Use of a Novel Biphasic Calcium Phosphate with Submicron Surface Topography as an Extender to Autograft in Posterolateral Spinal Fusion

MagnetOs™ Whitepaper

MAGNETOS
for predictable fusions

Kuros Biosciences

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Introduction

In recent years, spinal arthrodesis surgeries have increased in the United States (U.S.), with the number of cases expected to continue to rise.[1] One challenging complication of spinal arthrodesis is a pseudarthrosis of an operated segment. Recent literature reports the pseudarthrosis rate at approximately 17%, resulting in 149,000 non-unions in the U.S. per year.[1,2] Over half of these non-unions are revised at the index level, leading to 92,000 revisions per year.[3]

One important factor in obtaining a solid fusion is the bone graft chosen for the procedure.[2] Autograft bone in the form of Iliac Crest Bone Graft (ICBG) is the gold standard, but there is limited supply and co-morbidities with harvesting, such as pain at the donor site.[4] Additionally, there is significant variability in autograft bone due to age, metabolic disease, or other factors.[5] As a result, multiple products have entered the market as an alternative or adjunct to bone autograft. Synthetic calcium phosphate bone graft usage has increased due to its efficacy, reasonable cost, low incidence of adverse reactions, and reduced need to harvest large amounts of autologous bone.[6-8]

Harnessing the power of osteoimmunology, or the relationship between the body's immune system and skeletal system, leads to more predictable bony fusions in spinal arthrodesis procedures.[9-14] Macrophages are among the first responders of the immune system after tissue trauma, and polarizing macrophages toward the pro-healing M2 phenotype versus the pro-inflammatory M1 phenotype can activate bony healing.[15,16] MagnetOs is a biphasic calcium phosphate (BCP) bone graft that grows bone in soft tissue without added cells or growth factors, thanks to its unique NeedleGrip™ surface technology, which provides traction for the body's vitally important pro-healing immune cells (M2 Macrophages).*†[9,13] This, in turn, unlocks previously untapped potential to stimulate stem cells and form new bone throughout the graft.*[10-12]

Non-unions are challenging for the surgeon and patient alike, and can lead to poorer clinical outcomes, continued spinal instability at the affected level, and the need for revision surgery. The purpose of this case series is to assess radiographic success, functional outcomes, and pain scores following on-label use of MagnetOs in posterolateral fusion as an extender to bone autograft.

Methods

Two patients undergoing posterolateral fusion using MagnetOs as an extender to autograft bone were included in this case study. Pre-operatively, the patient's symptoms on presentation, previous treatment, past medical history, past surgical history, medications, Visual Analog Scale (VAS) scores, and pre-operative radiographs were reviewed. The surgery and post-operative details were reviewed, including post-operative radiography and VAS, as well as objective and subjective analysis of the patient's outcomes.

Radiographically, posterolateral fusion was evaluated through assessment of spinal osteogenesis observed in anteroposterior and lateral plain X-rays. Four grades were used to characterize osteogenesis: One (1) was described as slight discontinuous osteogenesis between transverse processes; Two (2) was described as discontinuous osteogenesis between transverse processes and Three (3) was described as continuous osteogenesis between transverse processes. An osteogenic score of 3 was considered fused.

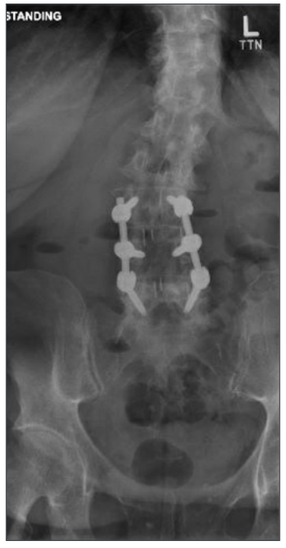
Case Study 1

This is a 66-year-old female with a history of a previous lumbar spine surgery two years prior to consultation, including laminectomies at L3-L5 with bilateral facetectomies and foraminotomies at L3-4 and L4-5; decompression of cauda equina and exploration of nerve roots bilaterally at L3, L4, and L5; and posterior spinal arthrodesis with instrumentation at L3-L5. Additionally, the patient underwent epidural steroid injections on the left side at L2-3, as well as radiofrequency ablation in the lumbar region. Ultimately the patient's pain failed to improve, and she presented with chronic back pain and lumbar radiculopathy.

