Wood KB, Fritzell P, et al. Effectiveness of Spinal Fusion Versus Structured Rehabilitation in Chronic Low Back Pain Patients With and Without Spondylolisthesis. A Systematic Review. Spine 2011;36 (21S):S110-S119.

Design: Systematic Review of Randomized Clinical Trials

PICOS:

- Patients: Adults with chronic low back pain with and without spondylolisthesis
    - Studies of patients with predominantly neurological involvement, spinal stenosis, lumbar tumors, osteomyelitis, infection, trauma, and osteoporosis were excluded
- Interventions: Spine fusion with or without instrumentation or decompression
    - Studies comparing surgery other than fusion were excluded; head-to-head comparisons of different kinds of surgery were excluded
- Comparison: Supervised rehabilitation without surgery, provided that the rehabilitation is multidimensional
- Outcomes: Pain (VAS back/leg), function/disability, satisfaction with treatment, quality of life measures
- Study types: Randomized clinical trials

Study selection and evaluation:

- Databases searched included MEDLINE and the Cochrane Collaboration through January 2011, with two independent reviewers extracting data and deciding on inclusion of candidate studies
- Same two authors independently rated risk of bias for each article using methods commonly used by Cochrane and other evidence reviewers: randomization, allocation concealment, blinding of outcome assessors, etc.; complete follow-up of at least 85% was included as a consideration (methods specified in Norvell et al 2011)
- Overall strength of evidence was determined primarily on risk of bias, but additional considerations were used: consistency of results between different studies, directness of evidence (greater when the measured outcome is directly related to variables important to patients), and precision of effect estimates (narrow versus wide confidence intervals for the treatment effect)

Results:

- 16 full text articles were evaluated for inclusion, but only 4 met inclusion criteria; the other 12 were excluded for inclusion of patients with spinal stenosis, for comparison of fusion with other operations, or for not having multidisciplinary rehabilitation as a control intervention
- The primary question was whether the presence of isthmic spondylolisthesis modifies the effect of fusion compared with supervised multidisciplinary rehabilitation in patients with chronic LBP

- 3 RCTs compared fusion and rehabilitation in patients with chronic LBP but without spondylolisthesis; 1 study made the comparison in patients with spondylolisthesis (this study also had a later follow-up report)
- Data were not pooled because the studies differed in patient populations (e.g., inclusion of patients with previous spine surgery, type of fusion, rehabilitation programs, length of follow-up)
- Two of the studies in patients without isthmic spondylolisthesis measured pain scores for both leg and back pain, reporting only moderate differences in favor of fusion at 2 years for both outcomes (the largest effect, leg pain at 2 years, was 0.63 standard deviations, where 0.4 to 0.6 SD is generally considered moderate and an effect size greater than 0.8 SD is considered large)
- For the study of patients with isthmic spondylolisthesis, on the other hand, the effect on leg pain at 2 years was large (2.3 SD) in favor of fusion
- All 3 studies of patients without isthmic spondylolisthesis reported function with the Oswestry Index; the study of patients with isthmic spondylolisthesis used the Disability Rating Index
    - For patients without isthmic spondylolisthesis, the treatment effect for function favored fusion at two years, but the effect sizes were small (less than 0.4 SD) and statistically not significant in 2 studies, and only moderate (0.5 SD) in a third
    - In contrast, the treatment effect for function in favor of fusion in patients with isthmic spondylolisthesis was large (3 SD)
- Two studies asked patients about their willingness to go through their same treatment again, most patients with and without isthmic spondylolisthesis indicated that they would undergo fusion again, and large differences between studies were not observed

Authors' conclusions:

- Fusion may offer slightly greater pain and functional benefits over multidisciplinary rehabilitation, but the presence of isthmic spondylolisthesis appears to be an effect modifier; the treatment effects of fusion are larger when it is present than when it is absent
- Fusion should be considered for patients with isthmic spondylolisthesis when nonoperative treatment has not been effective
- The overall strength of evidence for this conclusion is low; further research is very likely to have an important impact on the estimate of the treatment effect

Comments:

- In the study involving isthmic spondylolisthesis, 111 patients were randomized; of these, 60% had a grade 1 slip, 38% had a grade 2 slip, and 2% had a grade 3 slip
- The "low" strength of evidence was derived from the consideration of several factors; having high quality articles and a large effect size upgraded the strength of evidence, but the strength was downgraded for lack of consistency (having only one article on isthmic spondylolisthesis precludes that criterion from being met), for indirect evidence (lack of a direct head-to-head

comparison between patients with and without isthmic spondylolisthesis), and for not being based on an a priori hypothesis

- Figure 4 could easily be misinterpreted; for "willingness to go through treatment again," the value of 0.22 for Fritzell is based on the 22% difference between the fusion patients' value (75%) and the rehabilitation group (53%); similarly, the Moller & Hedlund value of 0.11 is based on the 11% difference between the fusion patients' 78% and the rehabilitation patients' 67%

Assessment: Adequate for some evidence that fusion is likely to be more beneficial than multidisciplinary rehabilitation for patients with isthmic spondylolisthesis than for patients with nonspecific chronic low back pain

References:

Ekman P, Moller H, Hedlund R. The long-term effect of posterolateral fusion in adult isthmic spondylolisthesis: a randomized controlled study. Spine J 2005;5:36-44.

Fairbank J, Frost H, Wilson-MacDonald J, et al. Randomised controlled trial to compare surgical stabilisation with an intensive rehabilitation programme for patients with chronic low back pain: the MRC spine stabilisation trial. BMJ, doi:10.1136/bmj.38441.620417.8F

Fritzell P, Hagg O, Wessberg P, et al. 2001 Volvo Award Winner in Clinical Studies: Lumbar Fusion *Versus* Nonsurgical Treatment for Chronic Low Back Pain [LBP]. Spine 2001;26:2521-2534.

Moller H, Hedlund R. Surgery Versus Conservative Management in Adult Isthmic Spondylolisthesis. Spine 2000;25(13): 1711-1715.