P15:106

COMPLICATIONS ASSOCIATED WITH THE ARTIFICIAL BONE GRAFT SUBSTITUTE €žGeneX€

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Background: Artificial bone graft substitutes like GeneX, a tricalciumphosphate-calcium - sulphate - compound, are widely used to refill bone defects after curettage of benign tumours. At our clinic we observed severe postoperative complications after initiation of GeneX.

Methods: We designed a prospective single cohort study with 40 patients with bone tumours who should receive curettage and defect filling with GeneX. Due to serious postoperative complications the study had to be stopped after inclusion of 31 patients (11 male, 20 female). Mean age at operation was 40-years (range, 6-71). The lesions were located in the proximal humerus (9), the femur (7), the tibia (3) or fibula (2) and the small bones of hand (8) or foot (2). The tumour entities included 17 enchondroma, five simple/juvenile bone cysts and nine other benign bone lesions.

Results: Five out of 31 patients (16%) developed serious complications following surgery and GeneX refilling. Three presented sterile inflammation adjacent to GeneX and two developed inflammatory cystic formations (up to 15cm) in the soft tissue with time dependant growth regression. Of those three patients with sterile inflammation, two showed delayed wound healing and local pain, and the third needed revision due to severe skin damage.

Conclusion: In the current series, GeneX caused severe soft tissue inflammation and pain. Therefore, surgeons should be warned not to place this artificial bone graft substitute next to thin walled structures (erosion!), and further, to seal fenestrated bone carefully after curettage and defect filling. We state the notion that general mandatory detailed safety testing of artificial bone graft substitutes should be performed before market launch.

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