work was significantly earlier for those who underwent arthroplasty than for those who underwent arthrodesis (thirty-two days compared with forty-one days).

Analyses of explants from patients undergoing revision have demonstrated excellent durability of the metallic and polymeric bearing surfaces. Chemical analysis of the polyurethane that was used as a nuclear component in one device did not show any signs of oxidation or fragmentation of the polymer structure. In a metallurgical study in which the surfaces of two retrieved metal-on-metal prostheses were compared with those of similar devices that were tested in simulators, the wear patterns were similar; however, the amount of wear that was observed in the retrieved devices was only one-tenth of that predicted by the simulators. The findings in this small sample indicate that cervical devices may be significantly overdesigned for wear.

Because some patients may require reoperation, magnetic resonance imaging with arthroplasty devices in place is important. Prostheses that contain metals including cobalt-chromium and titanium alloys are available; these devices have various magnetic properties that may interfere with magnetic resonance imaging quality. Studies have shown that postoperative image quality is totally dependent on the quality of the metal that is utilized with titanium.

Complications
Vocal cord dysfunction following anterior surgery is believed to result from compression of the recurrent laryngeal nerve between the larynx and retractors or from direct trauma. A prospective study documented that vocal cord paralysis occurred in 3.2% of patients and that dysfunction occurred in 14.9%. Risk factors included a longer duration of retraction.
and a right-sided approach. Deflation of the endotracheal cuff and limiting its pressure to 20 mm Hg did not prevent this complication.

The off-label use of bone morphogenetic protein-2 (BMP-2) for anterior cervical fusion has been reported to result in a severe inflammatory reaction and bleeding in some patients. This has led to a warning submitted by the product’s distributor. In a study from Atlanta, the rate of swelling complications was 27.5% among patients who had been managed with BMP, compared with only 3.6% among controls.

The use of anterior cervical plates for cervical arthrodesis has been shown to increase postoperative dysphasia two-fold to threefold. An anatomical investigation revealed that the esophagus lies most closely to the spine in the midline. Laterally, however, there are 2 to 3 mm of separation, with the right side having about 1 mm more space. Minimizing the midline plate thickness and using the lateral potential spaces may decrease the prevalence of postoperative dysphasia.

Cervical collars are commonly used for fracture stabilization or for postoperative immobilization. In patients who wear an orthosis that abuts the mandible, mastication causes the head to move into extension when the jaw opens. Cine-fluoroscopy revealed that this motion translated to substantial extension between the occiput and C2. Loosening the collar during mastication eliminated this tendency.

**Whiplash**

Whiplash is a broad group of disorders resulting from a variety of mechanisms that occur during vehicular crashes. It has been postulated that some patients may sustain an injury of the alar and transverse ligaments. These ligaments can be evaluated with use of specific magnetic resonance imaging techniques. In one study, fat-suppressed T2-weighted images documented structural abnormalities in 29.7% of patients with whiplash-associated disorders compared with only 5.3% of controls. The importance of these findings and how to treat these disorders is yet unknown.

Many factors have been associated with a poor outcome following whiplash. A recent study demonstrated that abnormal scores on the SF-36 bodily pain and role-emotional domains were strongly associated with a poor prognosis. Another important negative predictor was a history of a Workers’ Compensation or personal injury claim and having a lawyer involved with the case. The amount of automobile damage had no influence on outcome.

**Myelopathy**

Patients with symptomatic ossification of the posterior longitudinal ligament are often managed with posterior decompressive surgery. An important unknown is the question of whether they will have progressive ossification after surgery. Recent studies have shown that 75% of patients had progression. Risk factors were a younger age (less than forty years) and disease rostral to the C4 level.

**What’s New in Spine Surgery**

Posterior cervical decompression for the treatment of multiple-level myelopathy or ossification of the posterior longitudinal ligament is theoretically effective because it allows the spinal cord to shift posteriorly, away from ventral pathology. The degree to which this happens and its importance were evaluated by investigators who found that wider and more complete laminoplasties (compared with more limited approaches) were associated with more shifting of the cord posteriorly. However, no difference in any outcome parameter was correlated with the degree of posterior cord translation. This brings into question how laminoplasty relieves the symptoms of myelopathy and suggests that conventional multiple-level posterior techniques may not be necessary.

An important neurologic dysfunction in patients with myelopathy is impaired proprioception, presumably a major cause of gait abnormalities. This is often thought to be a late finding that carries a poor prognosis. One investigator measured knee proprioception and found significant differences between patients with myelopathy and controls. Patients with myelopathy improved rapidly within two weeks postoperatively following decompression. This improvement persisted at two years and strongly correlated with improvement in overall function. Surprisingly, proprioception improved more rapidly than muscular strength did.

**What’s New in Biologic Topics Related to the Spine**

Biologic tools for reconstruction and regeneration continue to be one of the most widely researched areas related to the spine today. There is a continued effort to enhance the process of achieving spine fusion and to eliminate the need to harvest autogenous iliac crest bone for grafting. Since the United States Food and Drug Administration’s post-marketing approval of rhBMP-2 in 2002 and Humanitarian Device Exemption for rhBMP-7 late in 2004, the era of using recombinant bone morphogenetic proteins to achieve spine fusion has officially begun. Only two or three companies have access to proven bone growth factors, and this has resulted in increased efforts by the device industry to develop and promote motion-sparing technologies for which intellectual property regulations are less restrictive. As well, there continues to be increased activity in the development of lower cost bone-graft substitutes. Finally, an increasing amount of research continues to be focused on understanding the biology of the intervertebral disc and on developing biologic strategies to retard or reverse degeneration.

