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What's new in spine surgery

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SPECIALTY UPDATE

WHAT'S NEW IN SPINE SURGERY

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Spinal Deformity Surgery

The Scoliosis Research Society (SRS) was founded in 1966 with a principal interest in pediatric spinal deformity. Quite a bit has changed since then, and the main interest is no longer simply teenage idiopathic scoliosis. Other interests and concerns include adult deformity, tumors, fractures, and spondylolysis, which are conditions that can affect patients throughout life. The current mission statement of the Scoliosis Research Society is "to foster optimal care of the patient with any disorder that may affect the shape, alignment or function of the spine, throughout life. The SRS accomplishes this, through education, research, advocacy and ethical practice."

Idiopathic Scoliosis

It is debatable whether lumbar and thoracolumbar curves are best treated surgically through an anterior or a posterior approach. Problems that have been associated with anterior treatment in the past have included loss of segmental lordosis and early failure of the implants. However, three studies that were presented at the Scoliosis Research Society meeting in Quebec City in September 2003 suggested that modern anterior instrumentation is associated with better results. The use of solid-rod implants with structural interbody anterior-column support and/or a two-screw two-rod technique reportedly leads to better correction of the curvature, fewer levels being fused, and better "spontaneous correction" of adjacent curves.

Posterior surgical methods for the treatment of thoracic and double-major curves are tending toward the use of segmental pedicle-screw fixation. The use of screws allows for improved segmental purchase and appears to offer potentially greater coronal, sagittal, and apical correction. This greater correction may allow surgeons to fuse fewer spinal segments in selected cases. However, the surgical technique of thoracic

pedicle screw placement has to be precise. Although greater correction is possible, the potential for catastrophe (e.g., placing the screws into the spinal cord or the great vessels) remains a great concern.

We continue to be very interested in long-term studies on the natural history of untreated idiopathic scoliosis. It is very difficult to find a substantial cohort of patients. Previous studies have suggested that curves of $>50^\circ$ have a high propensity for progression into adulthood. In a study from the Twin Cities Spine Center in Minneapolis, Minnesota, a total of forty-six patients with curves of 30° to 50° were followed for at least ten years after skeletal maturity. The investigators found that these curves progressed an average of 0.5° per year. However, only 4% of the curves progressed $>1^\circ$ per year, and only two patients "required" posterior spinal fusion. Therefore, it would appear that the prognosis for curves of 30° to 50° is better than that for larger curves.

Adult Spinal Deformity

Several studies have analyzed the validity of the SRS-22 questionnaire as an outcome instrument for the assessment of adolescent idiopathic scoliosis. Studies that are now emerging have suggested that this instrument is valid for the evaluation of adult spinal deformity.

The treatment of adult spinal deformity is more complex than the treatment of adolescent deformity and is associated with a higher rate of complications. In both adolescents and adults, there is a certain prevalence of proximal junctional kyphosis cephalad to the fusion. This is a topic about which we are just starting to scratch the surface, and additional studies are needed to analyze risk factors and the consequences of cephalad junctional deformity.

In many adults in whom lumbar scoliosis is the principal abnormality, there is rotatory subluxation at L3-L4 and fixed tilt at L4-L5. In these cases, a decision has to be made

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about whether to stop the fusion at L5 or at the sacrum. It would appear that stopping the fusion at L5 would be associated with fewer short-term complications, but investigators have reported a relatively high prevalence of later breakdown (kyphosis and accelerated disc degeneration) at L5-S1 with a subsequent need to extend the fusion to the sacrum. Therefore, controversy remains regarding the indications for stopping the fusion at L5 as opposed to the sacrum. Additional multicenter work is required in this area in order to achieve universal agreement.

It is also apparent that the risk of pseudarthrosis following a long fusion is much greater in adults than it is in teenagers. Furthermore, teenagers usually tolerate aggressive anterior surgery well whereas adults have a higher prevalence of postoperative pulmonary complications following trans-thoracic and thoracoabdominal approaches. One study from the Twin Cities Spine Center assessed the relationship between the rate of complications and the age of the patient. The investigators concluded that, although the number of complications in the elderly population was high, comorbidities were a more important factor for assessing risk than was patient age per se.

Surgical Complications

One of the most devastating complications of spinal deformity surgery is a major neurological deficit. Studies presented at the recent Scoliosis Research Society meeting in Quebec City indicated that the patients who are at highest risk are those with congenital spinal deformities and spinal stenosis with osseous dysplasia, those undergoing combined anterior and posterior procedures, adults undergoing revision surgery for the treatment of kyphosis, and those undergoing procedures in which multiple segmental vessels are harvested on the left side of the spine. Following a major perioperative neurological deficit, many patients demonstrate some return of function but few have complete recovery.

Spondylolisthesis

The Morbidity and Mortality Committee of the SRS has analyzed trends within the society with regard to the treatment of spondylolisthesis. For high-grade spondylolisthesis, there has been a trend toward more reduction, circumferential fusion, and instrumentation. For medium-grade spondylolisthesis in adults, it is also now more common to perform posterior instrumentation and circumferential fusion. It is believed that these techniques lead to a higher rate of fusion and a better outcome, although the more invasive the method used, the higher the neurological risks. The greatest neurological risk associated with aggressive treatment of spondylolisthesis continues to be foot drop.

Spinal Deformity Subspecialty Certification

On three occasions, the Board of Directors of the Scoliosis Research Society has endorsed the concept of applying for sub-

specialty certification through the American Board of Orthopaedic Surgery and the American Board of Medical Specialties. The potential benefits include improving the education of spine surgeons, as most spine fellowships currently do not focus on the full spectrum of spinal surgery. Quite a bit of work has been done in this regard, and an initial application has been made. This issue is highly contentious. Although most spine surgeons agree that subspecialty certification would improve surgeon education and patient care, this process is associated with many practice concerns and inconveniences that will have to be resolved. Whether it will become a reality for the field of spinal deformity remains to be seen.

