SPECIALTY UPDATE

What's New in Spine Surgery

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What's New in the Treatment of the Cervical Spine

Recent advances in cervical spine treatment derive from improved clinical outcome studies, new imaging modalities, and a focus on the causes of and treatment strategies for adverse events. This review of cervical spine developments will discuss myelopathy, disc arthroplasty, adverse events, and health economic data.

Myelopathy

A large multicenter international study of cervical myelopathy compared the outcomes of anterior and posterior cervical spine surgery in 280 patients. The anterior surgery group was younger, had less severe disease, and fewer comorbidities, whereas the posterior surgery group had a greater number of levels treated. Both groups had significant improvement in terms of neurologic function and health-related outcomes. Slightly greater improvement was seen in the anterior surgery group, but this difference was believed to be due to the older age and worse disease states in the posterior surgery group. Interestingly, there were significant differences at the time of baseline presentation between patients from varying continents, with Asia-Pacific and Latin-American patients presenting earlier for treatment (by as much as fifteen years) and having significantly better outcomes.

The short and long-term outcomes were compared following laminoplasty for the treatment of cervical myelopathy. Long-term patients had no differences in any outcome score, except for the sensory loss in lower extremities, suggesting the development of lumbar spinal stenosis. Thus, cervical spine laminoplasty appears to be a durable procedure, and recurrence of myelopathy is unlikely.

Specialty Update has been developed in collaboration with the Board of Specialty Societies (BOS) of the American Academy of Orthopaedic Surgeons.

One of the most common techniques to stabilize the lamina after laminoplasty is the use of plates. A computed tomography (CT) study showed that progressive healing occurred at three, six, and twelve months and that 97% of the laminae had united at the time of the latest examination. The canal opening was maintained, and only 2% of the screws loosened.

Disc Arthroplasty

European studies of the eight to ten-year results of disc arthroplasty demonstrated maintenance of good outcomes and cervical motion, without the need for revision and without wear-related complications. Randomized clinical trials comparing arthroplasty with anterior cervical fusion in the United States also showed excellent outcomes in both groups after as long as five years. The reoperation rates at adjacent segments trended toward being significantly greater in the anterior fusion group, which would justify the use of disc replacement, but further analysis of these data is needed. Two cases of severe abnormal inflammatory reactions after metal-on-metal cervical disc replacement have been reported in patients enrolled in Food and Drug Administration (FDA) trials. Both patients had myelopathy and were successfully managed with revision with arthrodesis. Histopathological findings were similar to the reactions seen in association with metal-on-metal hip arthroplasty.

Atlantoaxial Cystic Degeneration

Several authors have reported successful treatment of patients with nonrheumatoid destructive arthropathy at C1-C2. Symptoms have ranged from severe suboccipital neck pain to myelopathy. Severe facet degeneration, pannus formation, and osseous erosions, which can result in dens fracture and atlantoaxial subluxation, can be present on radiographs. Patients without neurologic symptoms are successfully managed with posterior atlantoaxial arthrodesis. No consensus regarding the

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best treatment for patients with myelopathy and large ventral masses resulting from pannus formation has been reached. One author performed transoral decompression and posterior fusion with good results, whereas others believe that the ventral mass will resolve after posterior fusion.

Soft-Tissue Complications Associated with Cervical Spine Surgery

Many investigations addressing the causes and prevention of soft-tissue complications after anterior cervical spine decompression and fusion have been performed. Retropharyngeal swelling occurs uniformly after anterior surgery but does not appear to be associated with dysphagia at two and six weeks postoperatively. Airway obstruction resulting from hematoma is the most feared complication. The trachea is stiffened by cartilage ribs; however, biomechanical tests show that the stiffness is far greater in the sagittal plane, and significantly less force is required when pressure is applied from the lateral direction as would occur postoperatively.

Instrumentation Complications

Attention to detail is essential during cervical spine surgery, especially when mobile spinal segments will be adjacent to instrumentation. Rods extending rostral to C2 with posterior fusion have been reported to erode into the C1 lamina and the vertebral artery. Pseudarthrosis at the site of a posterior fusion may result in excessive motion and may cause the failure of sublaminar cables. Such a case following C1-C2 posterior fusion resulted in intradural penetration, subdural hematoma, and blockage of the fourth ventricle.