**Recombinant Osteoinductive Proteins**

Data from two pilot studies evaluating rhBMP-7 (OP-1) were published in 2005. Preclinical studies and preliminary clinical data showed posterolateral fusion success rates of 50% to 70%. A two-year follow-up pilot study evaluating the use of OP-1 putty as an adjunct to iliac crest autogenous graft in patients managed with posterolateral lumbar arthrodesis without in-
instrumentation failed to demonstrate any benefit of adding OP-1 putty to the autogenous graft. Only five of ten patients had achievement of a solid fusion radiographically. In contrast, a similar investigation on the use of rhBMP-2 (INFUSE; Medtronic Sofamor Danek, Memphis, Tennessee) as an adjunct to autogenous iliac crest bone graft in patients managed with posterolateral arthrodesis with instrumentation demonstrated a 96% rate of successful fusion. A second study evaluated OP-1 putty as a replacement for iliac crest autogenous graft in patients managed with posterolateral lumbar arthrodesis without instrumentation. That study demonstrated successful fusion in 55% (eleven) of twenty patients managed with OP-1, compared with 40% (four) of ten patients managed with autogenous graft. While there do not seem to be major safety issues associated with OP-1, its efficacy may not be as consistent as that reported in association with INFUSE. At this time, it is unclear if these differences are due to product formulation or the relative potency of BMP-2 as compared with BMP-7 or a combination of both issues. A third osteoinductive protein, GDF-5 (MP-52), continues to be investigated in clinical trials, and results should be forthcoming in the next year. Another important issue is whether these more expensive bone-graft substitutes will improve clinical outcomes and whether improved rates of fusion will correlate with better outcomes. The answers to these questions will take longer follow-up and will likely also depend heavily on the preoperative diagnosis.

Two preclinical studies involving rhBMP-2 investigated the use of a second-generation carrier consisting of a collagen sponge impregnated with 15% hydroxyapatite and 85% tricalcium phosphate granules. This carrier performed well in a thoracoscopic porcine interbody fusion model. In addition, this new carrier, when wrapped with rhBMP-2 on the original absorbable collagen sponge, allowed posterolateral lumbar fusion to be achieved with a lower dose of BMP-2 in rhesus monkeys.

**Other Bone-Graft Substitutes**

Given the relatively high cost of recombinant BMPs, a variety of other bone-promoting strategies continue to be investigated. Demineralized bone matrix (DBM), which contains natural BMPs (which retain activity if properly processed), continues to be used in clinical practice. A common misconception is that all DBMs are the same. Recent studies have highlighted the point that the activity of different brands and formulations of DBMs can be highly variable. In fact, few DBMs have been validated in large rodent models and only one has been documented to be osteoinductive in a nonhuman primate spine fusion model. In 2005, the Food and Drug Administration began to require 510K approval for DBM products. This process requires documentation of at least a minimum common level of osteoinductivity. Few clinical studies have been performed to evaluate these materials in humans, but those that have been performed have suggested that the more active formulations in combination with local bone graft can perform as well as autogenous iliac crest bone graft.

The past year saw a continuation of the stream of studies demonstrating the failure of platelet gel concentrates to increase the rate of success of spine fusion. Despite the early heavy marketing of these platelet-based products as containing osteoinductive growth factors, the clinical data that have been reported by individual investigators have not supported this contention for spinal arthrodesis. In addition, a recent study in *The Journal* demonstrated that platelet-derived growth factor (PDGF) and platelet gel concentrate inhibited the osteoinductive properties of DBM.

Another area that continues to receive attention is the use of bone marrow as a source of progenitor cells. While it is commonly accepted that mesenchymal progenitor cells exist in bone marrow, they are extremely rare and usually require specific stimuli to proceed down the osteoblast lineage. Thus, the benefit of simply adding bone marrow to other bone-graft materials is something that has yet to be validated in a primate model. One recent study suggested that the concentration of osteogenic progenitors is lower in the vertebrae than in the iliac crest. Some laboratories continue to investigate culture-expanded bone-marrow cells, a process that selects and expands the osteoprogenitor cells. Studies involving a rabbit spine fusion model have suggested that cultured bone-marrow cells can act as a substitute for autogenous graft, but this requires a cell density of 100 million progenitor cells per mL, which is substantially more than is present even in concentrated fresh marrow aspirates. Another study demonstrated the successful use of genetically transformed bone-marrow cells in a rat spine fusion model, but this too required the implantation of 5 million transformed cells expressing BMP-2 in a very small volume.

**Biologic Treatments for Disc Degeneration**

Disc degeneration remains an endemic reality of aging. As is the case with most conditions, there is likely to be some genetic predisposition. At the present time, the biologic treatment of disc degeneration remains solely in the realm of research. Progress continues slowly to surpass a variety of obstacles. First, the development and validation of animal models of disc degeneration continue to be a major limitation. The vast majority of models are disc injury models, which may or may not be relevant to natural disc aging. Studies continue to examine the effect of mechanical forces on normal disc nutrition and health. A third area that requires advances is the quantitative noninvasive detection and monitoring of disc degeneration. More sophisticated use of magnetic resonance imaging may serve this role in the future.