The Cervical Spine

A paradigm change from fusion to motion preservation is occurring in the treatment of cervical spine disorders. In the United States, three cervical disc prostheses are currently under investigation in approved studies. The theoretical advantages of disc replacement are to prevent adjacent segment degeneration, to maintain cervical motion, to avoid complications related to fusion (such as pseudarthrosis, implant-related effects, and bone-graft morbidity), and to allow earlier return to activities. There have been no long-term follow-up studies thus far, and one should use caution when interpreting short-term results.

Justification for Disc Arthroplasty

Effects of Fusion

Anterior cervical fusion is a well-accepted procedure that is associated with a high rate of satisfactory results. However, long-term studies have shown a 25% prevalence of adjacent-segment symptoms within ten years. Researchers in Belgium recently presented additional evidence on the long-term adverse effects of cervical fusion. At a minimum of five years after cervical fusion, 92% of 120 patients had new-onset or progressive degenerative changes at adjacent levels. There was no significant difference between patients with traumatic and spondylotic etiologies with regard to the development of degenerative changes. This finding suggests that the interbody fusion acts as a triggering factor. Findings that were presented at the 2003 Annual Meeting of the Cervical Spine Research Society confirmed these observations. Disc pressures at adjacent segments were found to be significantly increased. With use of a finite-element model, a 20% to 30% increase in flexion-extension and rotation was noted adjacent to fused levels. This increase in motion more than doubled after two-level fusions.

In Vivo and In Vitro Analysis of Disc Arthroplasty

Kinematic studies have confirmed that disc replacement normalizes motion compared with fusion. In a biomechanical study, no differences in flexion-extension or coupled motions

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were observed at adjacent segments before or after disc replacement. Researchers from both Belgium and Denver, Colorado, evaluated adjacent-segment motion with use of cinefluoroscopy in ten normal individuals, ten patients with C5-C6 spondylosis, ten patients with a C5-C6 fusion, and ten patients with a C5-C6 disc replacement. The adjacent-segment motion was normalized following disc replacement. Compared with the patients with spondylosis and the patients with fusion, the patients with disc replacement had normal, synchronous patterns during motion.

Early Clinical Results of Disc Arthroplasty

The short-term results of disc arthroplasty have been reported to be equivalent to those of fusion. In one European study, eighty-three patients who had been treated with the Bryan disc were evaluated after a minimum duration of follow-up of two years. According to the criteria described by Odom, fifty-five outcomes were rated as excellent, seven were rated as good, thirteen were rated as fair, and eight were rated as poor. Functional improvements as measured with the SF-36 instrument were similar to those observed in fusion studies. Radiographically, the average range of flexion-extension at the site of the arthroplasty was 8°, although 11% of the patients had <2° of motion. Similar results were observed in a separate study of patients who had been treated with disc arthroplasty at two levels and in patients with myelopathy.

The two-year results associated with the Frenchay prosthesis (developed in Bristol, England) have been reported. The average range of flexion-extension was 6.5°, and the average anteroposterior translation was 2 mm. The clinical improvement also was similar to that associated with fusion. One patient had a revision to fusion because of loosening of the device.

Biological Effects of Disc Arthroplasty

Arthroplasty devices with bearing surfaces most commonly fail because of wear with the production of particulate matter and the development of an inflammatory reaction. A similar process is likely to occur in association with spinal prostheses. Hallab et al. measured inflammatory markers related to spinal fusion devices. The levels of tumor necrosis factor- α and the rates of cell apoptosis were increased. Furthermore, metallic devices release ions that can disseminate throughout the body and can be identified in the serum in as many as one-third of patients. The consequences of these findings are unknown.

Anderson et al. reported on the in vivo and in vitro wear response of the Bryan cervical disc prosthesis. After ten million simulated cycles, an average of 1.75% of the mass was lost. Elliptically shaped wear particles with a mean size of 3.8 μm were produced. In a caprine model, the biologic effect of wear was assessed. In four of eleven animals, small quantities of wear debris were observed in the periprosthetic tissues; however, no inflammatory response was noted. In another

caprine model, a different device (the Porous Coated Motion implant) showed excellent osseous ingrowth and no wear debris or inflammatory reaction at six months postoperatively.

Patient Safety

Patient safety is increasingly being scrutinized by physicians, regulators, insurers, and patients themselves. Recent attention has been directed to the soft-tissue morbidities associated with the anterior approach to the cervical spine, including dysphagia, voice disorders, and airway obstruction. Prospective studies have shown that dysphagia is far more common than was previously appreciated. Persistent symptoms are noted in 12% to 30% of patients at one year. These rates are increased in patients who are managed with cervical plates and in women. Similarly, symptomatic vocal cord paresis is present in 1% to 2% of patients at one year. Reported efforts to protect the recurrent laryngeal nerve from iatrogenic injury include intraoperative electromyography and repositioning of the endotracheal tube by deflating and reinflating the cuff after retractor placement.

The most devastating complication is airway obstruction. Approximately 2% to 6% of patients require reintubation postoperatively. Occasionally, this is an emergent or even fatal situation. Variables that have been associated with an increased likelihood of reintubation include prolonged operative time (more than three to five hours), the exposure of more cephalad levels (C2-C4), blood loss of >300 mL, a history of smoking, and other comorbidities. It has been recommended that high-risk patients remain intubated until the swelling resolves. Steroids are used frequently but have not been shown to be effective in a controlled, randomized study. Tracheostomy should be performed if needed. A new tracheostomy technique involving the use of percutaneous dilation has been shown to be more efficient than open surgical tracheostomy in patients with a spinal cord injury.