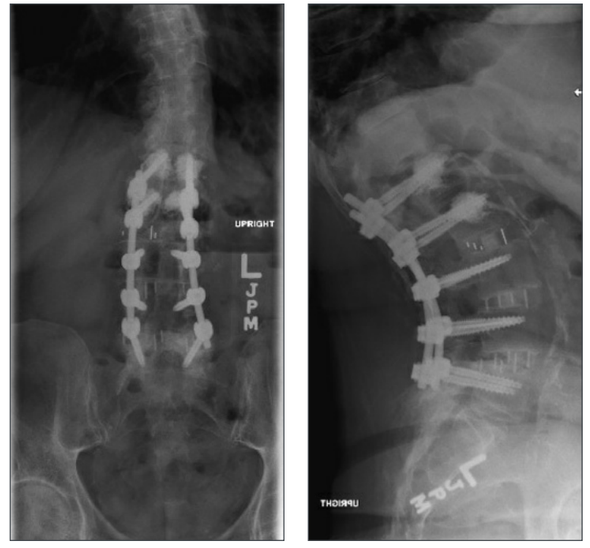
The patient's relevant past medical history included neuropathic pain, spinal stenosis, history of a right leg deep vein thrombosis, pulmonary embolism, and a history of smoking. Pre-operatively, the patient was on several relevant medications for pain control including gabapentin, morphine, Tylenol #3, and diazepam. At the time of surgery, she was a current smoker, smoking 1 pack a day for 50 years. At her pre-operative visit, her VAS was a 6.

Upon pre-operative radiographic evaluation and clinical examination, the patient was diagnosed with adjacent segment disease with degenerative spondylolisthesis and spinal stenosis in the lumbar region with radiculopathy. The patient underwent removal of hardware L3-5; arthrodesis of L1-L3, and revision arthrodesis of L3-L5 with cementation augmentation. **MagnetOs bone graft was used on-label as an extender in the posterolateral spine**.

The patient had an uncomplicated post-operative course with improvement in pain and functionality post-operatively. Plain film X-rays six-months post-operatively demonstrated a healed arthrodesis with bony bridging in the posterolateral space.



Pre-operative Anterior-Posterior (AP) and lateral X-rays showing a previous spinal arthrodesis from L3-L5.



Six-month post-operative AP and lateral X-rays showing primary arthrodesis of L1-2 and revision arthrodesis of L3-L5.

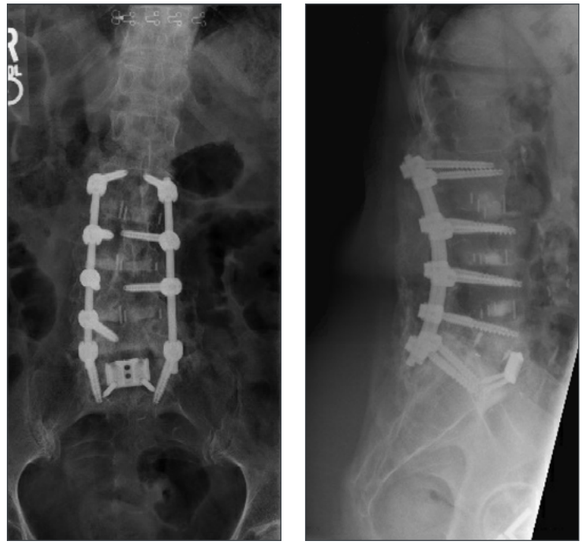
Case Study 2

This is a 62-year-old female with a history of lumbar fusion from L2-L5 five years prior to consultation. She continued to have pain after the initial surgery and underwent facet injections on the right at L4-5 and L5-S1, as well as transforaminal epidural injections. One-year prior to consultation she underwent Anterior Lumbar Interbody Fusion at L5-S1, which was complicated by post-operative infection needing irrigation and debridement one-month later.

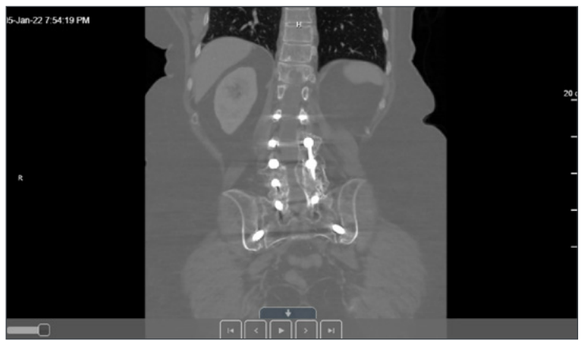
Relevant past medical history included chronic severe bilateral lower back pain, degenerative joint disease, osteoporosis, atrial fibrillation, and a history of deep vein thrombosis. Pre-operatively, the patient was on several relevant medications including alendronate, alprazolam, Eliquis, diclofenac gel, hydrocodone-acetaminophen, and pregabalin. At the time of surgery, she used an electronic cigarette, and had a history of 1 pack per day of cigarettes for 42 years. At her pre-operative visit, her VAS was a 7.