Atlantoaxial arthrodesis with use of lateral mass screw fixation of C1 is commonly performed. One refinement is to divide the C2 ganglion, which affords greater visualization for screw placement and less bleeding. Little is known about the long-term effects of sacrificing this nerve. In a case series, this technique was associated with less blood loss and shorter operative times and demonstrated no difference in terms of long-term outcome. Overall outcomes were satisfactory, and no complications related to the neurolysis were noted, but critical analysis of the residual effects of nerve transection was not performed.

Health Economic

The treatment of cervical spine disease represents vast expenditures, accounting for approximately 150,000 annual hospital admissions costing \$41,500 each. Total annual billings for surgical care exceeded \$6 billion. The majority of surgical procedures were for the treatment of adults who had degenerative disease. This anterior cervical fusion procedure performed anteriorly was shown to be cost-effective, with a cost per quality-adjusted life year (QALY) of only \$4500 based on a twenty-year time frame. This is very cost effective, as acceptable costs are between \$50,000 and \$100,000 per QALY.

What's New in Biologics Topics Related to the Spine

Biologics continue to be a major focus in spine research for patients with spinal disorders. The majority of the clinical attention remains on the use of biologics to enhance bone formation, but laboratory efforts continue to investigate the role of biologics in retarding or reversing intervertebral disc degeneration. A recent survey estimated that bone morphogenetic proteins (BMPs) were used in >50% of spine fusion surgical procedures in 2007.

Recombinant Osteoinductive Proteins

The prevalence of BMP usage in the United States recently was evaluated with use of the Nationwide Inpatient Sample between October 2002 and December 2007. During that interval, the annual number of surgical procedures involving BMP increased 4.3-fold. Spine fusion accounted for the vast majority (93%) of principal procedures in which BMP was used. The predominant use of BMP was for primary posterior lumbar interbody fusion or transforaminal lumbar interbody fusion (30%), followed by primary posterolateral spine fusion (20%), primary anterior lumbar interbody fusion (17%), primary cervical fusions (14%), and primary thoracolumbar fusions (4%). At least 85% of principal procedures using BMP were for off-label applications. Revision spine fusion accounted for 7% of the total usage.

In the past year, there were no reports of new clinical studies on spine fusion with use of rhBMP-7 (OP-1; Stryker, Hopkinton, Massachusetts). This biologic failed to achieve post-marketing approval for posterolateral spine fusion in 2009. There was a report of the frequency during which neutralizing antibodies were generated in the previously reported clinical trial of posterolateral fusion with OP-1 putty.

A primary concern with physician-directed use of recombinant BMPs continues to focus around local adverse events. The most commonly reported local side effects are heterotopic bone formation in the surgical approach track, transient radiculitis, transient vertebral body bone resorption when used near exposed cancellous bone, and sterile seroma fluid collections and/or local edema. Most of these local side effects are believed to be related to the use of too much BMP by the surgeon, either by increasing the concentration of the growth factor or by overstuffing the defect, which can result in a higher concentration of BMP or leakage of BMP into the surrounding tissues. These side effects mostly occur three to seven days following surgery; however, cancellous bone resorption is evident at two to six months.

The majority of local side effects have been related to the use of BMPs for posterior or posterolateral interbody fusion. A retrospective report on 204 consecutive patients undergoing transforaminal lumbar interbody fusion demonstrated a low rate of BMP-related complications. Thirteen of the 204 patients had persistent or worsened radiculopathy postoperatively, and five of them (representing 2.5% of the study group) demonstrated radiographic and clinical findings consistent with BMP-

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related radiculitis. Another study, involving thirty patients, demonstrated a 6% prevalence of postoperative radiculitis attributable to BMP. These frequencies are considerably lower than those originally reported in some smaller nonconsecutive series.

Several authors have reported severe perioperative swelling in the anterior cervical spine, sometimes when excessive BMP-2 doses were used or when the BMP was placed outside the structural cage/implant. This complication typically occurs several days following surgery and in a few cases has necessitated respiratory support of the patient. This side effect may be related to the use of excessive amounts of BMPs in small spaces or overstuffing of BMP into implants. Given the high success rate for anterior cervical discectomy and fusion in healthy patients with allograft and plating, surgeons must carefully balance any increased risk of side effects associated with the use of BMP with the actual need for increased healing potential based on specific patient factors (i.e., diabetes, smoker, steroids, multilevel, etc). A case report of a posterior cervical fusion with BMP highlighted the possibility of seroma or hematoma resulting in compression of neurologic elements.