In summary, disc replacement appears to diminish the adverse mechanical effects of fusion. Short-term results have been satisfactory, but long-term follow-up is needed to determine if the preservation of motion translates into a lower prevalence of adjacent-segment disease. Wear studies have indicated that particulate debris is produced without a substantial inflammatory effect; however, the clinical importance of these models has not been established. Finally, the effect of trauma following disc arthroplasty is unknown.

Biologic Research

One of the most active areas of study related to the spine continues to be biologic research. There is a continued effort to enhance bone-healing following spine fusion. With the United States Food and Drug Administration's first postmarketing approval of a recombinant bone morphogenetic protein (rh-BMP-2) last year, there have been continued efforts to develop BMPs as well as alternatives. In addition, a substantial amount of research continues to be focused on understanding the bio-

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logical characteristics of the intervertebral disc and on developing biological strategies to retard or reverse degeneration.

Bone-Graft Substitutes

Although preclinical and clinical trials on the use of rhBMP-7 for spine fusion have yielded less-than-consistent results, efforts are underway to utilize BMP-7 in other ways. In a study from the Hospital for Special Surgery, the use of an adenovirus to deliver BMP-7 cDNA in bone-marrow cells was successful in 70% of rats at eight weeks. One of the lingering questions regarding BMP-7 is whether its inability to achieve 100% successful bone induction in primates is due to suboptimal carrier and/or dosing or whether BMP-7 is less osteoinductive than some other BMPs. A study from the University of Chicago suggested that BMP-2, BMP-6, and BMP-9 are the most osteoinductive BMPs, both in vitro and in vivo. BMP-7 appears to be less osteoinductive, especially in uncommitted cells. Whether this finding will have any clinical implications remains to be seen.

Despite a successful European pilot study, the extracted mixture of bovine BMPs currently is not being further developed because of budgetary constraints. The largest number of clinical trials on the spine that are currently underway involve rhBMP-2. One of the major concerns associated with rhBMP-2 is that the dose and carrier that are currently approved by the Food and Drug Administration are geared for interbody spinal fusions inside cages and are not geared for posterolateral spinal fusions. As a result, the approved kit will not provide consistent results posterolaterally. A recent study of nonhuman primates suggested that, with the addition of a bulking agent (ceramic or allograft chips) to the absorbable collagen sponge carrier, the currently approved dose could produce consistent posterolateral bone formation. Similar studies of humans are currently underway.

With the approval of rhBMP-2 has come an increased interest in lower-cost enhancers of bone-healing. Trials are underway to examine the selective retention of bone-marrow progenitor cells on osteoconductive scaffolds. While the preliminary results in lower animal models have been encouraging, the results of human trials are still forthcoming. The key question is whether a five to sevenfold concentration of the relatively scant numbers of mesenchymal stem cells will be enough to achieve spine fusion consistently in primates.

Platelet-concentration strategies have been in clinical use for several years, despite the lack of stringent preclinical data to support their use. The primary growth factors that are present in platelets are transforming growth factor-beta and platelet-derived growth factor. Neither of these cytokines are considered to be osteoinductive, and under certain circumstances both can inhibit osteoblast differentiation. Three studies suggested that one form of platelet concentrate with "autologous growth factors" (AGF) does not enhance bone-healing in the spine and indeed may be inhibitory. The first study, from the Pennsylvania State College of Medicine, in-

involved fifty-nine patients who underwent a single-level posterolateral lumbar spinal arthrodesis. The rate of radiographic fusion decreased from 91% when autogenous iliac crest bone graft was used alone to 62% when AGF was added to the bone graft. The second study, from the University of Louisville, demonstrated that the rate of fusion was 88.2% in the control group and 80.3% in the AGF group ($p = 0.18$). The third study, from Tulane University, showed similar results in patients managed with transforaminal lumbar interbody fusion. The rate of radiographic fusion was 55% in the control group and 46% in the AGF group ($p = 0.12$). None of those studies showed a beneficial healing effect in association with the use of AGF, and all showed a trend toward a lower rate of successful healing compared with that associated with the use of autograft alone.

Biological Treatments for Disc Degeneration

The second area of increased interest involves an improved understanding of intervertebral disc biology and the development of animal models that will allow for the testing of strategies designed to retard disc injury or degeneration. There is not yet a universally accepted animal model of age-related disc degeneration. Most models involve an acute disc injury such as a needle puncture with acute loss of nuclear material. In a rabbit study from the University of Virginia in which disc degeneration was induced by the injection of a 30-kDa fibronectin fragment, osteophytes were evident radiographically by twelve weeks.

It has been several years since Hanley et al. studied the feasibility of disc allograft transplantation in canines. A study from the University of Hong Kong demonstrated successful transplantation of fresh-frozen intervertebral disc allografts in seventeen rhesus monkeys. The investigators reported survival of the allografts with some degree of cell metabolism and mobility, but they also noted severe disc degeneration by twenty-four months. If transplantation could be combined with a blocker of disc degeneration, this could be an effective strategy for the treatment of severely degenerated discs.

A biological strategy to retard disc degeneration would be very useful. In a rabbit study from Rush Medical College, a single injection of osteogenic protein-1 (OP-1) prevented the loss of disc height and hydration that is normally associated with the injection of chondroitinase ABC enzyme. The results of that study were similar to those of another study, by the same authors, in which OP-1 prevented the loss of disc height that is normally seen after an 18-gauge needle puncture. Other investigators are pursuing strategies involving the implantation of cells that have been culture-expanded and selected. Those results are less well developed, and the technique is less convenient compared with the injection of a recombinant protein.

