

Allograft Kyphoplasty: A New Technique with Promising Outcomes

Moshe Schneiderman¹, Jeri Wanzor Nieves, Edward S Yoon, Joseph M Lane²

¹Metabolic Bone Disease, Hospital For Special Surgery; SUNY Downstate School of Medicine, ²Hosp for Special Surgery

INTRODUCTION:

The use of cement in kyphoplasty has associated risks that may lead to postoperative complications. For example, if the cement leaks into the spinal canal or neuroforamen, compression of the neural structures can cause neurogenic pain and weakness, potentially requiring spinal decompression. Cement can also embolize to the lungs. Most of the pulmonary emboli are asymptomatic, but there have been cases resulting in respiratory failure and even death.

Early in 2022, we switched to performing kyphoplasty using allograft bone, instead of cement. The large size of the beads precludes them from entering the venous system, thus preventing them from embolizing to distance vasculature. We expect allograft to be a safer alternative to cement. However, we do not know if allograft and cement kyphoplasty differ in terms of postoperative pain and functioning, radiologic height restoration, kyphotic angle reduction, or extravasation rate. The purpose of the present retrospective study is to address these questions by comparing outcomes of our patients treated with allograft over the last year to outcomes of our patients from the preceding four years who were treated with cement. We examined both clinical and radiologic outcomes.

METHODS:

The study protocol was submitted to the institutional IRB and approved. We performed a longitudinal, retrospective cohort study of patients who underwent kyphoplasty between January 2018 and April 2023 for osteoporotic vertebral fractures. All patients were treated by the same surgeon at the same institution in a large urban area. Patients with at least one MRI/CT or PROMIS-29 completed within the 1-year postoperative period were included. If multiple scans or questionnaires were available for a given patient in the 1-year period, then all these data were included in the analysis. Thus, many patients had repeated measures during the 1-year postoperative period.

Radiologic Outcomes: Vertebral height (anterior, central, and posterior) and kyphotic angle were measured on pre- and postoperative MRI and CT scans. To evaluate extravasation, all available postoperative imaging was evaluated.

Patient-Reported Outcomes: To evaluate patient pain, and perceived physical and mental health, we utilized postoperative responses to the PROMIS-29, as recorded in patient charts. The questionnaire includes NRS assessment of pain intensity, and this recorded response was used as the measure of pain for the study.

The PROMIS-29 questionnaire also provides separate scores on the following domains of health: Physical Function, Anxiety, Depression, Fatigue, Sleep Disturbance, Participation in Social Roles and Activities, and Pain Interference. To comprehensively compare allograft to cement, we compared scores between treatment groups on all these subsections. The subsection scores were our outcome measure of patient health in each domain.

Statistical Analysis: Each outcome was analyzed individually. Longitudinal outcomes were analyzed with a Generalized Estimating Equations model. The unit of analysis for clinical outcomes was the patient, and for radiological outcomes, the vertebra. Covariates included: Age, biological sex, BMI, weekly alcoholic drinks, smoking status, and days of postoperative osteoporosis treatment.

Extravasation rates for the two procedures were compared using Fisher's Exact Test. First we compared overall extravasation rates, then performed an analysis of extravasation rate by leakage site for the two procedures.

RESULTS:

For radiologic outcomes, we had data on 53 patients/85 vertebrae/130 observations. For clinical outcomes, we had data on 49 patients/106 observations.

We found significant benefits of allograft versus cement on central vertebral height (Estimate = 1.71mm, $p = .04$), NRS pain (Estimate = -1.23, $p = .03$), Physical Function (Estimate = 5.98, $p = .03$), Depression (Estimate = -4.74, $p = .02$), Participation in Social Roles/Activities (Estimate = 5.29, $p = .01$), and Pain Interference (Estimate = -4.15, $p = .049$).

Overall extravasation rates were comparable between the 2 procedures: It occurred in 12 of 30 (40.0%) allograft vertebrae and 26 of 55 (47.3%) cement vertebrae, $p = .65$. However, when extravasation rates were analyzed by leakage site, we found a significant difference in the incidence of venous extravasation: It occurred in 0 of 30 allograft vertebrae compared to 7 of 55 (13.7%) cement vertebrae ($p = .048$).

In the other outcomes studied, we did not find a significant difference between the procedures.

DISCUSSION AND CONCLUSION:

Across all examined outcomes, we found either no significant difference between the two kyphoplasty techniques or significantly better outcomes associated with allograft kyphoplasty, including significantly greater central height, less pain, and better function. The outcomes from this initial series of patients suggest that allograft kyphoplasty is a well-tolerated and promising new technique. Not only does it demonstrate a potential for improved safety, but it also yields comparable, and in some cases, even better results when compared to cement kyphoplasty.

Our study was limited by the potential for ascertainment bias. In this study, the measurement of outcomes was not performed on a predefined schedule but rather based on patients' symptoms and their likelihood of returning to the

practice for follow-up assessments. This may have resulted in a higher likelihood of measuring outcomes in patients who experienced more postoperative symptoms, such as pain. Consequently, the study sample may have been biased towards patients with more severe symptoms, potentially underestimating overall improvement in patient outcomes following kyphoplasty.

Our findings support the notion that allograft kyphoplasty may be a preferable alternative to cement kyphoplasty in terms of patient outcomes. The promising results observed in this study indicate the potential advantages of adopting allograft kyphoplasty as a viable treatment option for osteoporotic vertebral fractures. However, further research and randomized clinical trials are warranted to validate these initial findings and establish the long-term efficacy and safety of allograft kyphoplasty.