

One year observation study upon a new augmentation procedure (Radiofrequency-Kyphoplasty) in the treatment of vertebral body compression fractures

Dept. of Trauma Surgery, Center of Spine Surgery, Asklepioskliniken, 76870 Kandel, Germany. *Licht AW**, *Kramer W*

Question: Vertebroplasty and **conventional balloon kyphoplasty (BKP)** are established minimally invasive procedures for the treatment of osteoporotic and traumatic vertebral compression fractures (VCFs). Since the introduction of conventional BKP, many innovative kyphoplasty devices for vertebral augmentation (VA) have been developed. In 2005, conventional BKP was introduced in our clinic. Since February 2009, an alternative kyphoplasty method, the **Radiofrequency-Kyphoplasty (RFK)**, has been employed for the treatment of VCFs. RFK uses RF energy to heat cement (significantly increasing cement viscosity immediately prior to delivery), a navigational cavity creation device and a remote-controlled cement delivery. This study analyzes advantages and disadvantages of both methods.

Method: Between 1/2005 and 12/2008 n=138 patients with n=203 VCFs were treated using conventional BKP (Medtronic) and evaluated in a prospective randomized study related to age of fracture (fresh vs. old). **Fresh VCFs were <6 weeks** (median=12d, n=81 patient/107 VCFs). **Old VCFs were ≥ 6 weeks** (median=159d, n=57 patients/ 96 VCFs). Vertebral body height restoration and improvement in VAS pain score (0-10 points) were evaluated post-op and after 12 months. Rate of cement extravasation and related complications were analyzed in all patients. Since 2/2009, 42 patients with 60 VCFs have been treated using the new vertebral augmentation procedure RFK (DFine). The procedure included site- and size-specific cavity creation, remotely controlled application of ultra-high viscosity cement and the availability of much longer time to work with the cement. Pain relief, fracture reduction and rate of cement extravasation were evaluated with the same methods as used for BKP.

Results: Average improvement in VAS pain score in the BKP treated patients was 5.4 in fresh VCFs and 3.4 in old VCFs ($p < 0.0001$) (Fig.1). Cement leakage rate was on average 18.7% (fresh VCFs 11.2% vs. old VCFs 27.7%) (Fig. 2). Average height restoration was 6.8mm in fresh VCFs and 4.6mm in old VCFs ($p < 0.001$), respectively (Fig. 3). Two major cement-leakage related complications were noted in patients of the BKP group (one cement-leakage related spinal cord compression with incomplete paraplegia and one pulmonary cement embolization). Patients treated with RFK showed an average improvement in VAS pain score of 4.9 in fresh VCFs and of 3.9 in old VCFs ($p < 0.001$). Average extravasation rate with no complications in RFK group was 10.6% (fresh VCFs 9.8% vs. old VCFs 11.6%). Average height restoration was 7.0mm in fresh VCFs and 4.4 mm in old VCFs.

Conclusion: Both VA procedures are comparable with regards to safety and effectiveness in the treatment of painful VCFs. A higher leakage rate in old VCFs in the BKP group was related to increased bone destruction and re-fracture of vertebra during balloon inflation. RFK showed similar pain relief and height restoration but lower rates of both cement extravasation and related complications. Decreased extravasation in RFK was due to increased cement viscosity induced by RF warming prior to entering the patient permitting better controlled cement delivery and extended working time prior to heating. Reduced radiation exposure to operator during cement delivery due to remote-controlled, automated delivery and reduced multi-level procedure time for RFK due to unipedicular approach using the navigational osteotome were beneficial for both the patient and physician.