Another potentially promising area of research involves the use of gene therapy to deliver cDNA encoding for certain growth factors. Various researchers have utilized the adenovi-

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rus vector to deliver a variety of anabolic and anticatabolic cytokines into the cells of the intervertebral disc. The theoretical advantage of gene therapy is to allow for a more sustained production of growth factors within the disc in order to up-regulate matrix production or inhibit matrix catabolism. For example, gene transfer with use of the cDNA for rhBMP-2 and Sox 9 has been shown to enhance proteoglycan and collagen synthesis, respectively. Furthermore, a study from the University of Pittsburgh demonstrated that gene transfer of the catabolic inhibitor TIMP-1 can increase proteoglycans in cells from degenerated human intervertebral discs. That study, along with other studies from the Pittsburgh group, suggests that a single cytokine may not be ideal and that a cocktail of anabolic and anticatabolic factors may be required for optimal stimulation of disc chondrocytes.

Spinal Cord Injury

Advances in the understanding and treatment of spinal cord injury continues to evolve at a slow but steady pace. The major research, as illustrated in abstracts submitted for the American Spinal Injury Association meeting that was held in May 2004, centers on understanding and modulating the secondary cascade of injury following a traumatic spinal cord injury, on rehabilitation techniques and devices for the injured patient, and on biological strategies for the regeneration of neural connections in the injured spinal cord.

Medical Complications of Spinal Cord Injury

Contemporary research efforts addressing the morbidities associated with spinal cord injury are focused on the understanding and treatment of bedsores, neuropathic pain, osteoporosis, and lipid-profile abnormalities. One prospective, randomized trial suggested that COX-2 inhibitors could be effective for the prevention of heterotopic ossification. Another study documented a high rate of lipid-profile and vitamin-D abnormalities among patients with spinal cord injury and suggested that close monitoring of these parameters was warranted. Indium(111)-labeled leukocyte scintigraphy was found to be more sensitive and specific than technetium bone-scanning for the evaluation of severe pressure sores for the presence of osteomyelitis.

Neurological Recovery and Basic Science

Secondary injury occurs in the minutes and hours following a traumatic spinal cord injury as a result of inflammation, apoptosis (programmed cell death), and cytokine release, thereby widening the zone of injury. The prevention of secondary injury is a major focus of basic spinal cord injury research. Another hot topic is the use of biological strategies to regenerate functional connections across the injured spinal cord. The p75 receptor has been shown to cause apoptosis and thus may be a good target for pharmacotherapy. Quercetin, a flavonoid, was shown to be neuroprotective by reducing apoptosis in a rat model. Other neuroprotective drugs are being

studied, including Rolipram, an inhibitor of cAMP hydrolysis, and minocycline, an antibiotic. A new drug, HP184, which blocks both Na⁺ and K⁺ channels, has been tested in healthy volunteers and in patients with spinal cord injury. In healthy patients, the drug was found to be safe and well tolerated. Early data have suggested that this drug may improve ASIA motor scores following an injury. These studies have paved the way for wider human clinical trials.

The healing of a spinal cord lesion may be promoted by activated macrophages. One study evaluated human monocytes that were stimulated by co-incubation with skin tissue. These cells were found to secrete proinflammatory cytokines, adhesion molecules, and high levels of CD80 and CD86, all of which are potentially beneficial to the injured spinal cord. When injected at the site of injury in ASIA-A patients within fourteen days after the injury, some patients demonstrated improvement in motor and sensory function. In rehabilitation medicine, early electrical stimulation of the common peroneal nerve was shown to improve the flexion-withdrawal response necessary for gait.

Prevention

The issue of spinal cord injury prevention continues to be evaluated by policy makers and automobile manufacturers. One study evaluated the relative risk of a cervical spine injury to motor-vehicle occupants when using seatbelts, airbags, a combination of seatbelts and airbags, or no restraint system. The combination of seatbelts and airbags provided the greatest protection against cervical spine injury relative to an unrestrained occupant, with an odds ratio of 0.19. The use of a seatbelt alone also significantly reduced the risk of cervical spine injury, while the use of an airbag alone did not have any significant effect on the risk of a cervical spine injury.

Spinal Cord Injury Outcomes

Both medical and surgical therapies continue to improve. Imaging studies have documented a strong correlation between the severity of a spinal cord injury and the degree of spinal canal compromise and spinal cord compression as seen on magnetic resonance imaging. A randomized clinical trial to determine the benefit of early surgical decompression of spinal cord injuries has begun. Early surgical stabilization of the spine following a spinal cord injury has been shown to reduce medical complications and to enhance early rehabilitation, but the effects on neurologic recovery remain controversial. The ASIA motor and sensory examination has been shown to have high interrater reliability when used by trained examiners and should be viewed as the state of the art for the neurological assessment of the patient who has a spinal cord injury. Although elderly patients continue to have poorer outcomes than younger patients, a strong multidisciplinary approach can produce better-than-expected outcomes in this challenging group.

Classification systems for spinal fractures continue to

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evolve. In one study, the Denis classification was compared with the AO classification for thoracolumbar fractures. Only a moderate degree of reliability and repeatability was found in association with either classification system when applied to a group of fractures by expert spine surgeons. Less motion of the cervical spine was found while using a kinetic treatment table (RotoRest Delta; Kinetic Concepts, San Antonio, Texas) as compared with the standard log roll procedure in two separate studies. Another study compared the outcomes and complication profiles for patients with thoracolumbar burst fractures who were treated with either an anterior or posterior surgical approach. The group treated through an anterior approach sustained fewer complications, had better sagittal alignment, and had less pain than did the group treated through a posterior approach. A prospective, randomized study comparing anterior and posterior treatment of unilateral facet injuries of the cervical spine demonstrated that the group that was treated through an anterior approach had better lordosis and a higher rate of fusion, although the clinical outcomes were not significantly different between the groups.

