



Case Report

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Early Radiographic and Clinical Outcomes of Three Patients Undergoing Open Instrumented Posterolateral Fusion Surgery with MagnetOs™ Easypack Putty



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Abstract

An important factor influencing spinal fusion outcomes is the choice of bone graft. Autograft is considered the gold standard bone grafting material. However, harvesting quality autologous bone from the iliac crest may require an additional procedure and can lead to complications such as extraction site pain. Next-generation calcium phosphate bone grafts provide surgeons an option without added cells, growth factors, or the need for autologous bone. MagnetOs is a biphasic calcium phosphate bone graft with a unique needle-shaped submicron surface topography. The surface of MagnetOs predictably polarizes M2 macrophages, which in turn secrete chemokines that stimulate mesenchymal stem cell (MSC) recruitment. Signaling from M2 macrophage cytokines stimulate MSCs to differentiate into osteoblasts, which lay down osteoid for healthy bone formation. To optimize the handling characteristics of MagnetOs biphasic calcium phosphate granules, MagnetOs Easypack Putty was developed containing a polyethylene glycol-poly(lactic acid) (PEG-PLA) polymer. This study includes three clinical cases where MagnetOs Easypack Putty was used on-label in the posterolateral spine. Patient reported outcomes demonstrate favorable outcomes using MagnetOs Easypack Putty.

Keywords: Posterolateral fusion; MagnetOs Easypack Putty; Osteoimmunology; Bone graft; M2 Macrophage

Introduction

The annual number of spinal fusion surgeries continues to rise in the United States, but the pseudoarthrosis rate remains the same [1,2]. Evaluating choice of bone graft can significantly improve fusion rates during spinal surgery [1,3,4]. Autologous bone, or autograft, remains the gold standard grafting material. However, an additional procedure is often necessary to obtain quality iliac crest bone graft, and local bone is limited based on procedure [5]. Furthermore, the quality of autograft varies based on the patient's biological factors such as age and comorbidities [6,7]. Other categories of bone grafts were developed to overcome the drawbacks of using autograft. Cell based allografts, demineralized bone matrices, and allograft each require a human donor and processing to remove biological contaminants. Other graft technology involves added peptides or growth factors. However, clinical studies with peptide-based grafts have reported migration from the site of the fusion, and grafts with growth

factors can lead to ectopic bone formation [8,9]. Next-generation synthetic grafts were developed to reduce or eliminate the need for autograft while mitigating the drawbacks of other advanced bone grafting devices.

MagnetOs is a biphasic calcium phosphate bone graft that contains a unique submicron needle-shaped surface topography (NeedleGrip™). The NeedleGrip technology of MagnetOs facilitates traction of pro-healing M2 macrophages [10,11*] Macrophages are monocyte-derived cells that polarize according to environmental cues. M1 macrophages are pro-inflammatory, secreting cytokines that promote fibroblast proliferation, leading to scar tissue formation [12]. M2 macrophages secrete pro-healing cytokines and chemokines that recruit mesenchymal stem cells (MSCs) to the site of MagnetOs [10,11,13*]. In response to M2 macrophage cytokines, MSCs differentiate into osteoblasts. Osteoblasts are responsible for bone mineralization through the

production of proteins such as osteonectin and alkaline phosphatase [11*]. MagnetOs Granules predictably polarize M2 macrophages for a pro-healing response that promotes healthy osteoid formation [10,13,14*].

With respect to handling properties, MagnetOs Easypack Putty contains the technology of MagnetOs Granules combined with a polyethylene glycol-polylactic acid (PEG-PLA) polymer. The PEG-PLA polymer is water soluble and biocompatible, resorbing within three days [15]. The polymer makes up 5% of the volume of MagnetOs Easypack Putty, creating a moldable graft while retaining the mechanism of action of the MagnetOs Granules [15].

