One Year Observation Study upon a New Augmentation Procedure (Radiofrequency-Kyphoplasty) in the Treatment of Vertebral Body Compression Fractures

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**Question:** Vertebroplasty and conventional balloon kyphoplasty (BKP) are established minimally invasive procedures for treatment of osteoporosis and traumatic vertebral compression fractures (VCFs). Since the introduction of conventional BKP, many kyphoplasty device innovations for vertebral augmentation (VA) have been developed. In 2005 conventional BKP was introduced in our clinic. Since February 2009 an alternative kyphoplasty method, Radiofrequency-Kyphoplasty (RFK), has been employed for treatment of VCFs. RFK uses RF energy to heat cement (significantly increasing cement viscosity immediately prior to delivery), uses a navigational cavity creation device and 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. chronic). Fresh VCFs were < 6 weeks (median=12d n=81 patient/107 VCFs. Chronic VCFs were ≥ 6 weeks, (median=159d, n=57 patients/96 VCFs). Vertebral body height restoration and improvement in VAS pain score (0-10 points) was 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 VCF were treated using new vertebral augmentation procedure RFK (DFine) that included site and size specific cavity creation and remotely controlled ultra-high viscosity, extended working time cement and evaluated using the same methods.

**Results:** Average improvement in VAS pain score in the BKP treated patients was 5.4 in fresh VCFs and 3.4 in chronic VCFs (p< 0.0001). Cement leakage rate was on average 18.7% (fresh VCFs 11.2%, chronic VCFs 27.7%) and height restoration was average 6.8mm in fresh VCFs and average 4.6mm in old VCFs (p< 0.001). Two major cement leakage related complications were noted in these 138 BKP patients (one cement extravasation related spinal cord compression with incomplete paraplegia and one pulmonary cement embolization).

Patients treated with RFK intervention showed an average improvement in VAS pain score of 4.9 in fresh VCFs and 3.9 in old VCFs (p< 0.001). Cement leakage rate with no complications was on average 10.6% (fresh VCFs 9.8%, old VCFs 11.6%) and height restoration was average 7.0mm in fresh VCFs and average 4.4 mm in old VCFs.

**Conclusion:** These VA procedures are comparable demonstrating both are safe and effective for treatment of painful VCFs. Higher leakage rate in old VCFs in the BKP group was related to increased bone destruction and re-fracture of vertebrae during balloon inflation. RFK revealed similar pain relief and height restoration but decreased rates of cement extravasation and related complications. Decreased extravasation was due to RF warming of cement just prior to entering the patient permitting more controlled cement delivery due to increased viscosity 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 provided benefit for both patient and physician.