Surgical Treatment of the Lumbar Spine

Dynamic changes in the field of lumbar spine surgery continued throughout 2003.

Surgery Outcomes

Persistent pain and dysfunction following lumbar fusion led investigators at State University of New York-Syracuse to question whether preoperative mental health testing could be predictive of outcomes following anterior lumbar fusion. Higher preoperative mental scores on the SF-36 were significant predictors of visual analog scale back-pain ratings at twelve months in a study of 168 subjects who had been enrolled in a multiple-site trial of two fusion systems (InFix and BAK). Patients with a mental score of <50 had significantly more pain and poorer function, suggesting that a lower mental health score may serve as a potential flag.

Patients with an age of more than eighteen years who had had lumbar spine fusion between 1991 and 1992 at the Twin Cities Spine Center were evaluated with regard to function, satisfaction, and the need for any additional spine surgery after a minimum duration of follow-up of ten years. Of the 178 patients who returned a questionnaire, thirty-one (17%) had had adjacent-level surgery. Fusion extension was required for 21% of the patients in whom the index operation had been a posterior procedure, compared with 16% of those in whom the index operation had been a combined anterior-posterior procedure. Adjacent surgery was performed for 18% of the patients in whom the index procedure had been performed for the treatment of degenerative disc disease, compared with 26% of those in whom it had been performed for the treatment of spondylolisthesis. Adjacent-segment extension was more commonly required when the index fusion had been to the sacrum (22% compared with 12%) and when de-

compression also had been done (24% compared with 15%). The overall rate of patient satisfaction at ten years was 70%.

One-year outcomes data from the Swedish national lumbar spine registry included data on 85% of all patients who had lumbar spine surgery in that country in 2001. The rate of patient satisfaction with surgery was 72% among patients with a disc herniation, 67% among patients with central spinal stenosis, 68% among patients with spondylolisthesis, and 61% among patients with degenerative disc disease. Reoperation within twelve months was necessary in 7% of the patients.

Trauma

Researchers at the University of Minnesota prospectively evaluated outcomes in patients in whom thoracolumbar burst fractures without an associated neurological deficit were treated with either anterior or posterior instrumented fusion. For the patients who were managed through a posterior approach, the average kyphosis was 12° at the time of admission, 5° at the time of discharge, and 12° at the time of the twenty-four-month follow-up. In this group, the average canal compromise was 39% at the time of admission and 20% at the time of follow-up. In the anterior fusion group, the average kyphosis was 13.7° at the time of admission, 2.6° at the time of discharge, and 3.7° at the time of follow-up. The average canal compromise was 40% at the time of admission and 18% at the time of follow-up. There were nineteen complications in sixteen patients who had been treated posteriorly but only three minor complications in three patients who had been treated anteriorly. Although both anterior and posterior approaches yielded acceptable rates of patient satisfaction and return to work, anterior surgery alone had a lower rate of complications and trended toward outcomes with less pain.

Magnetic resonance imaging scans that were acquired for 110 patients who had back pain following an injury demonstrated normal findings in only 9% of the patients and multiple-level abnormalities in 66%. Sixty-seven percent of these 110 patients demonstrated a disc protrusion, and 5% had a disc extrusion. That series included fewer patients with normal findings than had been previously reported in baseline studies of asymptomatic patients. The rates of disc protrusion and extrusion in the study group were significantly higher than those found in baseline studies of asymptomatic patients, suggesting that disc pathology was a possible etiology of the back pain.

Artificial Disc Replacement

Investigators at the Texas Back Institute evaluated the twelve to twenty-four-month results for a consecutive series consisting of the first fifty-seven patients to receive the SB Charite disc prosthesis at a single center. The mean visual analog score improved from 69.4 preoperatively to 34.1 at six weeks and remained stable during the twenty-four months of follow-up. The mean Oswestry disability score had improved by 40% at six weeks and by as much as 50% at twenty-four months. There were no in-

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stances of device failure, displacement, or migration.

In another study from the Texas Back Institute, seventy-eight patients with disabling degenerative disc disease that had been unresponsive to a minimum of six months of conservative treatment were randomized to surgical treatment with either an artificial disc (ProDisc; Synthes/Spine Solutions, Paoli, Pennsylvania) or a 360° fusion. Fifty-four of these patients had one-year follow-up data. The mean visual analog and Oswestry scores decreased significantly ($p < 0.05$) in both groups by six weeks postoperatively. Over time, the scores in the artificial disc group tended to continue to decrease whereas those in the fusion group remained stable. Patient satisfaction at each of the testing intervals was better in the artificial disc group. At the time of the one-year follow-up, 20% of the patients with a fusion stated that they would not have the surgery again whereas >95% of the patients with the artificial disc stated that they definitely would have the procedure again. None of the patients who had had the arthroplasty stated that they would refuse the operation. The clinically measured range of motion in terms of both forward flexion and lateral bend was significantly improved in the patients who had been managed with the ProDisc ($p = 0.02$).

The range of spinal motion as measured radiographically after artificial disc replacement with use of the ProDisc was reported in a separate series of forty patients (fifty-seven levels) who had been managed at the Spine Institute at St. John's Health Center in Santa Monica, California. In patients with a one-level artificial disc replacement, the postoperative range of motion was increased compared with the preoperative range of motion. In patients with a two-level disc replacement, the L4-L5 level showed increased motion, the L5-S1 level showed a tendency for decreased motion, and the total range of motion was maintained compared with the preoperative range.

Anterior Lumbar Surgery

One surgeon reported on 1315 anterior approaches to the lumbar spine that had been performed over a sixty-six-month period. Six patients had development of left iliac artery thrombosis, and four required thrombectomy. There were nineteen venous injuries to the left common iliac vein (prevalence, 1.4%); all were successfully repaired, with a mean blood loss of 650 mL. Fifteen of the venous injuries were exposures at the L4-L5 level.

