Ohtori S, Suzuki M, et al. Single-level instrumented posterolateral fusion of the lumbar spine with a local bone graft versus an iliac crest bone graft: a prospective, randomized study with a 2-year follow-up. Eur Spine J 2011;20:635-639.

Design: Randomized clinical trial

Population/sample size/setting:

- 82 patients (40 men, 42 women, mean age 66.5) undergoing posterolateral fusion for lumbar degenerative spondylolisthesis at the University of Chiba in Japan
- Eligibility criteria were spondylolisthesis at L4 with spinal stenosis at L4-L5
- X-ray, myelography followed by CT, and MRI were done in all patients for diagnosis
    - Criteria for surgery were >5% slip of L4 in the neutral position and >3 mm translation on flexion-extension films
- Exclusion criteria were previous spinal surgery, tumor, infection, and trauma

Main outcome measures:

- All patients had L4-L5 laminectomy and instrumented fusion with pedicle screws and bone graft
- Randomization was done with minimization method to two kinds of bone graft: local graft (n=42) or iliac crest bone graft (ICBG, n=40)
    - Local bone was harvested from spinous processes of L4 and L5 and the lamina between L4 and L5; no other bone was used
    - ICBG was harvested from the left iliac crest with a separate skin incision with a length of 40 mm and a depth of 30 mm; both ICBG and local bone were used in the fusion procedure
    - Total bone volume of local bone group was 14.0 g; total bone volume for ICBG group was 22.0 g
- Outcomes were both clinical and radiographic
    - Clinical outcomes were pain scores on a 10 point VAS, a Japanese orthopedic association score (JOAS) on a scale from 0 to 3, and the Oswestry disability index, measured before surgery and 24 months after surgery
    - Radiological outcomes were done with flexion-extension films and with CT
        - Fusion was defined as <1.5 degrees of instability on flexion-extension and as bridging bone formation across transverse processes on CT
    - Three observers evaluated the images for fusion; the agreement of at least two was the definition of bone fusion
    - Flexion-extension films were done 3, 6, 9, 12, 18, and 24 months after surgery; CT was done at 6,12, 18, and 24 months after surgery
- Blood loss in surgery was similar in the groups (about 328 ml), and the operative time was slightly shorter for local graft (180 min) than ICBG (195 min)
- Most patients had fusion at final follow-up
    - For local bone graft, fusion by flexion-extension was 83% and CT was 90%
    - For ICBG, flexion-extension fusion was and CT were both 85%
    - Pedicle screw loosening was observed in all patients but none had breakage of screws or rods
    - Time to fusion was similar between groups

- Pain, JOAS, and Oswestry improved in both groups about equally between randomization and 24 months
    - Back pain VAS from average of 4.45 at baseline to 2.0 at 24 months
    - Leg pain VAS from average 7.85 at baseline to 1.75 at 24 months
    - Oswestry disability from average 40.0 at baseline to 23.5 at 24 months
- Only one important complication of local bone graft was reported, a deep infection at the surgical site; the ICBG group, however, had sensory loss around the iliac crest in 8 patients and pain around the iliac crest in 6 patients

Authors' conclusions:

- Rates of bone union and clinical outcomes were similar for local bone graft and for ICBG
- Pain and disability improvements were similar for local bone and for ICBG
- Local bone graft had significantly shorter operative time
- ICBG had persistent symptoms at the graft site at 24 months: 20% had persistent sensory loss and 15% had persistent pain
- Local bone graft for single level instrumented posterolateral fusion surgery can be recommended over ICBG for the same operation

Comments:

- One or two points are not clearly described
    - The diagnosis of spondylolisthesis required x-ray, myelography, and MRI, but the role of myelography and MRI were not described
    - The randomization was done with minimization (which allocates patients sequentially so as to preserve prognostic balance between groups as the enrollment proceeds); this is an acceptable method of patient allocation, but the balancing prognostic factors are not clearly described
- In the discussion, blood loss was significantly less and hospital stay significantly shorter in the local bone group than for ICBG, but the data in the results section do not support these conclusions
- The authors note that they did not evaluate bone density to assess graft quality
- CT was done frequently; since this entails radiation exposure, the need to include it is not clear, since flexion-extension films were also being used to evaluate fusion

Assessment: Adequate for some evidence that when instrumented single-level fusion is done for lumbar spondylolisthesis, local bone graft requires less operative time, yields equal rates of fusion and clinical improvement, and avoids persistent local symptoms at the iliac crest graft donor site