This paper provides a case series of three patients who received MagnetOs Easypack Putty on-label, mixed with local morselized autograft, in open posterolateral fusion (PLF). Patients included two males and one female ages 46-74 with diverse medical and surgical histories. These cases report efficacy of MagnetOs Easypack Putty as measured by functional outcomes, pain scores, and radiographic success.

Case 1

Case 1 is a 59-year-old female with complaints of progressive bilateral upper extremity radiculopathy, loss of balance, and loss of dexterity. She was diagnosed with cervical spondylitic myelopathy with radiculopathy. On presentation, the patient had an Oswestry Disability Index (ODI) score of 66. Past surgical history included appendectomy and tonsillectomy. Past medical history included depression, hypertension, chronic kidney disease, low back pain, and migraines. Magnetic resonance imaging (MRI) revealed spinal cord compression at C5-6. Computed tomography (CT) revealed ossification of the posterior longitudinal ligament (OPLL). The patient underwent a posterior C5-6 decompression with instrumentation and fusion with MagnetOs Easypack Putty mixed with autograft. The post-operative course was uneventful with improvement in myelopathic symptoms and resolution of radiculopathy. A post-operative ODI score of 38 was recorded. Post-operative x-rays 1 year after surgery show stable hardware placement with no evidence of complications.



Figure 1a: Pre-operative sagittal MRI (1a) revealing spinal cord compression at C5-6.

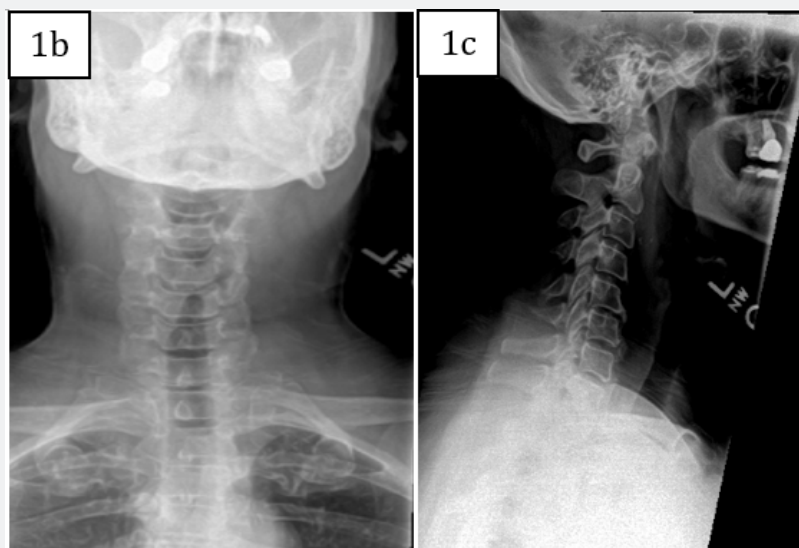


Figure 1b & 1c: Pre-operative anterior-posterior (AP) (1b) and lateral (1c) x-rays.

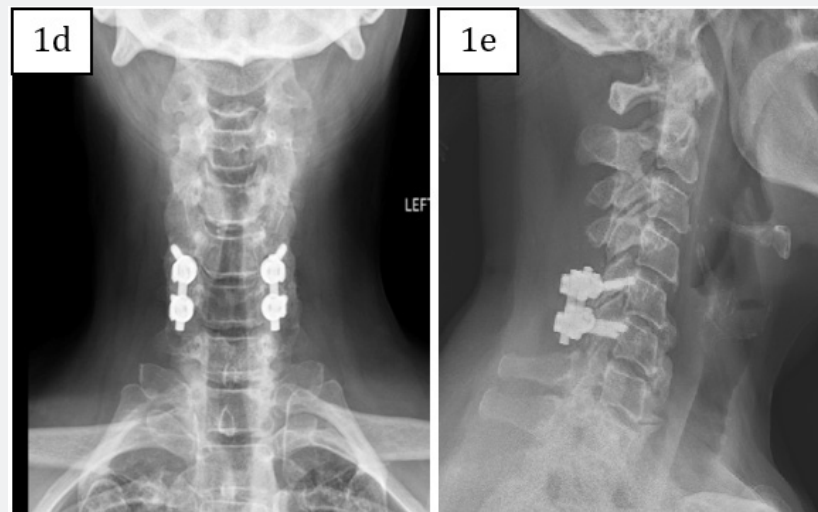


Figure 1d & 1e: One-year post-operative AP (1d) and lateral (1e) x-rays showing stable hardware placement and satisfactory alignment.

