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.

Design: Randomized clinical trial

Population/sample size/setting:

- 294 patients with chronic LBP (145 men, 149 women, mean age 43) referred by primary care physicians to 19 orthopedic clinics in Sweden
- Included if age 25-65 with non-radicular pain duration at least 2 years, on sick leave or equivalent major disability for at least 1 year, unsuccessful nonsurgical treatment, radiographic signs of degenerative changes at L4-L5 or L5-S1 with treating surgeon assessing pain as arising from same area
- Excluded for obvious psychiatric illness, previous spine surgery (except successful disc removal at least 2 years prior), specific radiologic findings of spondylolisthesis, fractures, inflammatory process, neoplasm
- Randomized to spinal fusion (n=222) or nonsurgical treatment (n=72); fusion further randomized into posterolateral fusion with or without internal fixation, with or without additional interbody fusion; all surgery groups combined for comparison with nonsurgical treatment
- Nonsurgical treatment was physical therapy with wide variety of components

Main outcome measures:

- Back pain on VAS of 0-100 measured at baseline, 6 months, 12 months, and 2 years; both groups improved, but surgery group had more relief after 2 years than nonsurgical group (32.7% vs. 6.8%)
- Back pain in surgical group increased between 12 months and 2 years
- Leg pain improved in surgical group by 18% but worsened in nonsurgical group by 20% at 2 years
- Three measures of disability showed large improvements (25-30%) in surgical group at 2 years, but small (4-7%) in nonsurgical group
- Depression scores (Zung) improved in both groups without significant difference
- Patient self-assessment at 2 years was “much better” in 29% of surgical group and 15% in nonsurgical group; either “better” or “much better” in 63% of surgical and 29% of nonsurgical group; “unchanged” or “worse” in 37% of surgical and 71% of nonsurgical group
- 21% of all patients were on full or supplemental disability pension at baseline and were excluded from analysis of work status (only 3 resumed part-time work after 2 years); but more pts in surgical group (39%) than in nonsurgical group (23%) returned to work after not working at entry into study
- Radiographic fusion seen in 83% of surgical group, but no correlation between fusion and patient’s overall rating of improvement
- 17% of surgical group had complications, most without lasting sequelae, but 9 pts had nerve root pain after pedicle screw placement

- Outcome analyses done by intention-to-treat, but some crossovers did occur; 7 pts changed from nonsurgical to surgical group (3 threatened suicide if not operated on); these 7 did better than most pts originally randomized to surgery

Authors' conclusions:

- Lumbar fusion can be used to reduce pain and decrease disability in carefully selected and well-informed pts with chronic LBP
- Longer observation times are needed for measuring outcomes; this group will be followed for 5 years
- Depressive symptoms did not seem to be contraindication to lumbar fusion

Comments:

- Generally high quality study with nearly complete follow-up
- Nonsurgical group may have had wide variation in treatments received; cognitive intervention, for example, were optional but not stated whether they were commonly offered or done
- Attendance of pts in PT sessions not ascertained (adherence to PT not clear)
- "Comorbidity" greater in surgical group (39% vs. 24%) but the nature of comorbidity not specified
- Very high percentage of both groups smoke (40% of surgical group); it would have been useful to have reported the outcomes separately for them
- Radiographic fusion did not correlate with patient self-assessment of outcome; correlation with VAS, Oswestry, etc, not reported but would have been valuable correlations to assess
- This 2 year follow-up was published in 2001; a 5 year follow-up would be expected in 2004, but this author has not yet published that study