Posterolateral spine fusion is the second most common surgical procedure for which BMP is used, and there may be a low rate of local side effects of BMP in this setting. A recent study evaluated 1037 patients for whom INFUSE was used as an adjunct for posterolateral spine fusion. Medical and surgical complications were observed in 190 patients (18.3%), with eighty-one major complications (7.8%) and 110 minor complications (10.6%). Neurologic complications were related to screw malposition in six patients and epidural hematoma in three patients. New or more severe postoperative radicular symptoms were noted in seven patients (0.7%). Psoas hematoma was identified by means of CT scanning in eight patients (0.8%). Complications directly related to rhBMP-2 were observed in at least one patient (0.1%), and, in a worst-case analysis, in as many as six patients (0.6%). This study of 1037 patients confirmed the relative safety of rhBMP-2/ACS for posterolateral spine fusion. The complication rate related to BMPs likely will be dependent on the anatomical site and exact delivery method (dose, carrier, etc.).

There is continued interest in the use of mesenchymal stem cells (MSCs) for bone and cartilage regeneration. In rodent models, both fat-derived and bone marrow-derived mesenchymal stem cells have been proposed for use in spine fusion. However, spine fusion is a challenging environment in which to form bone, and a recent study showed that neither bone marrow aspirate nor mesenchymal stem cell-enriched bone marrow aspirate was sufficient to heal critical-sized defects in rats. An injection of genetically modified mesenchymal stem cells expressing BMP-2 resulted in spine fusions in mice. The clinical future of strategies that propose to use MSCs alone as a biologic grafting solution for spine fusion remains unclear given the cost and regulatory complexity of using these cells.

What's New in Spinal Deformity Surgery

Presentations and publications from the last year regarding idiopathic scoliosis, adult spinal deformity, growing rod/growing spine techniques, three-column osteotomies, and neuromuscular deformities will be discussed in this section. Multicenter studies are more prevalent now than they were five years ago because of industry-sponsored study groups and database collection.

Idiopathic Scoliosis

School screening continues to be a topic of interest in the treatment of adolescent idiopathic scoliosis. At least one large retrospective cohort study from Hong Kong suggested the benefits of its mandated and universal school screening program. Brace studies continue to be presented and published. Clearly, the hours of brace wear correlate highly with lack of curve progression, with twelve hours a day being an important threshold. Convex-side vertebral stapling is still a technique of interest as an alternative to bracing for the treatment of idiopathic scoliosis. The indications and outcomes are not entirely clear, but it has been suggested that for thoracic and lumbar curves of $<35^\circ$, the results with vertebral body stapling are comparable with those of bracing. However, for thoracic curves of between 35° and 44° , the results with vertebral body stapling are poor.

One study from Korea demonstrated that the use of pedicle screw instrumentation in the thoracic spine for the treatment of idiopathic scoliosis was associated with good outcomes after more than ten years of follow-up. However, there continues to be debate about how much scoliosis correction is advisable. One multicenter study suggested that derotational maneuvers with pedicle screw implants may worsen sagittal balance by further decreasing thoracic kyphosis. Therefore, maximum correction may not always be advisable.

Adult Spinal Deformity

One of the complications of treating spinal deformity in adult patients is proximal junctional kyphosis and proximal junctional failure. At least one study suggested that prophylactic vertebroplasty may have some benefit. Another study suggested that CT-myelography demonstrates more stenosis, particularly in the loaded spine, than magnetic resonance imaging (MRI) does. One study suggested that the placement of prophylactic inferior vena cava filters prior to spinal surgery reduces the prevalence of deep venous thrombosis and pulmonary embolus in patients who are at high risk for these complications.

