# 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

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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. The aim of this study is to determine the non-inferiority of a novel submicron-sized needle-shaped surface biphasic calcium phosphate (MagnetOs™) 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 review and approval from the Medical Ethics Review Committee number 18-311. After instrumentation and preparation of the bone bed, the randomized allocation side of the graft type was disclosed. One side was grafted with 10cc of autograft per level containing a minimum of 50% iliac crest bone. The other side was grafted with 10cc of MagnetOs Granules standalone (without autograft or bone marrow aspirate). In total, 71 levels were treated. Prospective follow-up included adverse events, Oswestry Disability Index (ODI), and a fine-cut 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.

RESULTS: The first fifty patients enrolled are included in this analysis (mean age: 57 years; 60% female and 40% male). The diagnoses included deformity (56%), structural instability (28%), and instability from decompression (20%). The fusion rate determined by CT for MagnetOs was 76.1%, which compared favorably to the autograft fusion rate of 43.7%. Statistical analysis through binomial modeling showed that the odds of fusion MagnetOs was 2.54 times higher than that of autograft. 14% of patients experienced a procedure or possible device-related severe adverse event and there were four reoperations. Oswestry Disability Index (ODI) score decreased from a mean of 46.0 (±15.0) to a mean of 31.7 (±16.9), and 52.4% of patients improved with at least 15-point decrease. An overall non-inferiority proportions Z test for paired data (left and right) was performed with a noninferiority Margin (NIM) of 15%. A McNemar's test was used to determine heterogeneity of treatments. The observed difference in proportions between MagnetOs Granules and autograft was 36%, with a lower bound of the one-sided 95% confidence interval of 22.2%. With the *p*-value less than 0.01, and lower bound of the confidence interval well above the NIM, there is statistical evidence that MagnetOs Granules is not inferior to autograft ($p<0.001$).

DISCUSSION: This interim analysis found a 78% fusion rate of MagnetOs Granules by subject, and a 76.1% fusion rate of MagnetOs Granules by level. The results of this ongoing, prospective study aiming to determine the non-inferiority of MagnetOs Granules used standalone as compared to autograft are promising. Ongoing studies with more subjects are forthcoming.

SIGNIFICANCE/CLINICAL RELEVANCE: The current rate of non-unions in the spine is estimated to be 17%, which results in over 10% of all spinal fusion patients requiring a second intervention to relieve their symptoms. Using the most effective bone graft can improve fusion outcomes by up to 60%. This study demonstrates clinical evidence of the ability of MagnetOs Granules, a 100% synthetic bone graft, to improve fusion outcomes with interim results showing its non-inferiority to Iliac Crest Bone Graft, the gold standard.

REFERENCES: Not applicable.

ACKNOWLEDGEMENTS: Not applicable.

| (A) | MagnetOs Granules (% subjects) | Autograft (% subjects) |
|---|---|---|
| Overall | 78.0% (39/50) | 42.0% (21/50) |
| 1 Level Fusion | 73.5% (25/34) | 47.1% (16/34) |
| 2 Level Fusion | 84.6% (11/13) | 38.5% (5/13) |
| 3 Level Fusion | 100% (1/1) | 0% (0/1) |
| 4 Level Fusion | 100% (2/2) | 0% (0/2) |

| (B) | MagnetOs Granules (% levels) | Autograft (% levels) |
|---|---|---|
| Total Fusion | 76.1% (54/71) | 43.7% (31/71) |
| 1 Level Fusion | 73.5% (25/34) | 47.1% (16/34) |
| 2 Level Fusion | 73.1% (19/26) | 38.5% (10/26) |
| 3 Level Fusion | 100% (3/3) | 33.3% (1/3) |
| 4 Level Fusion | 87.5% (7/8) | 50.0% (4/8) |

**Figure 1:** Fusion percentages by Subject for MagnetOs Granules and Autograft (A), and fusion percentages and number of levels fused for MagnetOs Granules and Autograft (B).

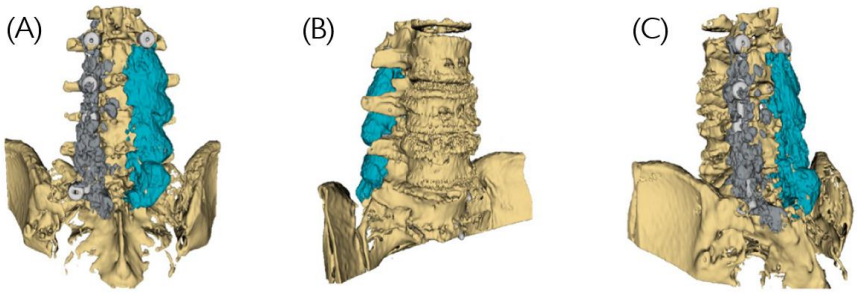


**Figure 2:** Coronal (A), Sagittal (B; right) and Oblique (D) 3D reconstructions of a L2-S1 four level fusion at one-year follow-up. (MagnetOs Granules: Blue; Autograft: Gray; Instrumentation: Light Gray). This case represents a 67-year-old male with a diagnosis of instability as a result of decompressive surgery. He underwent a four-level PLF from L2-S1. The PLF was combined with a TLIF at L3-4 and L5-S1. After 1 year, fine cut CT determined that the MagnetOs Granules side was fused at three levels and the autograft side was fused at two levels, while both interbody constructs fused. The patient was considered fused.