Thirty patients who had had an anterolateral interbody fusion were retrospectively compared with twenty-four matched patients who had had a 360° fusion for the treatment of discogenic lumbar pain. No significant difference was found between the groups in terms of clinical outcome, although patients who had undergone a single-level anterolateral interbody fusion had improved Oswestry scores compared with patients who had undergone a 360° fusion ($p = 0.007$). However, six patients in the anterolateral interbody fusion group required revision posterior fusion because of symptomatic anterior

nonunion. One patient in the 360° fusion group required revision fusion, and two additional patients required implant removal.

Schuler et al. attempted to determine the effect of preoperative disc height on clinical outcomes after a single-level anterolateral interbody fusion. Patients in the "collapsed disc" group, who had a mean preoperative disc height of 0.5 mm, showed better improvement in Oswestry scores both in the early postoperative period and at all follow-up visits, with the differences in outcome becoming more pronounced over time. Thus, patients with the most pronounced disc-space narrowing showed the earliest and greatest clinical improvement.

Intradiscal Electrothermal Therapy

Investigators in Tyler, Texas, reported the results of a randomized placebo-controlled trial of intradiscal electrothermal therapy for the treatment of discogenic low-back pain. Thirty-seven patients were allocated to intradiscal electrothermal therapy, and twenty-seven received sham treatment (needle placement to the anulus but no anular puncture and no thermal energy applied). Although patients in both groups demonstrated improvement, the mean improvement in terms of pain, disability, and depression was better in the intradiscal electrothermal therapy group. More patients in the sham group demonstrated deterioration over time. While approximately 40% of the patients who had been treated with intradiscal electrothermal therapy achieved >50% relief of pain, approximately 50% of the patients experienced no appreciable benefit.

Upcoming Meetings and Events Related to Spine Surgery

The next annual meeting of the Scoliosis Research Society (SRS) will be held on September 6 through 9, 2004, in Buenos Aires, Argentina. It will be preceded by a one-day course on Innovative Treatment Options in Spine Surgery, to be held on September 6, 2004. Web site: www.srs.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, to be held on Saturday, February 27, 2005, in Washington, DC. Web site: www.aaos.org.

The next annual meeting of the North American Spine Society (NASS) will be held on October 26 through 30, 2004, at the McCormick Place Convention Center, Lakeside Center, in Chicago, Illinois. Web site: www.spine.org.

The Twenty-second Annual Meeting of the Cervical Spine Research Society (CSRS) will be held on December 9 through 12, 2004, at the Marriott Copley Place Hotel in Boston, Massachusetts. In addition, an Instructional Course will be held on December 11 and 12, 2004. Web site: www.csr.org.

The meeting of the American Spinal Injury Association (ASIA) is the major event related to spinal cord injury medicine. The next meeting will be held on May 12 through 14,

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2005, at the Fairmont Hotel in Dallas, Texas. Web site: www.asia-spinalinjury.org.

Evidence-Based Orthopaedics

During 2002, the editorial staff of *The Journal* reviewed a large number of research studies related to spine surgery that received a Level of Evidence grade of I. Over forty 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, fourteen level-I 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 to guide your further reading, in an evidence-based fashion, in this subspecialty area.

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WHAT'S NEW IN SPINE SURGERY

Evidence-Based Articles Related to Spine Surgery

Fouyas IP, Statham PF, Sandercock PA. Cochrane review on the role of surgery in cervical spondylotic radiculomyelopathy. *Spine*. 2002;27:736-47.

The authors performed a meta-analysis in which operative and non-operative treatment of cervical myeloradiculopathy were compared with use of Cochrane methodology. They identified only two randomized, controlled studies that met their criteria. Both studies concluded that there were no differences in outcome variables between operatively and nonoperatively treated patients. The conclusion that there was no evidence to support surgical treatment must be tempered. The two studies had several shortcomings, and the findings cannot necessarily be generalized to patients who fail to respond to conservative therapy and then present for surgical consideration. Also, Carl Sagan has stated that the absence of evidence is not evidence of absence.

Touger M, Gennis P, Nathanson N, Lowery DW, Pollack CV Jr, Hoffman JR, Mower WR. Validity of a decision rule to reduce cervical spine radiography in elderly patients with blunt trauma. *Ann Emerg Med*. 2002;40:287-93.

The authors retrospectively examined the efficacy of the National Emergency X-radiography Utilization Study (NEXUS) decision instrument to identify cervical spine injuries in patients more than sixty-five years of age. According to the NEXUS instrument, patients who are at low risk for spinal injury as determined on the basis of five criteria do not require radiographic investigation. In this study, cervical spine injuries (especially odontoid fractures) were twice as frequent in elderly patients. No difference was observed between older and younger age-groups with regard to the performance of the NEXUS criteria. The NEXUS instrument had a 100% sensitivity for identifying clinically important injuries in elderly patients. Although this study included a large number of patients, inadequate descriptions of injuries and lack of follow-up after emergency room or hospital discharge limit the conclusions that can be drawn.

Kadanka Z, Mares M, Bednanik J, Smrcka V, Krbec M, Stejskal L, Chaloupka R, Surelova D, Novotny O, Urbanek I, Dusek L. Approaches to spondylotic cervical myelopathy: conservative versus surgical results in a 3-year follow-up study. *Spine*. 2002;27:2205-11.