One multicenter study suggested that adult patients with spinal deformity who have the worst outcome after surgery are those with greater preoperative pain, greater narcotic use, a greater body-mass index, and a greater prevalence of depression and anxiety. This study demonstrated that those factors were more important determinants than technical surgical factors were. One study demonstrated that the potential for improving outcomes in adult patients who have deformity is relatively comparable for both primary and revision spinal

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surgery. At least one study demonstrated that patients who were managed with BMP for spinal fusion had a complication profile similar to that of patients who were managed without BMP. The only exceptions were patients who had anterior cervical fusion, for whom the rate of complications was greater if BMP was used. A survey of spinal surgeons, presented at the Scoliosis Research Society (SRS) meeting, suggested that bone-graft substitutes are now preferred over iliac crest bone grafts. The majority of spine surgeons no longer consider iliac crest bone-grafting as the gold standard for spinal fusion surgery and prefer to utilize bone-graft substitutes to reduce the donor-site morbidity and to increase the fusion rate.

Growing Rod/Growing Spine Techniques

There is increasing interest in techniques of using spinal instrumentation to control or correct deformities, in patients under the age of ten years, without performing spinal fusion. One study demonstrated that most patients with early-onset scoliosis required growing-rod removal followed by fusion with instrumentation. Furthermore, the fusion included more levels than had been spanned by the growing rods and achieved <50% of the correction of the initial deformity that had been achieved at the end of treatment with the growing rods. The patients with early-onset scoliosis who are most difficult to manage with growing-rod techniques are those with substantial thoracic kyphosis. However, pedicle screw fixation points are better than hooks in this group of patients. It appears that use of this surgical technique improves overall nutritional status in children.

Three-Column Osteotomies

One study involving a porcine model demonstrated that spinal shortening at the thoracolumbar level can be performed safely with the shortening of 5.1% of the length of the spinal column (T1 to L6). However, if the shortening averaged 6.3% or more, there was substantial risk of spinal cord injury. Patients who have myelopathy that is substantial enough to create a situation of unobtainable intraoperative spinal cord monitoring data have a very high likelihood of substantial neurologic complications with the surgical procedure.

Neuromuscular Deformities

One study from Canada demonstrated that corticosteroid (deflazacort) treatment significantly reduced the prevalence of scoliosis that required treatment in patients with Duchenne muscular dystrophy. Preliminary data have suggested that there may be a role for growing rods in the treatment of spinal muscular atrophy. Another presentation demonstrated that preliminary untethering procedures were not necessary prior to deformity correction in patients with myelodysplasia.

What's New in Spinal Cord Injury

Surgical and pharmacologic strategies to optimize neurologic recovery continue to be at the forefront of basic science and clinical investigations. Perhaps the most debated topic revolves

around the appropriate timing of surgical intervention in the presence of acute spinal cord injury.

Early Versus Late Surgery

Despite basic-science and clinical data supporting early surgical decompression and stabilization in the setting of acute spinal cord injury, the timing of surgery remains controversial. This stems from a lack of prospective randomized controlled data to support early surgical intervention. In order to better define the appropriate timing of surgery, the Surgical Treatment in Acute Spinal Cord Injury Study (STASCIS) was executed. This prospective multicenter trial is in its final stages and will provide more evidence on whether early surgical intervention (defined in the study as that performed less than twenty-four hours after the injury) influences neurologic recovery. Although the final results have not been published, the preliminary data show that patients with early surgical decompression and stabilization have an increased likelihood of recovering two grades or more on the American Spinal Injury Association (ASIA) scale. Patients who were managed with late surgery were likely to achieve some recovery, but the recovery was not as significant as that in patients who were managed with early surgery.

Translational Studies

There has been an abundance of recent clinical and scientific research that has provided insight into the regenerative potential of the injured spinal cord. The translational gap between scientific discovery and implementing these treatments in clinical practice is narrowing. Many therapeutic approaches currently under investigation are already in or are about to begin the clinical trial phase.

Rho is an intracellular GTPase that regulates axonal growth and regeneration following exposure to the inhibitory elements of myelin. A strategy to directly target this pathway was developed with use of a Rho antagonist (C3 transferase). Animal studies have shown improved functional recovery, axonal regeneration, and inhibition of apoptosis following its delivery to the injury site. On the basis of the laboratory data, Cethrin (BA-210, BioAxone Therapeutic, Montreal, Quebec, Canada), a Rho antagonist, was engineered for human administration. A phase-IIA multicenter nonrandomized clinical trial in which Cethrin was applied to the dura at the time of decompression was completed in North America in 2007. The results verified its safety and showed improvement of one or more ASIA grade at the time of the latest follow-up. As a result, a prospective randomized clinical trial has been planned and is expected to begin in 2011.