One possible approach to the treatment of disc degeneration that is confined to the nucleus pulposus would be to revitalize the tissue by implanting or injecting cells that have the potential to restore functionality. These cells could be bone marrow mesenchymal cells or culture-expanded disc cartilage.
cells. A recent study of rabbit intervertebral discs demonstrated that bone mesenchymal stem cells could be transplanted and could survive to increase proteoglycan synthesis. Another group of investigators tested cell viability when cells were delivered with a fibrin gel into rabbit intervertebral discs, highlighting just one of the challenges of intradiscal cell therapy. If disc degeneration occurs because of, or results in, nutritional compromise, then the survivability of transplanted cells would be in question. Work continues in this area, although the challenges remain quite substantial.

**What’s New in Spinal Deformity Surgery**

Much of what is reported in this section summarizes presentations from the fortieth annual meeting of the Scoliosis Research Society that was held in October 2005 in Miami, Florida.

**Adolescent Spinal Deformity**

There is still not universal agreement with regard to the appropriate fixation points and implants to use for the surgical treatment of idiopathic adolescent scoliosis. Investigators from various centers have not agreed on the best treatment of a thoracic curve when there is a false double-major curve pattern. Is it better to treat a thoracic curve with anterior arthrodesis and instrumentation, with a hybrid construct, or with a pedicle screw construct? Investigators at some centers believe that anterior treatment is preferable, others prefer pedicle screw implants, while others believe that a hook-wire construct accomplishes the necessary goals. It appears that the use of thoracic pedicle screws with a convex derotation maneuver has a lordosing effect on the thoracic spine. In many cases this is desirable, but in other cases it may not be desirable if the patient is very hypokyphotic preoperatively. To some extent, with posterior segmental spinal instrumentation, a component of proximal junctional kyphosis is seen with all of the constructs.

With regard to the anterior treatment of lumbar and thoracolumbar curves, the use of structural or morselized rib grafts has been debated. The authors of one study that was presented at the 2005 Scoliosis Research Society (SRS) meeting concluded that structural grafts were better for maintaining lordosis. That study involved the use of a single screw/single rod construct. Debate continues with regard to whether single screw/single rod or double screw/double rod constructs are better for the anterior treatment of thoracolumbar and lumbar curves.

**Adult Spinal Deformity**

Classification is necessary in order to understand the natural history of adult spinal deformity and to facilitate the study and treatment of adult scoliosis and spinal deformity. Work is under way to classify adult spinal deformity in a fashion similar to the classifications that are used for adolescents. Classifying adult deformity is more complex. Disc degeneration caudad to the major curve, progression of the fractional lumbar-sacral curve, the existence of spinal stenosis and rotatory subluxations, coronal imbalance, and, in particular, sagittal imbalance are more prevalent problems in the adult population than in the adolescent population. Several investigators are coordinating multicenter projects to accomplish this goal.

The most challenging deformity in an adult patient is one that requires a long fusion to the sacrum. Although most investigators agree that providing anterior structural support at L4-L5 and L5-S1 as well as bilateral iliac fixation leads to better balance and a lower rate of pseudarthrosis, this is not universally accepted at all centers. There is still discussion regarding whether to stop a long construct at L5 or at the sacrum. There also is controversy on where to stop proximally. Risk factors that can lead to the development of proximal junctional problems and progressive kyphosis are currently being investigated.

It is known that the surgical treatment of spinal deformity in adults is associated with a substantially higher complication rate than is the case in the adolescent patient population. Various complications that were discussed at the recent SRS meeting included morbidity associated with the anterior approach, pseudarthrosis, and sagittal thoracic decompensation after lumbar instrumentation and fusion. When thoracolumbar, lumbar oblique, and paramedian-type anterior approaches to the lumbar spine are compared, the thoracoabdominal and lumbar oblique approaches appear to be associated with greater morbidity. The most common complication is chronic pain and asymmetric bulging of the ipsilateral abdominal body wall musculature.

**Congenital Spinal Deformity**

Numerous reports have indicated that hemivertebra resection in the thoracolumbar and lumbar-sacral regions results in substantial correction with relatively low morbidity. It appears that resecting the hemivertebra through a posterior-only approach is often a reasonable alternative to combined anterior-posterior surgery.

Numerous investigators continue to work to define the concept of “thoracic insufficiency syndrome.” The ideal treatment for a young patient who has this condition secondary to congenital scoliosis associated with multiple fused ribs is still evolving. Expansion thoracoplasty with use of “titanium rib” technology is gaining acceptance over early fusions at many centers. As is the case with the growing-rod technique, the complication rates associated with this technique are quite high. The goal of this technique is to favorably impact pulmonary mechanics and growth. Follow-up to adulthood will be required to determine the efficacy of this technique.

**Early-Onset Scoliosis**

There are many causes of scoliosis in children under the age of ten years other than a congenital etiology. These include connective-tissue disorders, inherited syndromes, and idio-
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Pathologic infantile and juvenile scoliosis. The preferred initial treatment in most cases is bracing. In cases in which the curve progresses in spite of bracing, most investigators believe that it is beneficial to avoid arthrodesis at least until the age of eight to ten years. In these cases, instrumentation without fusion is usually desired. “Fusionless surgery” submits the patient and family to a prolonged and recurring surgical plan that is associated with a unique list of complications. It appears that the best results are achieved in association with a dual growing-rod construct with two-vertebra fixation at each end and scheduled lengthenings at six-month intervals.

