

IMPACT OF THE NUMBER OF TREATED VERTEBRAE ON THE SAFETY AND EFFICACY OUTCOMES OF VERTEBROPLASTY AND KYPHOPLASTY; SYSTEMATIC REVIEWS TO SUPPORT THE INDICATION EXPANSION OF THESE PROCEDURES FROM SINGLE-LEVEL TO MULTI-LEVEL FRACTURES IN JAPAN

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EQUITY in ACCESS, Single or Multi-level

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Introduction

The most common osteoporotic fractures are vertebral, leading to compromised lung capacity and gastrointestinal functionality when poorly managed, predisposing to increased morbidity and mortality. Vertebral augmentation that alleviates the devastating pain of these fractures, non-responding to conservative treatment of bracing and analgesic medication, had been applied only to single-level fractures that account for 64.2% of patients until January 2023 in Japan. Multi-level fractures, which constitute the remaining 35.8% of patients, could not have been treated under full reimbursement coverage in the absence of evidence on safety and efficacy, equivalent to that of single-level fractures.

Objective

To examine the impact of the number of fractures on the safety and efficacy outcomes of vertebroplasty (PVP) and balloon kyphoplasty (BKP).

Results

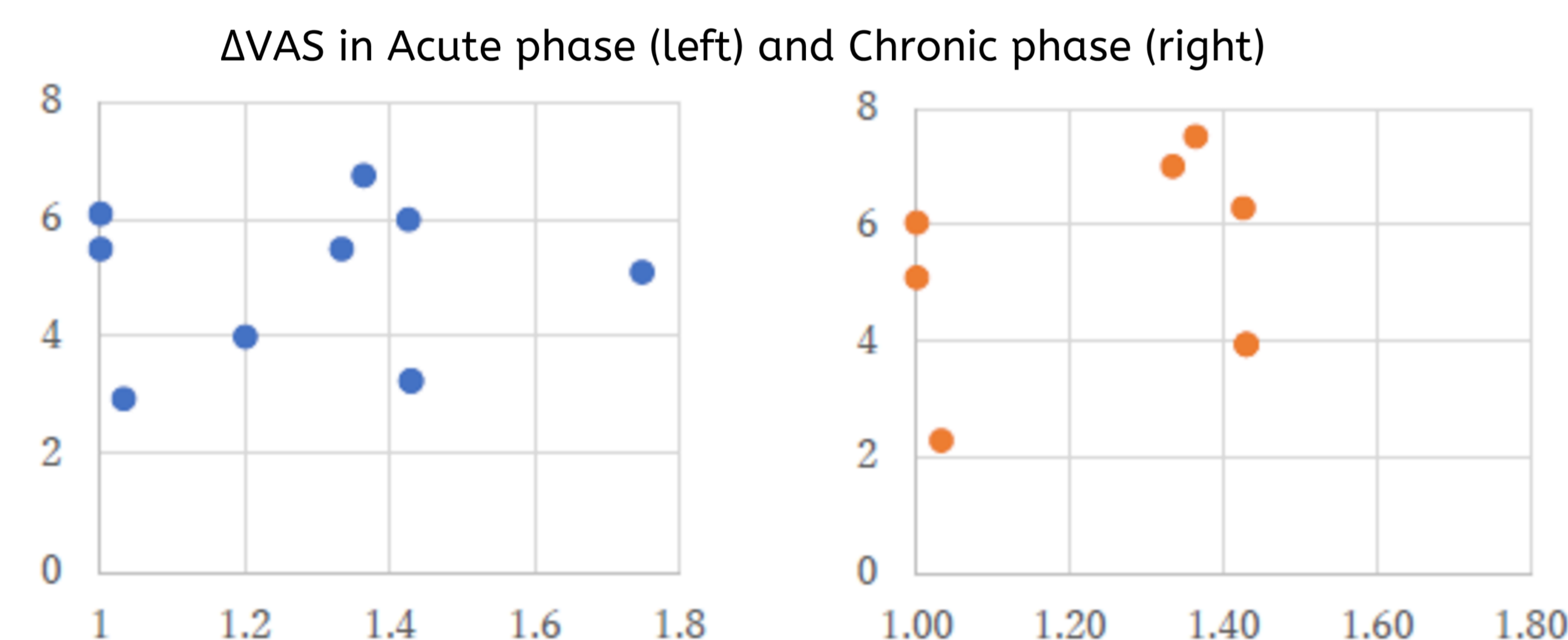


Fig. 1 No. of Fracture (Fx) and Alleviated Pain

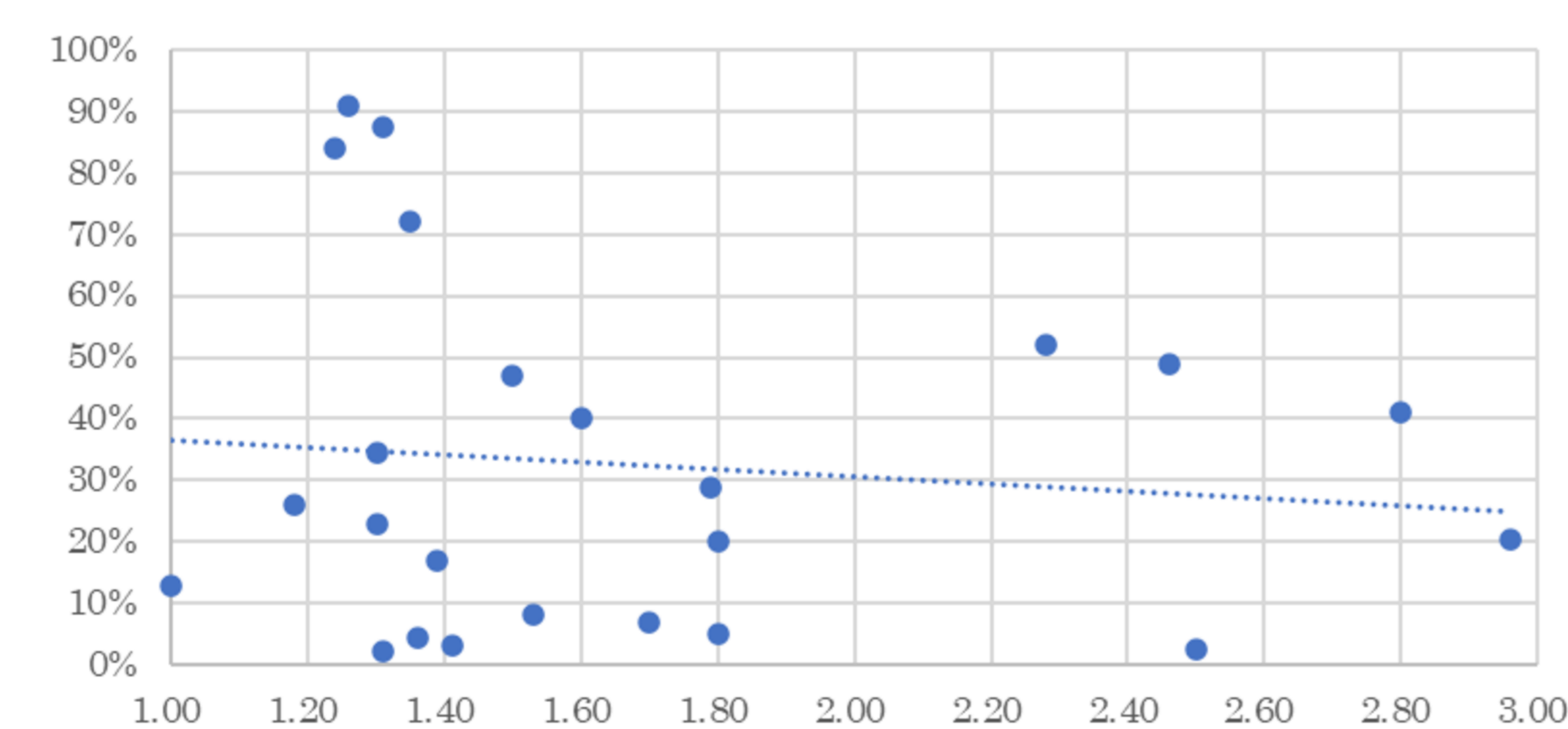


Fig. 3 No. of Fx and Cement Leakage %

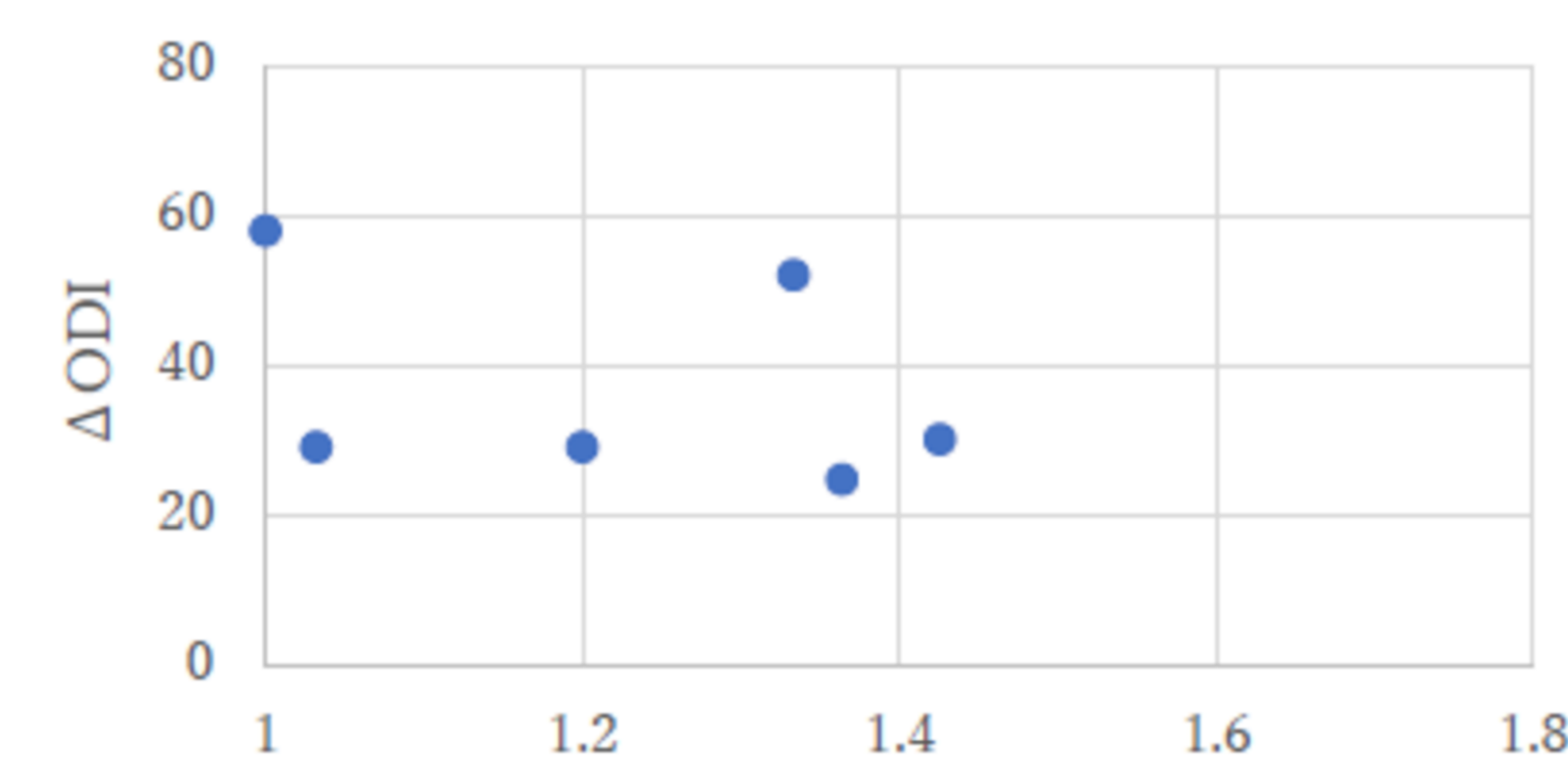


Fig. 2 No. of Fx and Activity Level

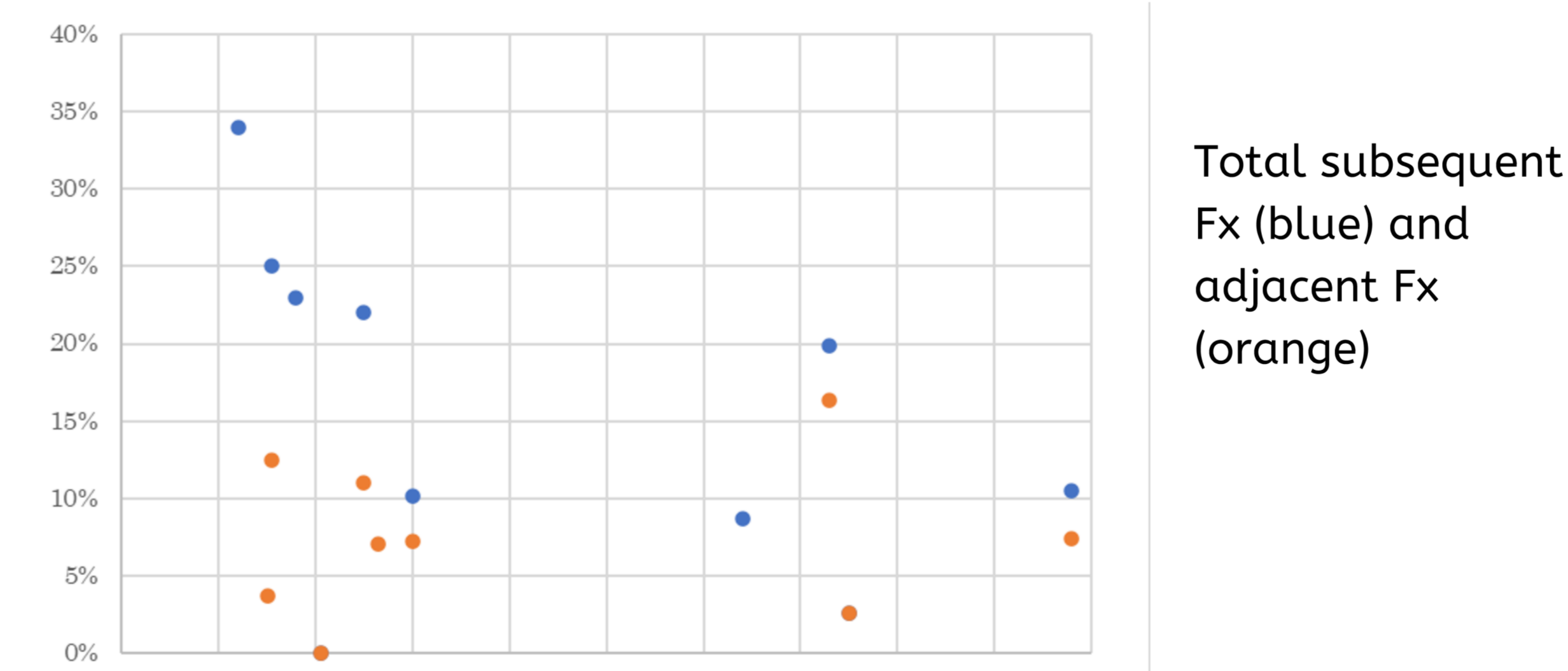


Fig. 4 No. of Fx and Subsequent Fx