Inhibitory constituents within central nervous system myelin, termed Nogo-A, have been found to inhibit axon sprouting and regeneration via the Rho pathway. Anti-Nogo IgG antibodies were developed and have been shown to promote axonal sprouting and functional recovery in rat and primate models. A multicenter nonrandomized clinical trial,

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sponsored by Novartis (Basel, Switzerland), is currently under way to evaluate safety and efficacy measures of anti-Nogo antibodies in patients with ASIA grade-A cervical and thoracic spinal cord injury. The treatment is administered intrathecally in the first four to fourteen days after the injury. To date, forty-five patients have been enrolled; the study is expected to be completed in the fall of 2010 (ClinicalTrials.gov NCT00406016).

Riluzole (Sanofi-Aventis, Bridgewater, New Jersey) is a sodium channel blocker that has long been used for the treatment of amyotrophic lateral sclerosis. Animal studies have shown it to have significant behavioral and neuroprotective effects and have encouraged the initiation of a multicenter prospective randomized clinical trial involving patients with ASIA grade-A, B, or C cervical and thoracic injuries. This study, sponsored by the Christopher and Dana Reeve Foundation, is currently ongoing and is expected to enroll thirty-six patients by August 2012 (ClinicalTrials.gov NCT00876889).

Oligodendrocyte progenitor cells, derived from human embryonic stem cells, have been shown to influence remyelination and functional recovery following acute spinal cord injury in rat models. Shortly after the end of federal funding restrictions for embryonic stem cell research, Geron (Menlo Park, California) was given approval by the FDA to begin a clinical trial on oligodendrocyte progenitor cells (GRNOPC1) in January 2009. In this phase I/IIa trial, patients with ASIA grade-A thoracic spinal cord injury will receive injection of the oligodendrocyte progenitor cells seven to fourteen days after the injury. In August 2009, the FDA placed a clinical hold on the trial because of concerns about microcyst formation surrounding the injury site. In July 2010, the hold was lifted and the trial began enrollment in October 2010 (ClinicalTrials.gov NCT01217008).

What's New in the Treatment of the Lumbar Spine

Lumbar spinal pathology continues to cause major clinical problems for a large number of patients. Motion-sparing technology, such as lumbar disc arthroplasty, has been widely studied, but it is unclear if it is beneficial in the long term and whether it alters progressive degenerative disease of the lumbar spine.

Lumbar Disc Arthroplasty

Lumbar disc arthroplasty continues to be a controversial area in the treatment of lumbar degenerative disc disease. Although the theory of motion-sparing technology is attractive, studies have yet to convince practitioners of the value and beneficial longer-term outcome of patients managed with this technology. A recent study investigated the five to eight-year follow-up results for one specific disc prosthesis. A total of 506 patients were enrolled in a prospective randomized study from 2000 to 2004 and were examined. Of the 506 patients, 352 had one-level, 109 had two-level, forty had three-level, and the others had multi-level implantation. The baseline mean Oswestry Disability Index (ODI) score was significantly improved at three months postoperatively, and this improvement was

maintained at all follow-up time points up to eight years after surgery. The average visual analog scale (VAS) pain intensity score was significantly improved at the three-month time point and was maintained to the eight-year follow-up time point. Radiographic parameters showed functional lumbar spine motion at the level of the prosthesis throughout the period of the study. This long-term follow-up study demonstrated successful clinical outcomes in association with this specific device that were maintained past the five-year follow-up time point.

A recent multicenter prospective randomized study directly compared two specific lumbar arthroplasty devices. A single-level surgical procedure was performed in 457 patients. At the time of the latest (two-year) follow-up, there were no significant differences between the two groups with the different devices in terms of surgical and follow-up variables or clinical outcomes. Both groups had significant improvement in the clinical scores as compared with baseline, with similar success rates. Notably, this study was the first to involve a direct comparison between two specific lumbar disc prostheses, and both devices were associated with similar clinical outcomes. In a separate presentation by the same authors based on the same study data, the radiographic data were examined and compared between the two groups. Overall, the operative level range of intervertebral segment motion decreased at the three-month time point, after which the motion increased to either the preoperative value or significantly surpassed the preoperative value. Having intervertebral segment motion of $>4^\circ$ was associated with a greater success rate. Both devices appeared to have maintained the range of motion throughout the period of the study.