Etiology of Idiopathic Adolescent Scoliosis
A small number of centers continue to study the genetics of familial idiopathic scoliosis and kyphoscoliosis. This work is heavily supported by the Scoliosis Research Society. Investigation is quite complex because of the substantial heterogeneity of these disorders. As one researcher stated at the recent SRS meeting, “Ultimately the independent association of genetic loci and these disorders will enhance the ability to elucidate prognosis, counsel patients, and guide therapeutic plans.”

Scheuermann Kyphosis
There is a trend toward treating Scheuermann kyphosis with a posterior-only surgical construct. This usually requires posterior column shortening through aggressive facetectomies or osteotomies in conjunction with pedicle screw implants. Although the follow-up is still relatively short, it appears that an acceptable rate of fusion is achieved. However, a substantial number of patients with Scheuermann kyphosis still have development of proximal and distal junctional kyphosis. The complication rate associated with the surgical treatment of adolescent Scheuermann kyphosis is higher than that associated with adolescent idiopathic scoliosis. Not surprisingly, the complication rate is even higher in adult patients than in adolescent patients with Scheuermann kyphosis.

Neuromuscular Scoliosis
Many investigators at the SRS meeting reported on the treatment of neuromuscular scoliosis, including the surgical treatment of both spastic and flaccid deformities. While surgical techniques varied, most investigators recommended a long instrumented fusion to the sacrum and some form of pelvic fixation. Although the complication rate was fairly high after follow-up periods ranging from two to ten years, most authors believed that patients did benefit from these procedures.

Spondylolisthesis
With respect to the surgical treatment of spondylolisthesis, there remains considerable controversy with regard to when to use implants (pedicle screws), when to perform a combined fusion as opposed to only a posterior fusion, and when to decompress and when to reduce a high-grade spondylolisthesis in pediatric patients. Seemingly all patients do well in the short run if a solid fusion is achieved without major systemic or neurologic complications.

What’s New in Spinal Cord Injury
Much of the research over the last year focused on the psychological, social, and medical challenges facing patients with spinal cord injury. This section provides an overview of the oral presentations that were delivered at the meeting of the American Spinal Injury Association that was held in May 2005 in Dallas, Texas.

Psychosocial Impact
The psychosocial impact of spinal cord injury appears to be especially strong on pediatric and adolescent patients. A cross-sectional study assessing the impact on quality of life demonstrated that adolescent patients with spinal cord injury had significantly lower quality-of-life scores than age-matched able-bodied individuals. Additionally, adolescents with a spinal cord injury had a lower quality of life as compared with age-matched obese children. Another study indicated that suicide was as frequent a cause of death as pulmonary disease among adolescent patients who had a spinal cord injury.

Pressure ulcers remain a common problem among young patients with a spinal cord injury. Patients at higher risk typically have a complete spinal cord injury, have a history of substance abuse, and have lower mental function scores. Pressure ulcers, although significantly impacting quality of life, have been shown not to preclude employment, independent living, or life satisfaction.

Nonetheless, patients with a spinal cord injury may become active and productive members of society. An analysis of >20,000 patients demonstrated a significantly higher likelihood of employment in association with certain factors, including younger age, white race, higher education level, marriage, a nonviolent cause of injury, ASIA grade-C or D paraparesis, a longer time after the injury, a higher employment rate in the general population, lower Social Security Disability benefits, and the number of calendar years since the passage of the Americans With Disabilities Act. The calculated work-life expectancy of individuals varied according to level of education; specifically, it was normal among individuals with professional degrees and was substantially reduced among those with less than a college-level education.

Neurologic Recovery
Some of the predictors of neurologic recovery have become clarified. Although age, gender, the mechanism of injury, and the level of injury are not independently predictive, other factors are. In general, less severe injury patterns are predictive of improved outcomes. Sparing of sensation to pin prickle, intact bladder function, spinal shock for less than twenty-four hours, and the early reappearance of deep tendon reflexes are positive factors. Negative factors include a complete lesion, spinal shock for more than one week, and flexor spasms oc-
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The results of various prostheses. Disorders, and a number of studies evaluated their efficacy and potentially exciting method for the treatment of lumbar spinal disorders, specifically with regard to their potential to reduce the risk of adjacent-segment degeneration. Such devices are a vice and their viability as a means of treating lumbar spinal disease among patients with a spinal cord injury has been well publicized, both male and female patients with a spinal cord injury are at substantial risk for cardiovascular disease. Abnormal lipid profiles, hyperglycemia, and the development of time-dependent carotid artery disease have been documented in otherwise young patients. The use of niacin may be beneficial for decreasing the cardiovascular risk among patients with chronic tetraplegia.

Medical Risks
Although the potential for pulmonary and thromboembolic disease among patients with a spinal cord injury has been well publicized, both male and female patients with a spinal cord injury are at substantial risk for cardiovascular disease. Abnormal lipid profiles, hyperglycemia, and the development of time-dependent carotid artery disease have been documented in otherwise young patients. The use of niacin may be beneficial for decreasing the cardiovascular risk among patients with chronic tetraplegia.

Rehabilitation
Advances in rehabilitation following a spinal cord injury have shown lasting effects. The use of body-weight-supported treadmill training has been effectively used to restore independent movement in patients with incomplete motor paralysis. Impressively, the individuals maintained independent walking ability well beyond the completion of treatment.

The use of new technologies also may improve quality of life by allowing patients, especially those who are most severely injured, to interact with their environment by simply thinking the correct thoughts. The BrainGate neural interface system attempts to translate cortical signals into computer actions through a sensor that is placed on the cerebral motor cortex. It has been used successfully by patients to move a computer cursor with neural activity. The ability to control computer function by means of mental function alone could redefine the “disabilities” associated with spinal cord injury.