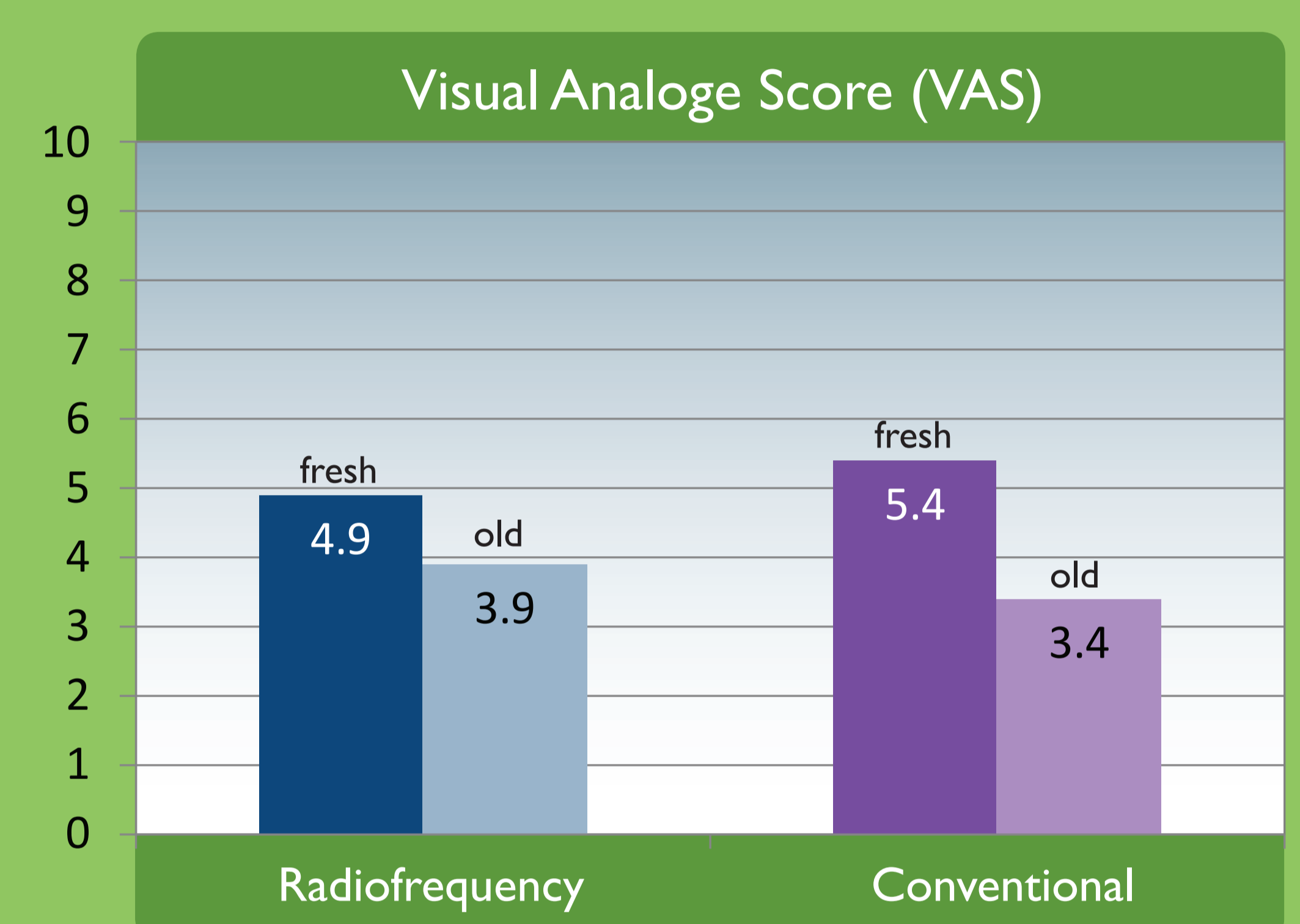


Fig. 1: Comparison of VAS using radiofrequency kyphoplasty or conventional kyphoplasty (balloon) for fresh (<6wks) and old (≥6wks) fractures.