Adjacent-Segment Disease and Progressive Degeneration

One of the theoretical benefits of disc arthroplasty is the possible decrease in the prevalence of adjacent-segment intervertebral disc disease, which can require revision surgery. A recent study examined patients who developed adjacent-segment disc degeneration and had a reoperation following a lumbar disc arthroplasty. Of 1000 patients who had a lumbar disc arthroplasty, twenty-one (2.1%) required a second surgical procedure for the treatment of adjacent-segment problems. The mean length of time from the index procedure to the reoperation was 28.3 months. Preoperative MRI studies of the adjacent-segment disc demonstrated that 38.3% were normal, 38.8% had moderate degenerative disease, and 22.2% had advanced degenerative disease. Of these twenty-one patients, fifteen had preoperative CT scans, with twelve (57%) of the facets being classified normal, seven (33.3%) being classified as grade I, and two (9.5%) being classified as grade II; no patient had an advanced grade of III or IV. The rate of adjacent-segment disease following disc arthroplasty was similar to that rate following fusion. Analysis of the patients who needed revision surgery demonstrated that many patients had preexisting degenerative disease prior to the index surgery. Consequently, the development of adjacent-segment disease may be related, to some extent, to preexisting adjacent-segment degeneration at the time of the index procedure.

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Another study examined the progression of adjacent-level disc degeneration and index-level facet joint degeneration following lumbar arthroplasty. The authors reported on ninety-three patients who underwent single-level lumbar disc arthroplasty. The average duration of follow-up was 53.4 months (range, 24.1 to 98.7 months). The prevalence of adjacent-level disc degeneration was 10.2% (eleven of 108 levels); however, the majority of these changes were mild and occurred a mean of 65.2 months following surgery. The rate of index-level facet joint degeneration was observed in 20% (forty-four) of all 220 facet joints and occurred significantly more often at the lumbosacral junction. These particular degenerative changes were associated with worse postoperative outcome and less lumbar spine motion. Therefore, ongoing facet degeneration can and does occur at the level of the implantation of the disc arthroplasty and can affect outcome.

Upcoming Meetings and Events Related to Spine Surgery

The Forty-sixth Annual Meeting of the Scoliosis Research Society (SRS) will be held on September 14 through 17, 2011, in Louisville, Kentucky. It will be preceded by a one-day course entitled "Techniques for Optimizing Safety and Outcomes in Spine Deformity Surgery," to be held on September 14, 2011. Web site: www.srs.org

The EuroSpine Annual Meeting will be held on October 19 through 21, 2011, in Milan, Italy. Web site: www.eurospine.org

The Twenty-sixth Annual Meeting of the North American Spine Society (NASS) will be held on November 2 through 5, 2011, in Chicago, Illinois. There will be a number of precourses, to be held on November 2, 2011. Web site: www.spine.org

The Thirty-ninth Annual Meeting of the Cervical Spine Research Society (CSRS) will be held on December 8 through 10, 2011, in Scottsdale, Arizona. Web site: www.csr.org

The Federation of Spine Associations will present the spine program at Specialty Day at the Annual Meeting of the American Academy of Orthopaedic Surgeons (AAOS) on February 11, 2012, in San Francisco, California. Web site: www.aaos.org

The Annual Meeting of the American Association of Neurological Surgeons/Congress of Neurological Surgeons (AANS/CNS) Section on Disorders of the Spine and Peripheral Nerves will be held on March 7 through 10, 2012, in Orlando, Florida. Web site: <http://spinesection.org>

The Spine Arthroplasty Society's Twelfth Annual Global Symposium on Motion Preservation Technology will be held

on March 20 through 23, 2012, in Barcelona, Spain. Web site: www.isass.org

The Thirty-eighth Annual Meeting of the American Spinal Injury Association (ASIA) will be held on April 19 through 21, 2012, in Denver, Colorado. Web site: www.asia-spinalinjury.org

The Annual Meeting of the International Society for the Study of the Lumbar Spine (ISSLS) will be held on May 28 through June 1, 2012, in Amsterdam, The Netherlands. Web site: www.issls.org

The Nineteenth Annual International Meeting on Advanced Spine Techniques (IMAST) will be held on July 18 through 21, 2012, in Istanbul, Turkey. Web site: www.imastonline.com

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