Boonen S, van Meirhaeghe JV, et al. Balloon Kyphoplasty for the Treatment of Acute Vertebral Compression Fractures: 2-Year Results From a Randomized Trial. J Bone Mineral Research 2011;26(7):1627-1637.

Design: Randomized clinical trial

Population/sample size/setting: As in Wardlaw 2009

Main outcome measures:

- Wardlaw et al provided data for the first year of follow-up after randomization to kyphoplasty or to control (nonoperative) treatment
- The same population was followed for an additional 12 months, tracking the same outcomes
- At 24 months, data were available for 120 of the original 149 kyphoplasty patients and for 112 of the original 151 control patients
- The main outcome in the 12-month study was group difference in the physical component summary of the SF-36 (PCS) at 1 month, with additional follow-up through 1 year
    - The kyphoplasty group had greater improvement in the PCS in the first month of the study, with the treatment effect diminishing over the course of 12 months
    - At the 24-month follow-up evaluation, the PCS treatment effect was not significantly different between groups
- In contrast to the PCS scores, two secondary outcomes continued to show greater improvement for the kyphoplasty group even at 24 months
    - These were the European Quality of Life score and the back pain score
- The Roland-Morris Disability score, like the PCS score, had been significantly better in the kyphoplasty group than the control group in the 12-month study, but at 24 months, the scores were no longer significantly different
- In the 12-month study, the kyphoplasty group had less use of opioid analgesics than the control group; at 24 months, both groups had decreased their use of opioids, with 8.8% of the kyphoplasty group and 9.5% of the control group still using opioids
- New radiographic fractures were similar in frequency between groups at 24 months; such fractures had been reported in 56 of the 118 kyphoplasty patients and in 45 of 102 control patients
    - Most were classified as nonpainful; however, 26 kyphoplasty patients had painful fractures and 17 control patients had painful fractures ($p=0.12$)
    - In the kyphoplasty group, 11 of the new fractures were considered as possibly or probably related to the kyphoplasty; this consideration did not apply to the fractures in the control group
- Two serious adverse events related to kyphoplasty occurred after 12 months
    - One case was a re-collapse of a treated vertebra with anterior migration of the cement

    - The second case was spondylitis which occurred in a patient who had had a urinary tract infection in the first 12 months, showing that late infection can occur in any implant surgery

Authors' conclusions:

- Balloon kyphoplasty rapidly reduces pain and improves function compared to nonoperative management of painful vertebral fractures
- Most outcome differences are no longer significant at 24 months, but reduction in back pain remains significant at all time points

Comments:

- The outcomes cited as remaining significant after 12 months (back pain and quality of life) were classed as secondary outcomes in the original study protocol; the primary outcome (SF-36 PCS) did not remain significantly different after 12 months
- There were 11 new fractures in the kyphoplasty group which were considered related or possibly related to the procedure; however, the criteria for classifying the fractures as such were not specified
- The lack of blinding is a potential source of bias, but there is a price to pay in controlling blinding with a sham procedure
    - With a sham procedure, the generalizability of the results is less clear than when the control group receives an intervention likely to be chosen in real-world clinical practice

Assessment: Adequate for evidence that kyphoplasty provides more rapid improvement of function for painful vertebral fractures than nonoperative treatment, but inadequate for concluding that the advantages are maintained over the course of two years (the outcomes showing this were secondary and not primary outcomes)