Case 2

Case 2 is a 46-year-old male who presented with symptoms of worsening cervical spondylitic myelopathy manifesting as loss of dexterity and loss of balance. Past surgical history included prior C3-4 anterior cervical discectomy and fusion (ACDF) for treatment of spinal cord injury with recovery of nearly all function. Six months post-operatively the patient noted worsening myelopathic symptoms. ODI upon presentation was 68. The patient had an MRI cervical spine and was found to have multiple levels of cervical spondylosis with spinal cord compression. He underwent a posterior C3-6 decompression and fusion using MagnetOs Easypack Putty mixed with local morselized autograft. The patient demonstrated improvement in myelopathic symptoms after surgery and his 3-month ODI score improved to 42. Six months post-operative, the patient was involved in a motor vehicle accident and sustained a bilateral fracture of C2 and a laminar fracture of C7. CT performed at the time of admission revealed evidence of fusion across the facet joints of C3-6. The patient later underwent posterior C2-T1 instrumentation and fusion and was eventually discharged to rehabilitation.



Figure 2a: Pre-operative sagittal MRI (2a) demonstrating stenosis and cervical spondylosis.

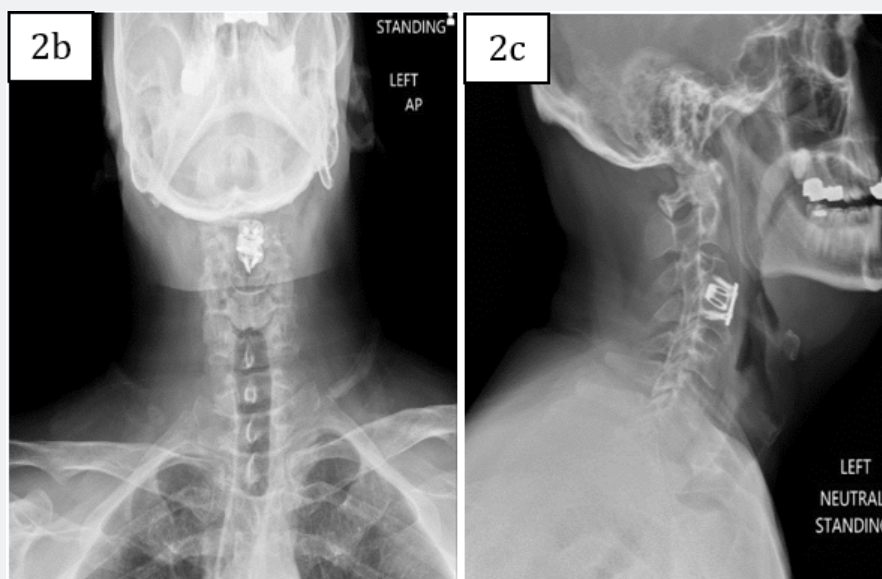


Figure 2b & 2c: Pre-operative AP (2b) and lateral (2c) x-rays demonstrating a prior ACDF at C3-4.

