Schimmel JJ, de Kleuver M, et al. No effect of traction in patients with low back pain: a single centre, single blind, randomized controlled trial of Intervertebral Differential Dynamics Therapy. Eur Spine J 2009;18:1843-1850.

Design: randomized clinical trial

Population/sample size/setting:

- 60 patients (33 men, 27 women, mean age 44) treated for chronic low back pain at an orthopedics department in the Netherlands
- Eligibility criteria were at least 3 months of axial pain from lumbar degenerative disc disease with a bulging disc and residence within 25 km from the treating hospital
- Exclusion criteria were radicular pain, previous surgical treatment with dynamic stabilization, fusion, or disc replacement, malignancy, pregnancy, and osteoporosis

Main outcome measures:

- All patients received 20 sessions during six weeks with the Intervertebral Differential Dynamics (IDD) traction device, and a standard graded activity program
- Randomized to true IDD (n=31) or sham IDD (n=29)
- True IDD received traction with traction weight applied as 50% of body weight minus 10 lb initially, later increased in 5 lb increments until a traction weight of 50% body weight plus 10 lb was attained
- Sham IDD received traction with less than 10% of body weight in order to assure a sensation of traction similar to that in the IDD group
- The physiotherapist applying the traction was aware of the treatment assignment; the patient and the clinician evaluating the effect of treatment were blinded to treatment group
- The graded activity program was started after 2 weeks of IDD/sham IDD, and continued for 12 weeks (ending 14 weeks after the start of traction and ending 8 weeks after the end of traction)
- Primary outcome was back pain on a 100 mm VAS scale
- Secondary outcomes were VAS for leg pain, Oswestry Disability Index (ODI), and SF-36
- All outcomes were measured at 2, 6, and 14 weeks after the start of treatment
- All patients completed the 6 weeks of traction, but 3 patients in the sham group and 1 patient in the IDD group failed to complete the graded activity program
- 14 weeks after the start of treatment, both groups had experienced significant decreases in LPB VAS (from 61 to 32 in the IDD group and from 53 to 36 in the sham group); there was no difference between the groups in the treatment effect (p=.695), and only time was a significant factor in the improvements
- Secondary outcomes (leg VAS, ODI, and SF-36) also improved over the course of the study, with no group differences for treatment effect

- Sensitivity analyses using best-case and worst-case assumptions for dropouts from the graded activity program did not change the conclusions concerning the lack of group differences in treatment effect

Authors' conclusions:

- The addition of IDD to a graded activity program does not result in greater symptomatic and functional improvement over graded activity alone with sham IDD in patients with non-radicular chronic LBP
- The improvements in both groups could have arisen from the graded activity program and from the attention that each patient received during the course of treatment

Comments:

- Sources of bias appear to be well-controlled
- Retention rates were high and a sensitivity analysis was done on the dropouts, which improves the credibility of the study results
- In addition, a power analysis was carried out both before and after the completion of the trial, which helps to assure that the numbers of patients actually enrolled in the trial were sufficient to make the group comparisons meaningful
- Although the IDD group had slightly higher VAS at baseline and slightly lower VAS at the end of treatment, the analysis (controlling for baseline pain scores as a covariate) is appropriate for the study question

Assessment: Adequate for evidence that intervertebral lumbar traction does not add significantly to a graded activity program for resolution of non-radicular chronic LBP