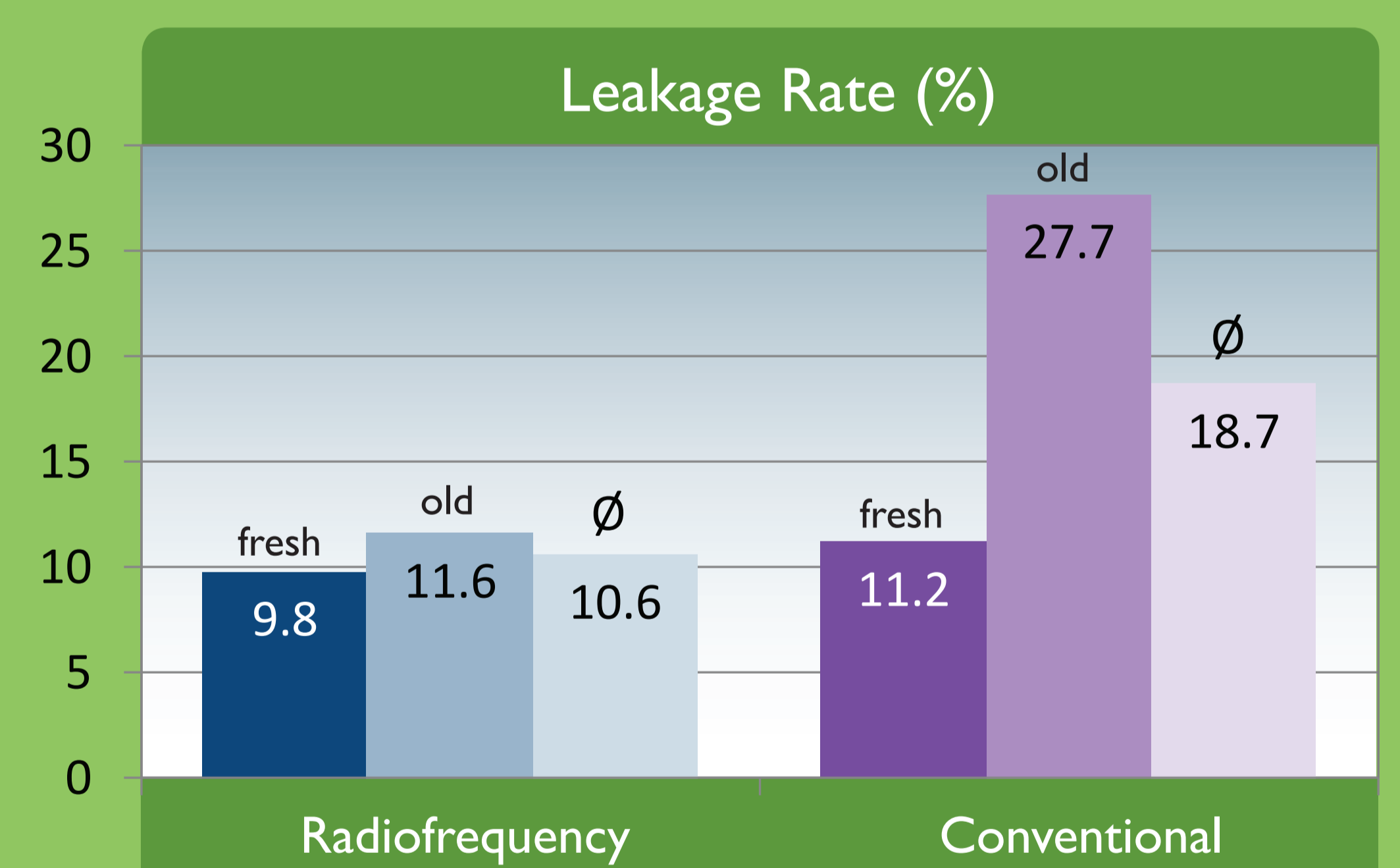


Fig. 2: Comparison of leakage rate using radiofrequency kyphoplasty or conventional kyphoplasty (balloon) for fresh (<6wks) and old (≥6wks) fractures.