What’s New in the Treatment of the Lumbar Spine
Novel developments related to the treatment of degenerative lumbar spinal disorders have occurred at a rapid pace. It is hoped that these new implants and techniques will allow investigators to address one of the most problematic areas of the spine. Much of the information that is described here was presented at the annual meeting of the International Society for the Study of the Lumbar Spine (ISSLS) that was held in May 2005 in New York, NY.

Lumbar Disc Arthroplasty
Many recent studies have evaluated motion-preservation devices and their viability as a means of treating lumbar spinal disorders, specifically with regard to their potential to reduce the risk of adjacent-segment degeneration. Such devices are a potentially exciting method for the treatment of lumbar spinal disorders, and a number of studies evaluated their efficacy and the results of various prostheses.

One prospective study evaluated artificial disc replace-ment as an alternative to spinal fusion in the lumbar spine. That study, which included twenty consecutive patients with at least two years of follow-up, demonstrated good preservation of lumbar motion, good outcomes, and the absence of adjacent-segment disease.

Another study examined the use of disc arthroplasty for the treatment of adjacent-segment degeneration in twenty consecutive patients who had had a previous fusion. There was significant improvement in the pain scores as well as in patient satisfaction scores in the postoperative period. On the basis of the early success rate of 86% after one year of follow-up, the authors concluded that lumbar disc arthroplasty was efficacious for the treatment of symptomatic adjacent lumbar discogenic low-back pain following a previous fusion.

In another prospective study, sixty-four consecutive patients who had been managed with a metal-on-metal disc replacement were evaluated after at least two years of follow-up. That study demonstrated significant improvement in the Oswestry Disability Index ($p < 0.0001$) and in visual analog scores ($p < 0.0001$). Outcomes analysis with use of the SF-36 instrument showed 85% improvement in the physical scores and 43% improvement in the mental scores. Complications related to the anterior approach included ureteral tearing, common iliac vein tearing, and posterior wall fracture. There were no implant-related complications.

In another study, which included a total of 105 patients with a minimum of twelve months of follow-up, two-level total disc replacements were compared with single-level replacements. The two-level disc replacement group had significant improvements in terms of pain and functional scores and had outcomes similar to those in the single-level group, confirming the efficacy of performing disc arthroplasty at two adjacent levels.

Lumbar Fusion Compared with Arthroplasty
A review comparing the outcomes of disc arthroplasty with those of lumbar fusion identified a common theme in the disc-replacement studies as well as in the fusion studies involving the use of recombinant BMP-2. Both groups did better than did their respective control groups, in which the treatment involved fusion with use of autogenous iliac crest bone graft. The review also demonstrated that the groups treated with spinal fusion with recombinant BMP-2 and the groups treated with disc arthroplasty had similar improvement in terms of both the Oswestry Disability Index and pain at the time of the two-year follow-up. The investigators suggested that additional studies should be performed in which fusion in the control group is accomplished with rhBMP-2 instead of autogenous iliac crest bone graft in order to allow for more accurate comparisons.

Complications of Disc Arthroplasty
One of the main concerns associated with disc replacement is the challenge of revising failed implants. One study evaluated...
the complications that occurred in a group of 347 patients undergoing lumbar disc arthroplasty and a control group of ninety-nine patients undergoing lumbar fusion. The rate of reoperation was 7.8% (twenty-seven patients) in the study group, compared with 10.1% (ten patients) in the control group. Common reasons and complaints that necessitated reoperation in the disc-replacement group were persistent pain, pseudoradicular symptoms, mechanical low-back pain, and lower extremity cramping. Fifteen patients underwent repeated anterior approaches with removal of the prosthesis. Five of these fifteen patients had a revision with another artificial disc, typically one of a smaller size. The other ten patients had a successful conversion to a fusion.

**Lumbar Disc Herniation**

There has been little research assessing the long-term outcome of lumbar discectomy. It is thought that patients who have had lumbar discectomy may be more prone to further degeneration at the level of surgery in the postoperative period and may eventually require a fusion.

One study evaluated the five-year results of lumbar discectomy in fifty-three patients. This multicenter, retrospective study demonstrated significant improvements, both mentally and physically, with a low level of pain and functional disability. In general, the patients were quite satisfied with the results of surgery. Although additional study and longer follow-up are needed, lumbar discitis appeared to have excellent results, with a low level of symptomatic discogenic back pain, within the five-year follow-up period in this outcome study.

Another study analyzed the results of total disc replacement in fifteen patients who had discogenic low-back pain following a previous discectomy. After a minimum duration of follow-up of two years, these patients had significant improvement in outcomes. The investigators concluded that total disc replacement is a viable option for the treatment of discogenic back pain following a previous discectomy.

**Interspinous Process**

**Distraction for Spinal Stenosis**

Lumbar decompression with the placement of a distracting device between the spinous processes has been shown to be effective for the treatment of spinal stenosis and neurogenic claudication. In one study, data were presented on a series of sixty-one patients who had neurogenic claudication secondary to degenerative spondylolisthesis at one or two levels. These patients were part of a Food and Drug Administration-approved prospective, randomized, multicenter study in which patients who were managed with the X STOP device (St. Francis Medical Technologies, Alameda, California) were compared with those who were managed conservatively with epidural steroids. After two years of follow-up, there were significant improvements in the group that had been managed with the interspinous process decompression device as compared with the control group. The patient-satisfaction scores and outcome-analysis scores also improved significantly in the operative group. The authors of the study concluded that interspinous process decompression with use of this device was more effective than conservative treatment for patients with grade-I degenerative spondylolisthesis.