The authors performed a prospective, randomized, controlled study of patients with mild cervical spondylotic myelopathy to compare the results of operative and nonoperative treatment. Sixty-eight patients were randomized to operative or nonoperative treatment and were analyzed with use of the Benzel myelopathy score, gait analysis, and self-evaluation. Only patients with mild myelopathy (as indicated by a Benzel score of ≥ 14) were included. No difference in outcome between the groups was observed at three years. The conclusions of the study are justified but are limited to a very narrow group of patients (those with mild spondylotic myelopathy). The long-term effect on spinal cord function if the canal is allowed to remain stenotic is unknown as the patients in this study had only three years of follow-up.

Hurwitz EL, Morgenstern H, Harber P, Kominski GF, Belin TR, Yu F, Adams AH; University of California-Los Angeles. A randomized trial of medical care with and without physical therapy and chiropractic care with and without physical modalities for patients with low back pain: 6-month follow-up outcomes from the UCLA low back pain study. *Spine*. 2002;27:2193-204.

The authors reported the results of a randomized, controlled study of patients with more than a three-month history of low-back pain who were treated with chiropractic manipulation with or without physical therapy modalities. These modalities included ultrasound, heat or cold therapy, and electrical stimulation. Patients were assessed at two, six, and twenty-six weeks with regard to pain, functional disability, and satisfaction. Significant improvements were seen in both treatment groups. Patients who were managed with physical therapy modalities performed slightly better at two and six weeks. However, no differences between the groups were noted at six months, leading to the conclusion that adjunctive physical therapy modalities do not improve results in patients treated with chiropractic manipulation.

Hagen KB, Hilde G, Jamtvedt G, Winnem MF. The Cochrane Review of ad-

vice to stay active as a single treatment for low back pain and sciatica. *Spine*. 2002;27:1736-41.

Four trials, involving a total of 491 patients with low-back pain and sciatica, were selected from a database of randomized studies. In all four trials, patients who had been advised to stay active were compared with patients who had been advised to rest in bed. Only one study demonstrated significantly better results in association with activity, but that study was thought to have a moderate to high risk of bias and included only male military trainees. Although there was no significant difference in terms of improvement in either group, no harmful effects in terms of back pain or sciatica were identified in association with increased activity.

This was a generally weak study that predominantly involved subjects in Europe, where different customs and disability standards make comparison with American patient care difficult. No strong conclusions can be drawn.

Hurwitz EL, Morgenstern H, Harber P, Kominski GF, Belin TR, Yu F, Adams A; University of California-Los Angeles. A randomized trial of medical care with and without physical therapy and chiropractic care with and without physical modalities for patients with low back pain: 6-month follow-up outcomes from the UCLA low back pain study. *Spine*. 2002;27:2193-204.

In this study, patients who were members of health maintenance organizations and who presented with back pain agreed to be randomized to one of four treatment groups. Of 1469 eligible patients, 681 were enrolled. After six months of follow-up, chiropractic care and medical care for low-back pain were deemed to be comparable in terms of the changes in pain intensity and disability. There were no significant differences in disability time, days in bed, or medication usage between the groups.

The weaknesses of this study included the patients' ability to self-enroll, the failure to recruit >50% of eligible patients, and the "captive" nature of patients in a health maintenance organization system, which may limit extrapolation of these results to a more general population of patients who have the ability to change services if they are unhappy with their progress.

Petersen T, Kryger P, Ekdahl C, Olsen S, Jacobsen S. The effect of McKenzie therapy as compared with that of intensive strengthening training for the treatment of patients with subacute or chronic low back pain: a randomized controlled trial. *Spine*. 2002;27:1702-9.

In this study from Denmark, 260 patients with chronic back pain (defined as back pain of at least eight weeks' duration) were randomized to treatment with McKenzie exercises performed under the supervision of a physical therapist or group exercises that included supervised dynamic strengthening. In both groups, patients received a maximum of fifteen treatments over eight weeks and then participated in a self-administered program for an additional two months before assessment. No significant differences were found between the two groups in terms of disability. Pain tended to be lower in the McKenzie group at two months, but the difference was not significant.

As 30% of the patients in both groups withdrew from the study, and as there was no untreated control group, it is difficult to draw any meaningful conclusion from this report.

Cardenas DD, Warms CA, Turner JA, Marshall H, Brooke MM, Loeser JD. Efficacy of amitriptyline for relief of pain in spinal cord injury: results of a randomized controlled trial. *Pain*. 2002;96:365-73.

The authors describe the results of the first placebo-controlled, double-blind, prospective, randomized study evaluating the efficacy of a tricyclic antidepressant, amitriptyline, for the treatment of chronic pain following a spinal cord injury. The mechanism of action of amitriptyline is through the selective reuptake inhibition of serotonin and norepinephrine. It has been hypothesized that pain relief occurs as a result of central and peripheral pain-inhibition mechanisms. Tricyclic antidepressants have been found to be effective for relieving discomfort in patients with migraine headaches, fibromyalgia, atypical facial pain, and diabetic neuropathy. Their benefit in the treatment of dysesthetic pain in patients with spinal cord injury has never been demonstrated, although they frequently are used for this purpose. In this study, intent-to-treat analysis did not support the use of amitriptyline when it

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was compared with an active placebo, benzotropine mesylate, for the relief of pain. This finding is important because spine surgeons often choose this medication for the treatment of chronic neuropathic pain and pain associated with degenerative disc disease although its efficacy has never truly been confirmed in a prospective, randomized study. In fact, only one previous study has evaluated the effect of this medication in the treatment of pain associated with spinal cord injury, and that study also did not support its efficacy. The investigation by Cardenas et al. is a well-designed study and represents the largest clinical trial to date evaluating the use of a medication for the treatment of chronic pain in the setting of spinal cord injury.

Bracken MB. Methylprednisolone and acute spinal cord injury: an update of the randomized evidence. *Spine.* 2001;26(24 Suppl):547-54.