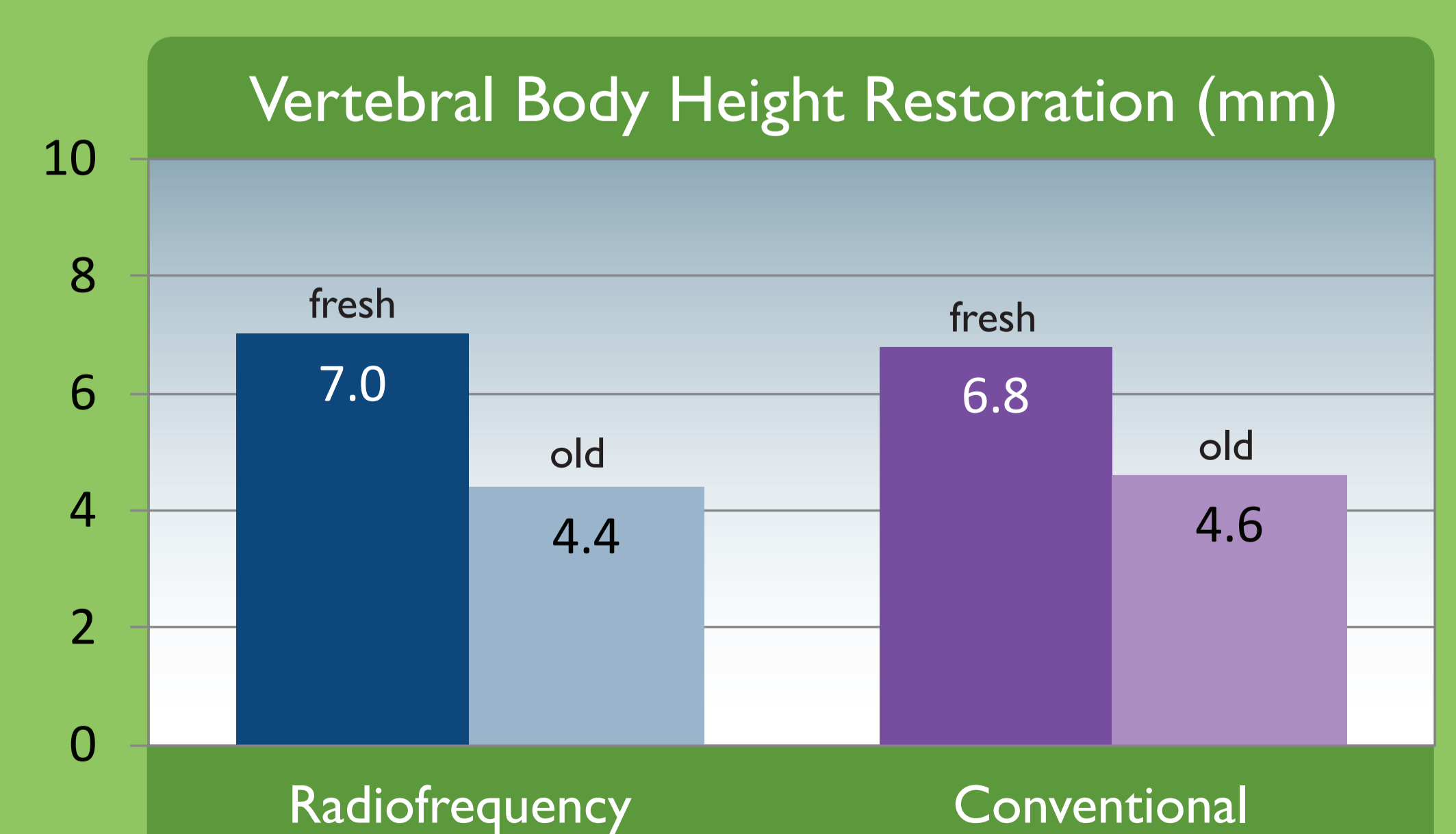


Fig. 3: Comparison of vertebral body height restoration using radiofrequency kyphoplasty or conventional kyphoplasty (balloon) for fresh (<6wks) and old (≥6wks) fractures.