A similar study examined 260 consecutive patients who were managed with a similar type of device, the Wallis interspinous process device. The authors noted significant improvement in outcomes categories when the postoperative findings were compared with the preoperative findings.

Another study evaluated the results associated with the X STOP device in a group of 100 patients who were managed with either a one-level procedure (sixty-four patients) or a two-level procedure (thirty-six patients). After a minimum of two years of follow-up, there were no significant differences between the two groups, confirming success at two levels as well as one.

**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 1. Over 100 medical journals were reviewed to identify these articles, which all have high-quality study design. In addition to articles published previously in this journal or cited already in this Update, thirty-one level-1 articles were identified that were relevant to spine surgery. A list of those titles is appended to this review after the standard bibliography. We have provided a brief commentary about each of the articles to help guide your further reading, in an evidence-based fashion, in this subspecialty area.

**Upcoming Meetings and Events Related to Spine Surgery**

The forty-first annual meeting of the Scoliosis Research Society (SRS) will be held on September 13 through 16, 2006, at the Monterey Conference Center in Monterey, California. It will be preceded by a one-day course entitled “Modern Techniques in Spine Deformity Surgery: Is the Evidence as Good as the Theory?” to be held on September 13, 2006. Web site: www.srs.org.

The twenty-first annual meeting of the North American Spine Society (NASS) will be held on September 26 through 30, 2006, at the Sheraton Seattle Hotel and Towers in Seattle, Washington. There will be a number of precourses on September 25, 2006. Web site: www.spine.org.

The thirty-fourth annual meeting of the Cervical Spine Research Society (CSRS) will be held on November 30 through December 2, 2006, at The Breakers in Palm Beach, Florida. Web site: www.csrs.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, to be
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Keith H. Bridwell, MD
Department of Orthopaedic Surgery, Washington University School of Medicine, One Barnes-Jewish Hospital Plaza, Suite 11300 West Pavilion, Campus Box 8233, St. Louis, MO 63110. E-mail address: bridwellk@wudosis.wustl.edu

Paul A. Anderson, MD
Department of Orthopaedics and Rehabilitation, University of Wisconsin

References


Evidence-Based Articles Related to Spine Surgery


Part I was a prospective, randomized, multicenter study that demonstrated that the clinical outcome following lumbar disc replacement with the CHARITE device was at least equivalent to the clinical outcome following anterior lumbar interbody fusion. In fact, by most measures, the CHARITE group performed better than the fusion group. The control group may not have been entirely appropriate in that these patients underwent a more invasive surgical procedure in which autologous bone was harvested from the iliac crest. Otherwise, the study was well done and the conclusion was sound.

McAfee PC, Cunningham B, Holsapple G, Adams K, Blumenthal S, Guyer RD, Dmietriev A, Maxwell JH, Regan JJ, Isaza J. A prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of lumbar total disc replacement with the CHARITE artificial disc ver-

The authors of this study attempted to correlate clinical outcomes with radiographic results in patients managed with the CHARITÉ device and those managed with anterior interbody fusion and threaded cages. The CHARITÉ group demonstrated better restoration of disc-space height and significantly less subsidence than did the anterior interbody fusion group. The CHARITÉ group maintained the range of flexion-extension twenty-four months following surgery. It appears that disc replacement has advantages over fusion with threaded cages.


This prospective, randomized trial investigated the use of rhBMP-2 inside a cortical allograft bone dowel in the anterior lumbar interbody arthrodesis setting. Two years after surgery, the rate of successful fusion in the BMP-2 group (98.5%) was superior to that in the autogenous bone graft control group (76.1%). Clinical outcomes were also superior in the BMP-2 group. Transient peri-allograft bone resorption was noted in some patients. Clearly, BMP-2 is emerging as a very useful drug to facilitate spinal fusion. (BMP-2 is a drug, but it is considered to be a device by the Food and Drug Administration.)


The purpose of this randomized study was to determine if a prediction rule is effective for identifying patients who would benefit from spinal manipulation. Although the prediction rule was effective, the conclusions of the study were limited because of the large number of patients who were lost to follow-up and the inadequate power for many of the outcome variables.


This study pointed out the difficulty of identifying atlanto-occipital dislocation in trauma patients. Various radiographic parameters exist, but identifying the landmarks is quite complex. The authors analyzed five methods in a study of 104 patients and concluded that a two-dimensional reconstructive computed tomography scan is the best radiographic tool for identifying atlanto-occipital dislocation. The authors concluded that computed tomography scans of the cervical spine are warranted for all trauma patients with a suspected cervical spine injury in order to rule out atlanto-occipital dislocation. This should be considered a landmark article.


This prospective, randomized trial investigated the benefit of lumbar fusion compared with that of intensive rehabilitation for patients with chronic low-back pain who were considered to be candidates for spinal arthrodesis. No clear evidence emerged that primary spinal arthrodesis was any more beneficial than intensive rehabilitation as measured with use of the Oswestry Disability Index.


This prospective, double-blind trial failed to demonstrate any significant benefit of intradiscal electrothermal therapy over placebo.