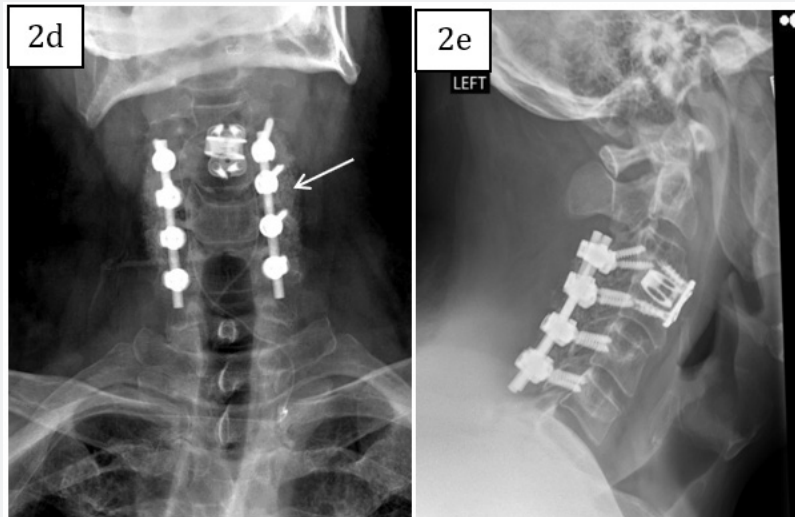


Figure 2d & 2e: Three-month post-operative AP (2d) and lateral (2e) x-rays showing MagnetOs Easypack Putty in the posterolateral gutters.

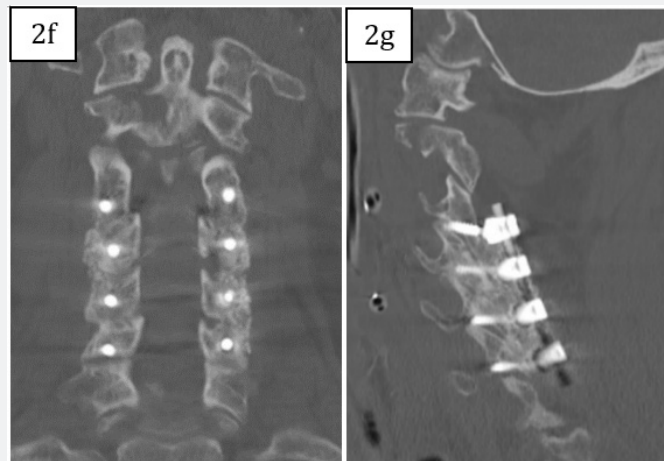


Figure 2f & 2g: Six-month post-operative coronal (2f) and sagittal (2g) CT showing interim traumatic injury and evidence of successful C3-6 arthrodesis with MagnetOs Easypack Putty and local morselized autograft.

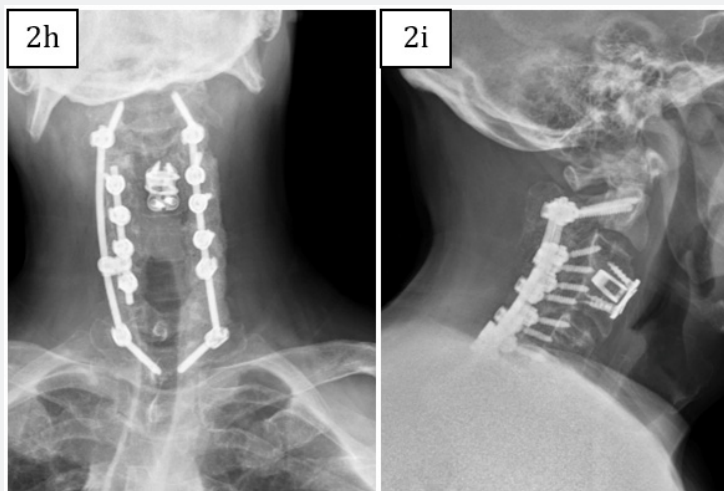


Figure 2h & 2i: Three-month post-operative second surgery AP (2h) and lateral (2i) x-ray showing extension of instrumented from C2 to T1.