The authors of this study performed a systematic review with use of Medline, CINAHL, and the Cochrane Library to determine the effectiveness of methylprednisolone in the treatment of acute spinal cord injury. The lead author has been the lead investigator in three National Acute Spinal Cord Injury studies (NASCIS). These studies have demonstrated that the administration of high-dose methylprednisolone within eight hours after an acute spinal cord injury is safe and is modestly effective for improving functional outcome following a spinal cord injury. These data have come under criticism over the last several years because the intent-to-treat groups in the NASCIS II and III studies showed no significant neurological improvement with methylprednisolone and only after a post ad-hoc analysis did a subgroup of patients show improvement in motor scores. To date, the United States Food and Drug Administration has not approved the use of high-dose methylprednisolone for the treatment of spinal cord injury. In the spinal community, this medication is generally recommended because a better alternative is not available, because it involves minimal cost, and because it may be effective in certain patient subgroups if given early. The search continues for an optimum pharmacological intervention that may ultimately modify or alter the secondary injury cascade following a spinal cord injury.

Ishida Y, Tominaga T. Predictors of neurologic recovery in acute central cervical cord injury with only upper extremity impairment. *Spine.* 2002;27:1652-8.

The authors of this study observed that patients who had a central cord syndrome that involved impairment of motor and sensory function of only the upper extremities but who had no evidence of abnormal changes to the cervical spinal cord on magnetic resonance imaging often responded well to nonoperative treatment, with substantial neurological recovery after six weeks of follow-up. The authors did not study patients with a dense central cord syndrome that involved impairment of both upper and lower extremity function. It is clear that patients who show substantial recovery and have mild deficits without instability following a spinal cord injury respond favorably to nonoperative intervention. The pressing issue is the degree of aggressiveness (i.e., surgical intervention) that should be afforded to a patient with both upper and lower extremity dysfunction in the setting of a dense central cord syndrome. Should certain parameters be defined in which surgical intervention is not in the patient's best interest, as in the case of an elderly patient with multiple comorbidities or a patient with severe motor impairment? Such questions can only be answered through controlled, prospective, randomized studies, which are necessary to provide a better understanding of the natural history of all degrees of central cord syndromes.

Fritzell P, Hägg O, Wessberg P, Nordwall A; Swedish Lumbar Spine Study Group. Chronic low back pain and fusion: a comparison of three surgical techniques: a prospective multicenter randomized study from the Swedish lumbar spine study group. *Spine.* 2002;27:1131-41.

This was a multicenter, randomized study with a two-year follow-up.

Over a six-year time-period, 294 patients who had been referred to nineteen spinal centers were blindly randomized into four treatment groups. Three groups were treated operatively, and one was treated nonoperatively. The operative procedures were (1) posterolateral fusion, (2) posterolateral fusion with pedicle screws, and (3) posterolateral fusion with pedicle screws and interbody fusion. All surgical techniques were found to reduce pain and to decrease disability substantially, but there were no significant differences among the groups with respect to clinical outcome. The overall fusion rate was 72% in group 1, 87% in group 2, and 91% in group 3.

Gibson S, McLeod I, Wardlaw D, Urbaniak S. Allograft versus autograft in instrumented posterolateral lumbar spinal fusion: a randomized control trial. *Spine.* 2002;27:1599-603.

This study from Scotland evaluated the clinical outcomes for sixty-nine patients who had been managed with instrumented lumbar fusion. The patients were randomized to receive either their own bone (harvested from the iliac crest) or allograft bone (fresh-frozen bone obtained from the femoral head at the time of total hip arthroplasty). The same surgeon performed all procedures, and Steffee plates were used for all patients. Thirty-seven patients received allograft bone, and thirty-two received their own bone. The allograft bone was thawed at the time of surgery and was morselized with use of a manually operated bone mill in the operating room. On the basis of Roland and Morris scores at the time of the one-year evaluation, the two groups were identical when the patients with donor-site pain were excluded. The fusion rates in both groups were somewhat unclear, and the authors did state that the results deteriorated over time. Furthermore, at the time of "long-term follow-up," they stated that 33% of the patients in the allograft group and 40% of those in the autograft group had no improvement in their scores or had a poor result. This article points out the morbidity that is associated with harvesting bone from the iliac crest. However, without a better assessment of fusion status, it is hard to truly compare the two groups. We know that implants often will maintain immobilization without failure for two to five years postoperatively.

Furlan AD, Brosseau L, Imamura M, Irvin E. Massage for low-back pain: a systematic review within the framework of the Cochrane Collaboration Back Review Group. *Spine.* 2002;27:1896-910.

In an effort to assess the effects of massage therapy for nonspecific low-back pain, the authors assessed nine publications describing eight randomized trials. The authors concluded that massage might be beneficial for patients with subacute and chronic non-specific low-back pain, especially when combined with exercises and education. However, the results of the eight trials were not strongly conclusive. A large-volume, multicenter, prospective, randomized study probably would be needed to truly answer the question regarding the effectiveness of massage therapy compared with other nonoperative modalities in the treatment of lumbar back pain.

Hofstee DJ, Gijtenbeek JM, Hoogland PH, van Houwelingen HC, Kloet A, Lötters F, Tans JT. Westeinde sciatica trial: randomized controlled study of bed rest and physiotherapy for acute sciatica. *J Neurosurg.* 2002;96(1 Suppl):45-9.

In this study from The Netherlands, the investigators attempted to compare the efficacies of three nonoperative treatment strategies for patients with sciatica. The three methods were bed rest, physiotherapy, and continuation of activities of daily living. The analysis of the primary and secondary outcome measures showed no significant differences among the three treatment groups. Neither bed rest nor physiotherapy had a more favorable effect on recovery from sciatica than did continuation of activities of daily living. This article from the neurosurgery literature seems to confirm what has been published in orthopaedic literature.