This was a prospective, randomized, controlled trial of ninety-three patients who were randomly assigned to a control group (managed with standard exercise therapy) or a motivational group (managed with a combined exercise program and a motivational program). Follow-up assessments were performed at varying time-points up to five years. The combined exercise and motivational program was superior to the exercise-alone program, and patients in the motivational group had significant improvements in terms of disability, pain intensity, and working ability. It appears that the concept of a motivational program has promise.


This meta-analysis of thirty-five randomized, controlled studies evaluated the efficacy of acupuncture and dry-needling. A small short-term effect in terms of pain reduction and functional improvement was noted when acupuncture was compared with sham treatment or no treatment. Dry-needling may be useful only as an adjunct to other therapies. No evidence is available with regard to whether the effect is sustained in the long term.


This systematic review evaluated randomized or quasi-randomized studies of the outcome of surgical treatment of lumbar degenerative conditions including spondylosis, degenerative disc disease, instability, spinal stenosis, and/or degenerative spondylolisthesis. The authors noted the reporting of a variety of outcomes, most of which had inadequate follow-up or poorly reported specific outcome measures. There appeared to be limited evidence to support certain aspects of surgical intervention. The authors recommended additional well-designed controlled, prospective studies to evaluate the effectiveness of surgical intervention in specific subgroups of patients with lumbar degenerative spinal disease.


This prospective study of 135 patients with whiplash injury demonstrated that the SF-36 bodily pain and role-emotional scales are useful means of identifying patients who are at prolonged risk of disability.


In this prospective, parallel-groups, randomized, controlled trial of 109 senior patients with an age of more than sixty years, patients who were managed with a six-week program for the treatment of chronic back pain (with one session per week) were compared with patients who had no treatment. At the six-month follow-up, there was no difference between the groups in terms of reduction in pain, general health, self-efficacy, and self-care attitudes. A benefit was suggested for emotional well-being, fatigue, functional disability, and days with disability. This study shows that perhaps some directed self-management advice may help with the management of aspects of back pain.


This prospective diagnostic trial of 150 subjects suggested that electrodiagnostic testing may be useful for the evaluation of spinal stenosis. The
authors concluded that electrodiagnostic testing could differentiate patients with spinal stenosis from those with only lumbar back pain and from asymptomatic subjects. Furthermore, the authors claimed that the testing could detect common neuromuscular diseases that could mimic spinal stenosis. How this fits in with magnetic resonance imaging and treadmill testing will require further investigation.


This was a meta-analysis of sixty-one randomized, controlled trials evaluating the outcomes of exercise therapy in adults with nonspecific low-back pain. Exercise therapy appeared to be slightly effective for decreasing pain and improving function in adults with chronic low-back pain. For patients with subacute low-back pain, there was some evidence that a graded activity program improved absenteeism outcomes. For those with acute low-back pain, exercise therapy was as effective as either no treatment or other conservative treatments. The benefits of exercise therapy may be more dramatic in patients with chronic and subacute low-back pain than in those with acute low-back pain.


This was a systematic review of forty-three randomized, controlled trials of exercise therapy for the treatment of chronic low-back pain. There were seventy-two exercise treatment groups and thirty-one comparison groups. Improvements in terms of pain and function were noted in association with specific exercise interventions that were delivered in an organized fashion with the addition of a variety of conservative modalities such as anti-inflammatory medications and advice. The two most important factors that were noted to decrease pain and to improve function appeared to be stretching and strengthening exercises, respectively.


This systematic review demonstrated moderate evidence suggesting that back schools, in an occupational setting, reduced pain and improved function and return-to-work status as compared with the findings for exercise, manipulation, myofascial therapy, advice, placebo, and waiting list controls. The overall quality of studies was low, but the evidence suggested that back schools in an occupational setting may reduce pain and improve function for patients with chronic and recurrent low-back pain.


A retrospective review of 458 patients who had a cervical spine injury and were managed at a single tertiary referral center was performed to evaluate postoperative mortality. Patients were divided into two groups (older than sixty-five years or younger than sixty-five years). During the initial hospitalization, the mortality rate was 12.2% for elderly patients and 2.3% for patients under the age of sixty-five years. All elderly patients without a neurologic deficit survived the perioperative period. The authors concluded that patients with a cervical spine injury who are more than sixty-five years old can expect an 87.8% rate of postoperative survival following surgical intervention.


The purpose of this study was to assess and to modify psychosocial prognostic factors regarding low-back pain in general primary-care practices. A group of Dutch general practitioners used the Roland-Morris disability questionnaire as their measure. This was an interesting and novel concept, but unfortunately the study did not provide any evidence that strategizing treatment according to psychosocial prognostic factors altered the outcome in patients with low-back pain.


The purpose of this systematic review of the literature was to determine the effectiveness of transcutaneous electrical nerve stimulation for the treatment of chronic low-back pain. There were two randomized, controlled trials involving a total of 175 patients that differed significantly in terms of their methodology and application of this treatment. One trial demonstrated significantly greater relief of pain with the use of the transcutaneous electrical nerve stimulation whereas the other showed no difference. The evidence regarding the efficacy of transcutaneous electrical nerve stimulation as an isolated intervention for the treatment of low-back pain is limited and inconsistent.


The authors performed a systematic review of randomized or controlled clinical trials with quasi-randomization to evaluate the effectiveness of electrotherapy in the treatment of mechanical neck disorder or acute whiplash. The authors commented on the low quality of the various trials and could find no definitive evidence supporting pulsed electromagnetic field therapy, iontophoresis, electronic muscle stimulation, transcutaneous electrical nerve stimulation, permanent magnets, or galvanic current (direct or pulse) for the treatment of mechanical neck disorders or acute whiplash.


