Kiva Kyphoplasty (BENVENUE MEDICAL, INC.) - A New Kyphoplasty System in Comparison to (VP) Vertebroplasty: A Prospective Evaluation

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Background: Kiva Kyphoplasty provides a new minimally invasive procedure to treat vertebral compression fractures (VCF). The purpose of our study was to investigate the functional outcomes, safety and radiographic outcomes after the treatment of painful osteoporotic vertebral fractures treated with Kiva Kyphoplasty. The VP group served as control group.

Materials and methods: 47 patients (32 females and 15 males, mean age 69) with 72 osteoporotic vertebral compression fractures (VCF) were treated with Kiva. Three months follow up in 40 patients (27 females and 13 males) with 61 treated VCFs are reported. Thirty nine patients (28 females and 11 males, mean age 66 years) underwent 52 VP procedures. Three months follow up in 28 patients (22 females and 6 males) with 38 vertebrae treated are reported.

Patient-related outcomes of pain (Visual Analogue Scale) and disability (Oswestry Disability Index) were assessed pre- and postoperatively and after 3 months. Correction of vertebral height and kyphotic deformity were assessed by radiographic measurements. Cement leakage was evaluated by CT scan postoperatively.

Results: Mean pain visual analogue scale and Oswestry Disability Index significantly improved in both patients groups from pre- to post-treatment (P< 0.0001), this improvement being sustained up to 3 months follow up. A gain in height restoration and a reduction of the post-operative kyphotic angle were seen post-operatively and at 3-months in the Kiva Kyphoplasty group. Cement leakage was noted in of 5.5% of the Kiva procedures and 59.6% of the VP procedures.

No symptomatic cement leaks or serious adverse events were seen in the Kiva group during 3-months of follow up. Two patients in the VP group had a lung embolism due to a cement leakage, both of which were treated conservatively.

Conclusion: Kiva Kyphoplasty and vertebroplasty are two minimally invasive procedures that provide immediate pain relief and improved functional ability in patients with osteoporotic VCFs. Both procedures are able to stabilize the fracture in the three months follow-up. Site specific application of a PEEK device and delivery of the cement through PEEK implant resulted in the added benefits of height restoration and lower cement leakages intra-operatively in the Kiva Kyphoplasty group.