

Appendix

Evidence-Based Articles Related to Spine Surgery

Auerbach JD, Anakwenze OA, Milby AH, Lonner BS, Balderston RA. Segmental contribution toward total cervical range of motion: a comparison of cervical disc arthroplasty and fusion. *Spine (Phila Pa 1976)*. 2011 Dec 1;36(25):E1593-9.

In this prospective radiographic study, one-level cervical disc arthroplasty was compared with anterior cervical discectomy and arthrodesis with regard to the effect on neck range of motion at both the operative and nonoperative levels. The authors found that the total cervical range of motion, operative-level range of motion, and adjacent-level range of motion were unchanged in the disc arthroplasty group at the time of the two-year follow-up. In contrast, the cervical fusion group demonstrated decreased motion at the operative level, with increased motion at adjacent levels.

Bracken MB. Steroids for acute spinal cord injury. *Cochrane Database Syst Rev*. 2012 Jan 18;1:CD001046.

This was a review of eight randomized trials of the use of corticosteroids for human spinal cord injury. Seven trials involved the use of methylprednisolone. The author concluded that high-dose methylprednisolone steroid therapy was the only pharmacologic therapy with efficacy in a phase-III randomized trial when administered within eight hours after an injury. One of the trials showed additional benefit by extending the maintenance dose from twenty-four to forty-eight hours if the start of treatment was delayed to between three and eight hours after the injury. The author also concluded that there is a substantial need for more trials of pharmacologic therapies for spinal cord injury.

Cepoiu-Martin M, Faris P, Lorenzetti D, Prefontaine E, Noseworthy T, Sutherland. Artificial cervical disc arthroplasty: a systematic review. *Spine (Phila Pa 1976)*. 2011 Dec 1;36(25):E1623-33.

This systematic review of thirteen case series, four randomized clinical trials, and one nonrandomized comparative study compared cervical disc arthroplasty with anterior cervical discectomy and arthrodesis. The results at up to two years of follow-up demonstrated conclusively that disc arthroplasty is not inferior to arthrodesis. Methodologically weaker components of this literature suggest that disc arthroplasty offers some benefit for the treatment of neck and arm pain.

Dunning JR, Cleland JA, Waldrop MA, Amot CF, Young LA, Turner M, Sigurdsson G. Upper cervical and upper thoracic thrust manipulation versus nonthrust mobilization in patients with mechanical neck pain: a multicenter randomized clinical trial. *J Orthop Sports Phys Ther*. 2012 Jan;42(1):5-18.

This was a randomized clinical trial of two therapeutic modalities for the treatment of neck pain: high-velocity low-amplitude thrust manipulation and non-thrust manipulation. The authors found that high-velocity low-amplitude thrust manipulation was associated with greater decreases in Neck Disability Index scores and pain scores than non-thrust manipulation. There was also a significant increase in the high-velocity low-amplitude thrust manipulation group with respect to cervical range of motion.

Gebremariam L, Koes BW, Peul WC, Huisstede BM. Evaluation of treatment effectiveness for the herniated cervical disc: a systematic review. *Spine (Phila Pa 1976)*. 2012 Jan 15;37(2):E109-18.

This was a systematic review of the literature assessing the effectiveness of interventions for the treatment of cervical disc herniations. Eleven randomized controlled trials were included. The results showed that there was no evidence for the effectiveness of conservative treatment compared with surgery. There was moderate evidence for the effectiveness of some surgical interventions, although there was no unequivocal evidence for the superiority of one particular surgical treatment. No outcomes regarding adjacent-level disease were reported, and there was conflicting evidence for the effectiveness of anterior cervical discectomy compared with anterior cervical discectomy and arthrodesis.

Gnanenthiran SR, Adie S, Harris IA. Nonoperative versus operative treatment for thoracolumbar burst fractures without neurologic deficit: a meta-analysis. *Clin Orthop Relat Res*. 2012 Feb;470(2):567-77. Epub 2011 Nov 5.

This was a meta-analysis comparing pain (assessed with a visual analog scale) and function (assessed with the Roland Morris Disability Questionnaire) in patients with thoracolumbar burst fractures without neurologic deficit who were managed non-operatively and operatively. The authors identified four trials, including two randomized controlled trials consisting of seventy-nine patients (forty-one with operative treatment and thirty-eight with nonoperative treatment), with the mean duration of follow-up ranging from twenty-four to 118 months. The authors found no differences in terms of baseline pain scores, kyphosis, Roland Morris Disability Questionnaire scores, or return-to-work rates. They concluded that the operative treatment of thoracolumbar burst fractures in patients without neurologic deficit did reduce residual kyphosis but did not appear to reduce pain or to improve function at an average of four years after injury and that such treatment was associated with higher complication rates and costs.

Gornet MR, Burkus JK, Dryer RF, Peloza JH. Lumbar disc arthroplasty with MAVERICK disc versus stand-alone interbody fusion: a prospective, randomized, controlled, multicenter investigational device exemption trial. *Spine (Phila Pa 1976)*. 2011 Dec 1;36(25):E1600-11.

Single-level metal-on-metal total disc arthroplasty was performed for 405 patients, and anterior lumbar interbody arthrodesis was performed for 172 control patients. The Oswestry Disability Index, SF-36 Physical Component Subscale, and low back pain scores were all significantly better for the total disc arthroplasty group at all time points up to two years of follow-up. The patients in the total disc arthroplasty group returned to work sooner but had longer operative times and more blood loss.

Guilfoyle MR, Mannion RJ, Mitchell P, Thomson S. Epidural fentanyl for postoperative analgesia after lumbar canal decompression: a randomized controlled trial. *Spine J*. 2012 Aug;12(8):646-51. Epub 2012 Aug 25.

