Autologous Iliac Bone Graft versus Biphasic Hydroxyapatite/Calcium Sulfate Cement for Treatment of Bone Defects in Tibial Plateau Fractures: A Multicenter, Prospective, Randomized Clinical Trial

Alex Hofmann, MD*; Stanislav Gorbulev; Paul Alfred Grützner; Arndt Peter Schulz, MD, PhD; Rupert Schupfner, OT; Michael Raschke, MD; Martijn Van Griensven; Pol Maria Rommens, MD*
University Medical Centre, Mainz, Germany

Purpose: Bone graft substitutes are widely used for augmentation of traumatic bone defects in tibial plateau fractures, but their clinical outcome in comparison to autologous bone grafting remains under debate. This study investigates the differences in quality of life, pain and radiographic subsidence in the treatment of tibial plateau fracture-associated bone defects using either autologous iliac bone graft (AIBG) or a bioresorbable hydroxyapatite/calcium sulfate cement (BONE VOID FILLER [CBVF]).

Methods: 137 patients with acute traumatic depression fractures of the proximal tibia (AO types 41-B2 and AO 41-B3) were enrolled in a prospective, controlled, randomized, multicenter trial including 20 centers. Patients were randomized to receive either AIBG or CBVF to reconstruct the subchondral bone defect after open reduction and internal fixation. Primary outcome measure was the Short Form-12 version 2 (SF-12v2) Physical Component Summary (PCS) score at week 26. The co-primary end point was the pain level 26 weeks after surgery measured by a visual analog scale (VAS). The SF-12v2 Mental Component Summary (MCS) score after 26 weeks and subsidence of the tibia plateau on radiographs at 26 weeks served as key secondary end points.

Results: Age, gender, fixation method (locking vs non-locking plates), and fracture patterns were comparable in the 2 groups. CBVF was noninferior to AIBG regarding the SF-12v2 PCS and MCS, as well as in the pain score (VAS) at 26 weeks. There was a significant reduction of blood loss and a trend towards a shorter duration of surgery (not significant) in the CBVF group. Rate of articular subsidence during the 3 to 6-month follow-up period was equal in both groups.

Conclusion: Equal patient-reported outcomes and radiological results can be achieved in tibial plateau fractures if hydroxyapatite/calcium sulfate cement or AIBG are used. The indication for autologous bone grafting in tibial plateau fractures therefore needs careful consideration.