The patient underwent a three-level laminectomy with instrumented posterior spinal fusion, with removal of hardware L2-S1 as well as revision posterior spinal instrumentation of L2 to pelvis. **MagnetOs bone graft was used on label as an extender in the posterolateral spine**.

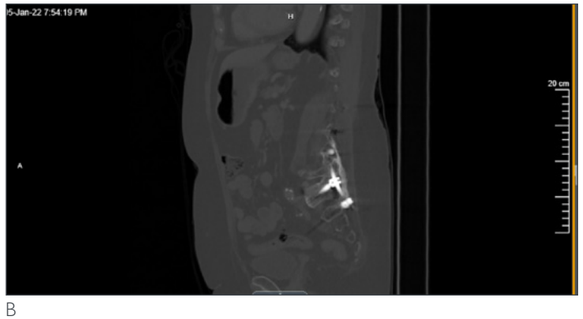
The patient had an uncomplicated post-operative course with improvement in pain and functionality post-operatively. CT was obtained nine-months post-operatively showing bone remodeling and graft resorption in the MagnetOs fusion bridge, evidenced by the trabecular structure and loss of granular appearance.



Pre-operative Anterior-Posterior (AP) and Lateral X-rays showing a previous spinal arthrodesis from L2-S1.



A



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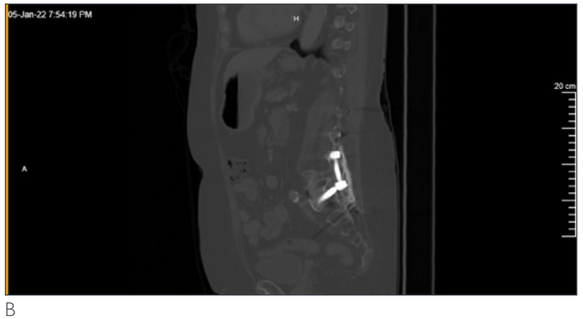

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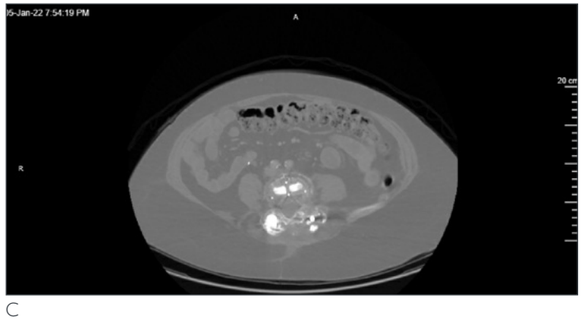

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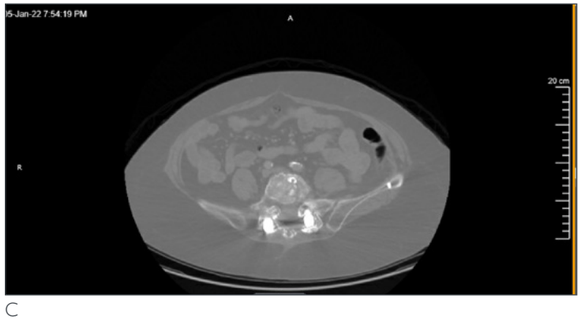

C

Nine-month post-operative (A) coronal, (B) sagittal, and (C) axial CT images of revision arthrodesis L2-pelvis.

Discussion

Low supply and co-morbidities involved with harvesting gold standard bone graft from the iliac crest, have caused surgeons to turn to alternative options for bone graft to achieve bony fusion in the spine. Each category of bone graft has advantages and disadvantages, and no one bone graft is ideal for every procedure or every patient. Utilizing a novel submicron needle-shaped surface topography, called NeedleGrip, MagnetOs provides traction for our body's vitally important pro-healing immune cells (M2 Macrophages).*†[9,13] This, in turn, unlocks previously untapped potential to stimulate stem cells and form new bone throughout the graft, leading to a predictable bony fusion.*‡[10-12]

Each of the reported case studies in this series demonstrated successful radiographic outcomes. There were no device-related adverse events reported and none of the patients required revision surgery within 12 months following the index procedure. Despite this being a small cohort of patients, these preliminary findings indicate that MagnetOs is an effective bone graft for posterolateral fusion, worthy of future clinical research.

Conclusion

This case series review demonstrates the efficacy of MagnetOs as an extender to autograft in a retrospective cohort of patients undergoing posterolateral fusion.

With acknowledgement to Rachael Wolfe.

References

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*Results from in vivo laboratory testing may not be predictive of clinical experience in humans. For important safety and intended use information please visit kurosbio.com. †MagnetOs is not cleared by the FDA as an osteoinductive bone graft. ‡MagnetOs has been proven to generate more predictable fusions than two commercially available alternatives in an ovine model of posterolateral fusion.

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