Brox JI, Nygaard OP, et al. Four-year follow-up surgical versus non-surgical therapy for chronic low back pain. Ann Rheum Dis 2010;69:1643-1648.

Design: Randomized clinical trial

Population/sample size/setting:

- 124 patients (68 women, 56 men, mean age 42) treated for chronic low back pain
- Eligible if age 25-60, at least 1 year of back pain, at least 30 points on Oswestry, degeneration at L4-L5 or L5-S1 on plain x-ray
- Excluded for widespread myofascial pain, spinal stenosis, radiculopathy, generalized degeneration on plain x-ray, previous back surgery, or somatic/psychiatric disorder preventing acceptance of either treatment arm

Main outcome measures:

- Randomized to posterolateral fusion with transpedicular screws and autologous bone (n=66) or cognitive intervention and exercises (n=58)
- Cognitive intervention consisted of a lecture describing pain receptors in discs, facets, muscles, including instruction that ordinary activity cannot harm discs, that pts can use their backs and do not need to be extra cautious
- This advice was repeated each day during exercises, which included co-contraction of abdominal muscles and lumbar multifidus, aerobics, water gymnastics, and individual exercises
- Supervised instruction was 1 week, followed by 2 weeks at home, followed by 2 more weeks of supervised instruction (approximately 25 hours per week)
- In addition to instruction by physiatrists and physical therapists, cognitive group met with a peer for exchanging experiences
- 11 of the 66 patients randomized to fusion withdrew or crossed over to cognitive intervention; 17 of the 58 patients randomized to cognitive intervention withdrew or crossed over to fusion
- In the 4 year follow-up, 61 patients in the fusion group and 50 in the cognitive group contributed outcome data
- The Oswestry disability score was the principle study outcome; there was no significant difference in improvement from baseline (fusion group, from 44.1 to 29.7; cognitive group, from 43.4 to 27.0)
- Secondary outcomes such as general function, back pain, lower limb pain, emotional distress, life satisfaction, overall success, and work outcomes, did not differ between the treatment groups
- The only significant difference in secondary outcomes was in favor of the cognitive group, which had lower scores on fear-avoidance beliefs in physical activity and work

Authors' conclusions:

- In patients with chronic low back pain and no previous surgery for disc herniation, lumbar fusion was not superior to cognitive intervention and exercises aimed at relieving symptoms at 4 years

- Fusion may be indicated in selected patients with low back pain, but widening indications have contributed to the rise in rates of fusion surgery
- There was no placebo (sham surgery) group, and the observed improvements may reflect the natural course, placebo, or expectations and care
- The intention-to-treat results and the as-treated analyses were similar, and the crossover/withdrawal rates probably did not play a decisive role in explaining the results

Comments:

- This is a longer follow-up of the 2003 study by Brox et al, with more patients
- The randomization and follow-up methods have adequate control of bias
- The absence of a sham surgery group may not be a limitation of the study; if there had been a significant group difference in favor of surgery, such a comparison would have been more pertinent

Assessment; Adequate for evidence that cognitive interventions and exercise may be as effective as instrumented fusion in treatment of previously unoperated low back pain