The authors performed a randomized controlled trial of fifty-eight patients with lumbar stenosis in which a single bolus of placebo was compared with 100 µg of fentanyl placed 10 cm rostral to the decompression at time of wound closure. Pain in the recovery room was significantly less in the treatment group, but no difference between the groups was noted at twenty-four and forty-eight hours. The length of stay did not differ between the groups. Urinary retention was more common in the treatment group, although other adverse events did not differ between the groups. The results showed only a minimal benefit from this technique and did not justify the use of epidural fentanyl as described.

Jacobs W, Van der Gaag NA, Tuschel A, de Kleuver M, Peul W, Verbout AJ, Oner FC. Total disc replacement for chronic back pain in the presence of disc degeneration. *Cochrane Database Syst Rev*. 2012 Sep 12;9:CD008326.

This was a well-done Cochrane Systematic Review that was performed to determine if lumbar disc replacement resulted in better pain relief, functional recovery, and improved quality of life over nonoperative care or arthrodesis. Seven randomized controlled trials were included; only one compared disc replacement with conservative care, whereas the other six compared total disc replacement with arthrodesis. All treatments resulted in significant benefit compared with baseline, and improvements were better in the disc replacement group than in the arthrodesis and nonoperative treatment groups. The magnitude of improvement was small, and the authors did not believe that this difference was clinically important as it did not exceed the minimum clinically important difference. The authors cautioned that surgeons should be prudent about the use of lumbar disc replacement until the long-term risks are known, despite the observation that disc replacement is effective for the treatment of low back pain over the short term.

La Touche R, Parús-Alemany A, Mannheimer JS, Angulo-DÚaz-Parreño S, Bishop MD, LopÓz-Valverde-Centeno A, von Piekartz H, FernÁndez-Carnero J. Does mobilization of the upper cervical spine affect pain sensitivity and autonomic nervous system function in patients with cervico-craniofacial pain? A randomized-controlled trial. *Clin J Pain*. 2013 Mar;29(3):205-215.

Upper cervical pain frequently occurs in conjunction with craniofacial pain resulting from temporomandibular dysfunction. Theoretically, this pain complex can result in hyperexcitability of the central nociceptive system that can lead to muscle spasm, autonomic dysfunction, and chronic pain syndromes. The authors hypothesized that mechanical therapy may break this cycle, diminish pain, and reverse the central hypersensitivity. In a randomized trial, the authors compared anteroposterior upper cervical mobilization with sham manual therapy in patients with cervical-craniofacial pain. Significant decreases in pain and improvement in pain thresholds occurred in the manual therapy group in comparison with the sham group. Changes were noted in the sympathetic nervous system, such as increases in heart rate, breathing, and skin conductance. Thus, the authors showed that the anteroposterior mobilization results in hypoanalgesia, possibly as a result of activation of descendant pain-inhibitory pathways in patients with cervical-craniofacial pain syndromes.

Lee SH, Kim KT, Suk KS, Park KJ, Oh KI. Effect of retropharyngeal steroid on prevertebral soft tissue swelling following anterior cervical discectomy and fusion: a prospective, randomized study. *Spine (Phila Pa 1976)*. 2011 Dec 15;36(26):2286-92.

Fifty patients undergoing one or two-level anterior cervical discectomy and arthrodesis were randomized to receive local corticosteroids on morselized collagen sponge in the retropharyngeal space. Prevertebral soft-tissue swelling and odynophagia were significantly reduced in the local steroid group.

Longo UG, Loppini M, Denaro L, Maffulli N, Denaro V. Conservative management of patients with an osteoporotic vertebral fracture: a review of the literature. *J Bone Joint Surg Br*. 2012 Feb;94(2):152-7.

This review of papers on osteoporotic vertebral fractures revealed that there was no standardized conservative treatment protocol. This is a major shortcoming in the literature and precludes a meaningful meta-analysis of the effectiveness of cement-injection procedures in patients with osteoporotic vertebral compression fractures.

Shi MM, Cai XZ, Lin T, Wang W, Yan SG. Is there really no benefit of vertebroplasty for osteoporotic vertebral fractures? A meta-analysis. *Clin Orthop Relat Res.* 2012 Oct;470(10):2785-99. Epub 2012 Jun 23.

This systematic analysis of nine articles involving 886 patients was performed to assess the benefit of percutaneous vertebroplasty for the treatment of vertebral compression fractures. The conclusions of the study were that percutaneous vertebroplasty relieved pain more effectively and improved quality-of-life measures for more patients and to a greater extent than nonoperative treatment did. Furthermore, percutaneous vertebroplasty did not increase the risk of new fractures. This was a Level-II therapeutic study.

Zhang X, Zhang X, Chen C, Zhang Y, Wang Z, Wang B, Yan W, Li M, Yuan W, Wang Y. Randomized, controlled, multicenter, clinical trial comparing BRYAN cervical disc arthroplasty with anterior cervical decompression and fusion in China. *Spine (Phila Pa 1976).* 2012 Mar 15;37(6):433-8.

This was a non-industry-sponsored randomized clinical trial comparing anterior cervical arthrodesis with disc arthroplasty for the treatment of single-level radiculopathy. One hundred and nine patients were randomized at two centers in China. The inclusion-exclusion criteria were similar to the recent studies of FDA trials; that is, the study included adults with single-level radiculopathy or myelopathy and no instability. Patient outcomes at two years were not significantly different between the groups, although range of motion was maintained in the disc replacement group. A reoperation was performed for one patient in the arthroplasty group and four patients in the arthrodesis group. This study was similar to other published randomized clinical trials of disc arthroplasty and showed that arthroplasty was associated with minimum initial improvement over arthrodesis while maintaining range of motion. ■