Results of Biphasic Calcium Phosphate Bone Graft with Submicron-Sized Needle-Shaped Surface Topography as Standalone Alternative to Autograft are Favorable in a Prospective, Multi-center, Randomized, Intra-patient Controlled Trial

Robert Kenneth Eastlack, Casey Butrico, Diyar Delawi, Eric Hoebink, Diederik Kempen, Job L C Van Susante, Moyo Kruyt

INTRODUCTION: Pseudoarthrosis after spinal fusion is an important complication leading to revision spine surgeries. Iliac Crest Bone Graft is considered the gold standard, but with limited availability and associated co-morbidities, spine surgeons often utilize alternative bone grafts. This study serves to determine the non-inferiority of a novel submicron-sized needle-shaped surface biphasic calcium phosphate (BCP<μm) as compared to autograft in instrumented posterolateral spinal fusion.

METHODS:

Adult patients indicated for instrumented posterolateral spinal fusion of one to six levels from T10-S2 were enrolled at five participating centers. After instrumentation and preparation of the bone bed, the randomized allocation side of the graft type was disclosed. One side was grafted with 10 cc of autograft per level containing a minimum of 50% iliac crest bone. The other side was grafted with 10 cc of BCP<μm granules standalone (without autograft or bone marrow aspirate). In total, 128 levels were treated. Prospective follow-up included adverse events, Oswestry Disability Index (ODI), and a fine-cut (<1mm) Computerized Tomography (CT) at one year. Fusion was systematically scored as fused or not fused per level per side by two spine surgeons blinded for the procedure. To correct for multilevel fusions, a performance score per treatment side was used as a primary outcome. The study was powered to detect >15% inferiority with binomial paired comparisons.

RESULTS: In total, 91 patients were enrolled and received fine-cut CTs for fusion assessment at 1 year post-operative. The fusion rate for BCP<μm was 79% (101/128 levels), which compared favorably to the autograft fusion rate of 47% (60/128 levels). Analysis of the primary outcome indicated superiority of BCP<μm with a difference in paired proportions of 39.6% (95% CI, $p<0.001$). Of the 91 patients, 19% were smokers. BCP<μm Granules showed an 80% fusion rate in the smoker population compared to a fusion rate of 32% with autograft.

DISCUSSION AND CONCLUSION:

This is the first clinical study demonstrating superiority of a standalone calcium phosphate graft compared to autograft for spinal fusion. These data challenge the use of autologous bone as the gold standard bone graft and support the use of BCP<μm in posterolateral spinal fusion. Furthermore, BCP<μm led to favorable fusion rates in a smoker population. The analyses of interbody fusion rate, changes in ODI, and adverse events are ongoing. Publication is forthcoming.