

Title Safety and reoperation rates in non-instrumented lumbar fusion surgery: Secondary report from A Randomized Controlled Trial of ABM/P-15 vs allograft with minimum 5 years follow-up.

Introduction Spinal fusion in the elderly is challenging, with low reported fusion rates and high risk of complications. To obtain fusion, autologous bone is considered gold standard, although peri- and postoperative complications due to harvesting bone has been reported. An anorganic bovine-derived hydroxyapatite matrix combined with a synthetic 15 amino acid residue (ABM/P-15, Peptide Enhanced Bone Graft), has been introduced as a substitute for autologous bone graft. Recent reports of perioperative wound complications and ectopic bone formation has questioned the reliability of these graft extenders.

Purpose The purpose of this study is to evaluate the peri- and postoperative complications rates, formation of ectopic bone, osteolysis and reoperation rates. Secondly to evaluate the 5-year patient reported outcomes, in patients treated with spinal decompression and non-instrumented posterolateral intertransverse fusion with ABM/P-15 or allograft.

Methods This is a secondary report on a randomized controlled trial, in which patients with degenerative spondylolisthesis were enrolled in a Randomized Clinical Trial. The patients were randomized 1:1 to either ABM/P-15 (mixed 50/50, 5cc/level) or allograft bone (30g/level), both mixed with local bone graft. Minimum 60-months post-operative the patients were invited to a clinical follow-up which included a computed tomography scan (CT) to evaluate signs of osteolysis, ectopic bone formation and bone migration as well as Patient Reported Outcomes were collected.

Results Of 101 subjects enrolled in the primary study, 83 patients were available for 5-year follow up. There were no differences in complications, reoperation- or infection rates between the two-groups. For the supplementary CT-scan 58 patients agreed to participate, revealing two asymptomatic patients with migration of graft material in the ABM/P-15 group. The patients reported a statistically significant difference between the groups in favor of the ABM/P-15 group in back pain and Oswestry Disability Index but no significant difference between leg pain or European Quality of life 5-Dimensions.

Conclusion Our study indicated that complication rates are no higher in patients treated with ABM/P-15 than allograft. Patients in the ABM/P-15 group reported less back pain and lower disability score than the allograft group.