Direction-based physical therapy matches the patient’s perception that flexion or extension causes less pain. For example, patients who have less pain in extension are managed with extension exercises. In a randomized, controlled study of patients with back pain, directional therapy that was matched to the physical therapy prescription was associated with significantly improved outcomes whereas nonmatched therapy was associated with significantly poorer outcomes. The authors concluded that mechanical assessment and direction-based therapy should be considered when ordering physical therapy for the treatment of chronic low-back pain. It will be interesting to see if other centers can perform a similar study with the same results and conclusions.


This randomized, double-blind, controlled study evaluated the efficacy of periradicular infiltration of corticosteroids versus bupivacaine for the treatment of chronic radicular pain. Eighty-six patients were randomized to either a single injection of methylprednisolone and bupivacaine or bupivacaine alone. After three months of follow-up, no significant difference in any outcome measure was noted between the groups. The chronicity of symptoms was correlated adversely with negative changes in the Oswestry Disability Index. Corticosteroids appeared to add no significant additional benefit over an analgesic alone in reducing chronic radicular pain.


This systematic review compared the results for patients managed with three behavioral treatment approaches (opponent, cognitive, and progressive relaxation [biofeedback]) with those for surgical wait-list controls. On the basis of three studies, the authors concluded that combined progressive relaxation-cognitive therapy and progressive relaxation therapy only are more effective than no treatment in the short term. No evidence is available as to whether the effect is sustained in the long term.

This was a literature review of thirty-two trials that examined the effects of oral nonsteroidal anti-inflammatory drugs, psychotropic agents, steroid injections, and anesthetic agents for the treatment of mechanical neck pain. The authors of this review concluded that intramuscular injections of anesthetics and intravenous injections of steroids were effective for the treatment of mechanical neck disorders. There was limited evidence supporting epidural injections, oral psychotropic medications, and nonsteroidal anti-inflammatory drugs. There was moderate evidence that botulinum toxin (Botox A) intramuscular injections were no better than saline solution. The evidence appears to support the use of more nontraditional approaches (such as intramuscular anesthetic and intravenous steroid injections) over more traditional treatments (such as nonsteroidal anti-inflammatory drugs, epidural injections, and oral psychotropic medications) for the treatment of mechanical neck pain.


Eighty patients undergoing a spinal fusion received either celecoxib (a cyclooxygenase [COX]-II-specific inhibitor) or a placebo one hour before the induction of anesthesia and every twelve hours for the following five days. After a one year follow-up, it was found that the perioperative administration of celecoxib resulted in a significant reduction of the consumption of pain medication and had no effect on bone-healing as seen on plain radiographs and tomograms and computed tomographic scans. The short-term use of a selective COX-II inhibitor appears to be effective for pain relief within the first week following surgery and should not result in any adverse effect on fusion healing.


In this prospective study, patients undergoing anterior cervical fusion were evaluated preoperatively and at three, six, and twenty-four months postoperatively with use of the Cervical Spine Research Society Outcome Questionnaire, which includes questions evaluating dysphagia. At two years, persistent dysphagia was observed in 21% of patients. A prolonged period of preoperative symptoms was identified as a risk factor. Dysphagia was associated with more disability and lower general health scores. Contrary to the findings of other reports, dysphagia was not associated with the use of plates or surgery at more rostral levels.


This cost analysis demonstrated that surgical fusion of the lumbar spine in patients with chronic back pain may not be a cost-effective use of health-care resources, although this conclusion could change if the number of patients who undergo rehabilitation and subsequently need surgery increases over time.


Over a two-year period, sixty-four consecutive patients with cervical fractures and/or dislocations underwent magnetic resonance angiography. Eleven patients (17%) had vertebral artery occlusion, including ten patients who had unilateral disease and one patient who had bilateral disease. Only the patient who had bilateral disease had transient symptoms. All patients had an intact circle of Willis. Follow-up magnetic resonance angiography demonstrated reconstitution of blood flow in three patients. Unfortunately, similar to the findings of other studies, no conclusions were available with regard to whether vertebral artery injuries in the absence of neurologic changes are clinically important or with regard to how such injuries should be treated.


In this prospective trial, patients with lumbar nerve root compression were randomized to treatment with an epidural injection of steroid or an intramuscular injection of local anesthetic and steroid. A significant reduction in pain was noted in the early period following epidural steroid injection, but there was no difference between the two groups with regard to long-term outcome.


This randomized, controlled study of forty patients undergoing lumbar fusion evaluated the effect of preoperative epidural anesthesia on blood loss, intraoperative blood pressure, and postoperative analgesic requirements. The use of epidural anesthesia was associated with a significantly lower requirement for postoperative analgesics, lower pain scores, and more stable blood pressure. No difference was observed with regard to the ability to monitor the neurologic status postoperatively. This small study demonstrates the potential benefits of preemptive analgesia with respect to postoperative pain and outcomes.


This was a randomized, controlled study in which one group of patients was managed nonoperatively for spinal stenosis and the other group was managed with the “X STOP” which basically keeps the spinal segment in a flexed position and prevents extension. The inclusion criteria for this technique were quite strict. Pain had to be relieved during flexion and the patients who had to be able to walk fifty feet (15.2 m). At the time of the two-year follow-up, the patients in the X STOP group were doing significantly better than the patients who received nonoperative treatment with epidural injections. It is very unclear which patients with spinal claudication can be managed with this technique as opposed to requiring formal decompression.