Response

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We greatly appreciate the careful, valuable scrutiny by Drs. O'Toole and Traynelis of vertebral augmentation in their analysis of practice-based evidence in the treatment of VCFs. Although the role of PV and KP for pain relief in acute and subacute VCFs has been covered well by many spine surgeons and interventionists, more well designed RCTs are needed to document this treatment effect of PV. Performing an RCT of a surgical procedure is complex and problematic due to difficulties with medical ethics and local legal concerns; recruiting an identical control–sham procedure group; patient enrollment and verification; and appropriate concealment and blinding methods for patients, providers, and assessors. Despite these difficulties in planning and performing a surgical RCT according to Consolidated Standards for Reporting of Trials guidelines, we completed an RCT that compared PV with OMT in patients with osteoporotic VCFs. Our study compared short- and long-term effects of PV on the following outcomes: 1) primary outcomes including pain and QOL; and 2) secondary outcomes including the incidence of new adjacent fracture, restoration of vertebral height, and correction of the deformity. We found a statistically significant improvement in pain in the PV group compared to the OMT group at all time points for 1 year up to 3 years. The patients’ QOL improved significantly in the PV group. We showed that PV can restore vertebral height and correct spinal deformity to some extent, and we also determined that the incidence of new VCFs was significantly higher in the OMT than in the PV group.