AlloMatrix Bone Graft in Distal Radial Fracture: A Prospective Randomized Controlled Clinical Trial

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Abstract

Background: The osteoinductive effect of demineralized bone matrix (DBM) has been documented in animal studies. Nevertheless, the therapeutic efficacy of this bone graft has yet to be proven in humans.

Methods: The clinical properties of AlloMatrix, an injectable calcium-based demineralized bone matrix allograft, were studied by a prospective randomized study of 50 patients with an isolated unstable distal radial fracture treated by reduction and percutaneous fixation of K-wires. Twenty-four patients were randomized to the Graft group and twenty-six to the No Graft group. At 1, 3, 6 and 9 weeks, 6 months and 1 year postoperatively, patients underwent assessments for range of motion, grip and pinch strength measurements, completed the Disabilities of Arm, Shoulder and Hand (DASH) questionnaire and underwent radiographic evaluations. At 1 and 6 weeks and 1 year postoperatively, bone mineral density evaluations of both wrists were performed. All adverse events were recorded.

Results: No statistically significant differences in wrist function and speed of recovery, rate and speed of union and bone mineral density was found between the two groups. The operating time was significantly higher in the Graft group ($p=0.004$). There was a significant difference in strength between the noninjured and injured side for pinch strength at 6 weeks ($p=0.01$) and grip strength at 9 weeks ($p=0.04$) in the Graft group. There was no substantial difference in morbidity or surgical revision rates. All AlloMatrix deposits observed radiographically disappeared after 9 weeks.

Conclusion: This prospective randomized controlled trial did not demonstrate a significant clinical effect of AlloMatrix DBM.

Level of Evidence: Therapeutic Level I.