Case 3

Case 3 is a 74-year-old male who presented with left upper extremity radiculopathy and cervical spondylitic myelopathy manifesting as loss of balance and loss of dexterity. Past medical history was significant for carotid endarterectomy, chronic obstructive pulmonary disease, and emphysema. ODI upon presentation was 16. MRI cervical spine revealed spinal cord compression most notable at C3-4, C5-6, and C6-7. The patient underwent a posterior cervical laminectomy at C3-4, C4-5, C5-6, and C6-7 (partial) with C3-6 instrumented fusion with 10cc of MagnetOs Easypack Putty and local morselized autograft. The patient had improvement in his left upper extremity radiculopathy, and his 6-month ODI score improved to 2.



Figure 3a: Pre-operative sagittal MRI (3a) demonstrating cervical stenosis most notable at C3-4, C5-6, and C6-7.

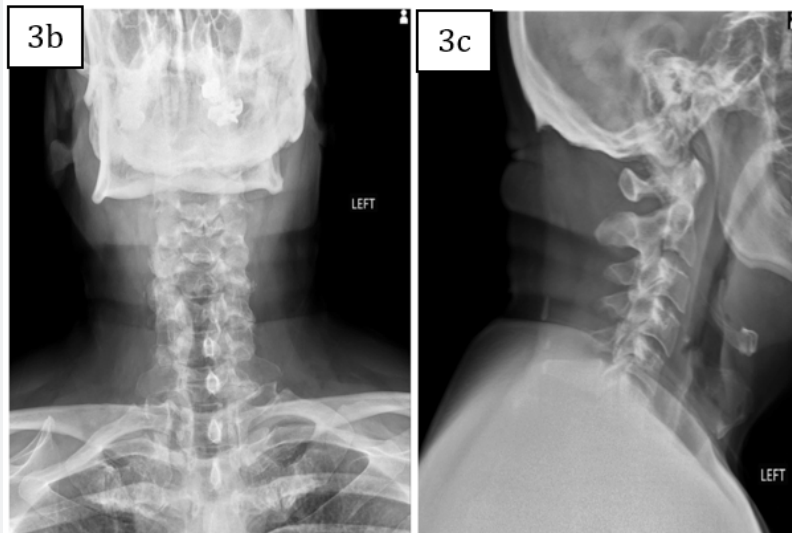


Figure 3b & 3c: Pre-operative AP (3b) and lateral (3c) x-rays.

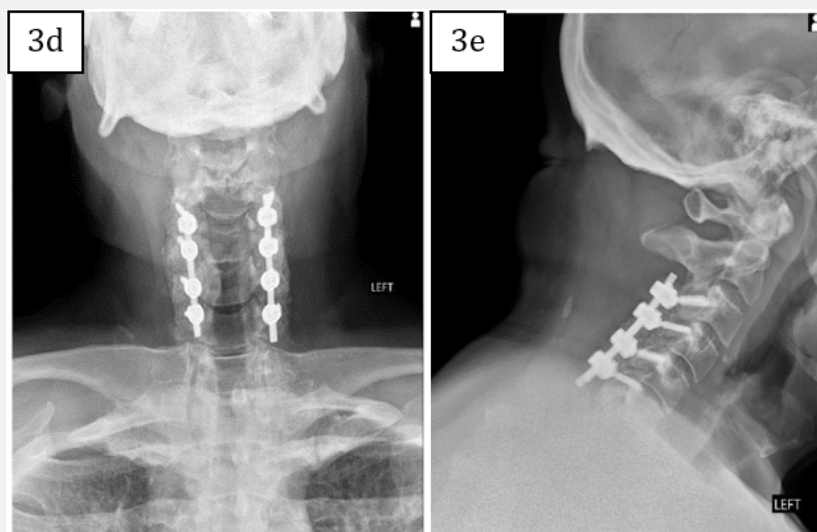


Figure 3d & 3e: Three-month post-operative AP (3d) and lateral (3e) x-rays demonstrating stable posterior instrumentation at C3-6 with satisfactory alignment.