Methods

- 1 The PubMed database was searched for literature on vertebroplasty with the keywords (“vertebroplasty”) and (“osteoporotic” or “osteoporosis”)
- 2 Likewise, another search was conducted for kyphoplasty using (“kyphoplasty”) and (“osteoporotic” or “osteoporosis”).
- 3 After removing redundant and/or irrelevant literature, Visual Analog Scores of Preoperative and Postoperative Pain (VAS) and changes in the Oswestry Disability Index (ODI) were compared across the selected studies as efficacy outcomes.
- 4 Safety outcomes, including cement leakage, subsequent vertebral fractures (symptomatic, all radiographic, adjacent, and all newly diagnosed), and other reported adverse events, were identified and examined for correlation with the number of treated vertebrae.

Discussion

In these literature reviews, stratification of outcomes by the actual number of treated fractures per patient was not possible, as most eligible studies reported only group-level outcomes and the average number of treated fractures. Therefore, all outcomes were examined for the coefficient on the number of treated vertebrae, yielding no relationship with the outcomes. The study results supported regulatory submission to expand the indication to multiple fractures.

Conclusion

Vertebral augmentation for multi-level fractures was considered as safe and effective as that for single-level fractures.

Reference

The list of eligible studies is available in the handout.
A few key citations below;
Sasaki (2015), Xin (2020), Kobayashi (2021),

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