

Journal Review II

By Ron Feise, DC

Discogenic Back Pain

Mirza SK, Deyo RA. Systematic review of randomized trials comparing lumbar fusion surgery to non-operative care for treatment of chronic back pain. *Spine* 2007;32:816-23.

Synopsis: This was a systematic review of randomized trials comparing surgical with non-surgical treatment of chronic discogenic back pain. The researchers searched electronic databases and bibliographies published by May 2006 and identified 4 randomized trials. All trials enrolled similar subjects and were conducted in Europe. One study suggested improvement in disability for fusion compared with unstructured non-operative care (a control intervention of questionable potency), but the trial suffered from troublesome flaws (e.g., data were not analyzed according to intent to treat). Three trials that used a more potent control intervention (a structured cognitive and behavioral treatment program) found conflicting differences in disability scores at follow-up. Two of these trials demonstrated small benefits that favored fusion, but the other found moderate benefit for the structured non-operative care. All 3 trials, however, suffered from methodological shortfalls (e.g., 2 were underpowered, and 1 had high rates of crossover).

Complication rates for patients with discogenic back pain:

	Surgery (min. – max.)	Non-operative
Mean Rate	13.8% (9-18%)	0

Research Quality: *Overall, this was a high-quality systematic review.*

Quality Details: This study used the following: 1) appropriate design; 2) a clearly focused question; 3) clearly stated and appropriate inclusion and exclusion criteria; 4) a clearly described search of the literature; 5) independent reviewers selecting and appraising the studies; 6) a thorough assessment of the studies; 7) a description of the

data extraction process; and 8) a conclusion that flowed logically from the evidence.

Conclusion: Methodological limitations of the selected randomized trials prevent conclusions.

Comment: *In all of these studies, fusion failed to demonstrate effectiveness sufficiently large to meet the FDA threshold for a clinically meaningful benefit. Moreover, structured rehabilitation with a cognitive behavioral component was essentially equivalent to surgery in efficacy, with no complications. Thus, a surgical approach to chronic discogenic back pain is without evidence of effectiveness. Based on the best evidence of the day, patients should be guided to explore non-surgical approaches first. Only in the light of failed conservative trials should surgery be considered for this patient population, if at all. (Note: Unfortunately, this research team found no trials comparing fusion with manipulation.)*

Conflicts of Interest

Fenton JJ, Mirza SK, Lahad A, Stern BD, Deyo RA. Variation in reported safety of lumbar inter-body fusion: influence of industrial sponsorship and other study characteristics. *Spine* 2007;32:471-80.

Synopsis: This was a systematic review that investigated the variability in undesirable outcomes among studies of lumbar inter-body fusion using stand-alone cage devices and examined whether author conflicts of interest contribute to variability. The reviewers searched electronic databases and bibliographies published by February 2005.

A potential financial conflict of interest was identified in 60% of the studies. Studies reporting fusion status had a non-union median rate of 8.3% (min. 0% - max. 83.3%). Potential author conflict of interest was associated with lower rates of non-union. Non-union rates exceeded 48% in 4 studies without conflicts of interest, while the highest rate of non-union among studies with potential conflicts of interest was 17.6%. The researchers could not explain variation with other complications and

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stated that the complication rate was likely to have been under-reported.

Surgical Complications	
Complication	Median Rate % (min. – max.)
Non-union	8.3 (0–83.3)
Re-operation	6.9 (0–53.8)
Major vessel injury	4.9 (0–11.8)
Retrograde ejaculation	5.5 (1.3–37.5)
Neurological complication	9.1 (0–44.4)
Dural injury	6.7 (1.7–14.9)
Infection	2.5 (0–7.1)

Research Quality: Overall, this was a high-quality systematic review.

Quality Details: This study used the following: 1) appropriate design; 2) a clearly focused question; 3) clearly stated and appropriate inclusion and exclusion criteria; 4) a clearly described, thorough search of the literature; 5) multiple independent reviewers selecting and appraising the studies; 6) a thorough assessment of the studies; 7) a description of the data extraction process; 8) sensitivity analysis; and 9) a conclusion that flowed logically from the evidence.

Conclusion: Authors with potential conflicts of interest reported higher rates of successful union. Complications were serious and not infrequent.

Comment: FDA approval for stand-alone cage devices was based on industry-sponsored studies. A recent survey, however, suggests that some U.S. surgeons are dissatisfied with the long-term performance of stand-alone cage devices for spinal fusion, and those reporting dissatisfaction are those physicians reporting the longest experience with the technology.¹

This review demonstrates an unexplained variation in reported complication rates of undesirable outcomes from authors with potential conflict of interest. Often, industry-sponsored studies with little rigor look promising. Independent in-

vestigations with better methodology demonstrate different results. For example, a recent paper with potential conflicts of interest (the author was paid by the manufacturer of the CHARITÉ Artificial Disc) concluded safety and efficacy of the CHARITÉ Artificial Disc.² A critical review of the study's methodology, however, showed serious flaws (e.g., uncontrolled, no blinding, inadequate outcome measures) and exaggerated findings.

Warning: Practitioners should not automatically use information from research studies to make decisions about patient care because health care literature suffers from inconsistent quality and frequently distorts research findings. Before relying on the findings of a research study, a practitioner should perform a critical appraisal to determine whether the conclusion is supported by the study's data. Moreover, the results of a study can provide only the likelihood of effects. Even conclusions from multiple studies do not provide a definitive answer. Instead, they indicate the direction of the evidence. ■

These reviews are excerpts from Direction of the Evidence, published by the Institute of Evidence-Based Chiropractic, whose aim is the integration of science into chiropractic practice to improve patient outcomes. Dr. Feise can be reached at rjf@chiroevidence.com.

References

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2. David T. Long-term Results of One-Level Lumbar Arthroplasty Minimum 10-Year Follow-up of the CHARITÉ Artificial Disc in 106 Patients. *Spine* 2007;32:661–666.