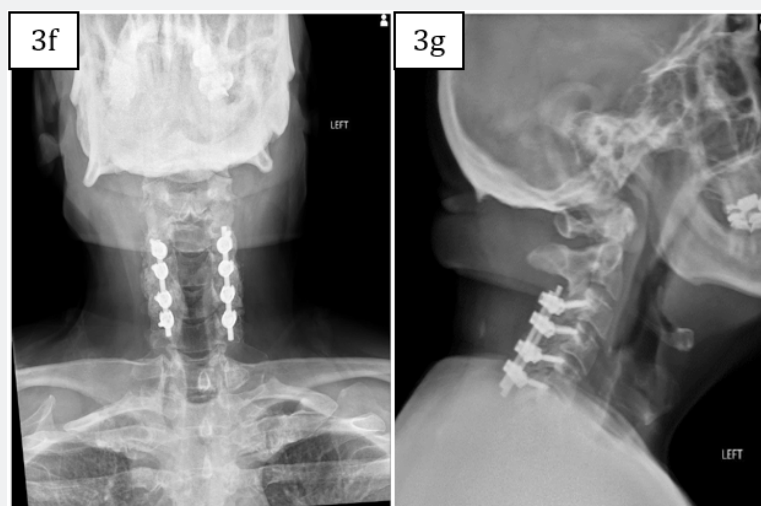


Figure 3f & 3g: Six-month post-operative AP (3f) and lateral (3g) x-rays demonstrating stable posterior instrumentation at C3-6 with satisfactory alignment.

Discussion

Time to fusion and patient reported outcomes are two measures of the success of spinal fusion surgeries. However, radiographic outcomes can be analyzed with a variety of imaging modalities and fusion criteria, with inconsistencies in literature [3]. Utilizing multiple imaging modalities at various time points provides comprehensive observations to evaluate time to fusion and extent of bone formation.

This case series of patients underwent posterolateral instrumented arthrodesis with MagnetOs Easypack Putty with satisfactory clinical outcomes. MagnetOs Easypack Putty was used on-label as an extender in the posterolateral spine in the cervical spine. Post-operative imaging includes three-month, six-month, and/or one-year follow-up. Case 2 demonstrated radiographic signs of successful arthrodesis on CT scan 6 months after the index operation.

MagnetOs promotes bone formation in the absence of added growth factors or human-derived cells. Bone is formed throughout the graft in response to the sub-micron needle-shaped topography, which provides traction for pro-healing M2 macrophages [10,11*]. In response, MagnetOs forms bone during PLF through core and creeping edge repair [14*]. The PEG-PLA polymer in MagnetOs Easypack Putty was optimized to maintain the surface topography of MagnetOs Granules while creating a malleable, ready-to-use graft formulation composed of 87% PEG and 13% PLA [15]. Pre-clinical radiographic and histologic analyses reveal resorption of the PEG-PLA polymer within three days and resorption of the biphasic calcium phosphate granules accompanied by mature bone formation within three months [15*]. No graft migration or adverse events were reported [15]. Although we do not have 1 year post-operative CT on all 3 patients, one of the patients demonstrated evidence of spinal fusion on post-operative CT scan 6 months after surgery. This publication provides a clinical case series that demonstrates safe clinical use of MagnetOs Easypack Putty and satisfactory post-operative outcomes in the three patients undergoing posterolateral fusion of the cervical spine.

Conclusion

This case series demonstrates positive patient reported outcomes of MagnetOs Easypack Putty in a retrospective cohort of patients undergoing posterolateral fusion of the cervical spine.

Conflict of Interest

The study was supported by a grant from Kuros Biosciences BV. CE is a consultant for Kuros Biosciences BV. CB and KS have financial disclosures with Kuros Biosciences BV.

*Results from *in vivo* laboratory testing may not be predictive of clinical experience in humans. For important safety and

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MagnetOs is not cleared by the FDA as an osteoinductive bone graft.
Results from in vivo and in vitro laboratory testing may not be predictive of clinical experience in humans.
Please refer to the Instructions for Use for a full list of indications, contraindications, precautions, and warnings.

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