Use of novel biphasic calcium phosphate with submicron surface topography in interbody fusion

MagnetOs™ Whitepaper

MAGNETOS™
for predictable fusions

Kuros Biosciences

Use of novel biphasic calcium phosphate with submicron surface topography in posterolateral fusion

Introduction

The number of people ≥ 60 years of age is predicted to rise from 90 million to 2 billion by the year 2050 (WHO 2019). As expected, the number of spine fusion procedures continues to increase proportionately with the aging population.[1,2] The average age for spinal fusion has increased in recent years as has the number of spinal fusion procedures performed annually.[3] Interbody fusion is an effective surgical treatment option to address back pain through the stabilization of painful motion segments. A common obstacle associated with spine surgery is the lack of available local autograft. As a result, surgeons continue to search for the most advanced and affordable bone graft in order to achieve successful spine fusion without the well-known co-morbidities related to harvesting autograft.[4] Synthetic calcium phosphate bone graft usage has increased in recent years as these have demonstrated support of bone formation and reduced the need to harvest large amounts of autologous bone.[5,6] This class of bone graft closely resembles the composition of human cancellous bone and has proven to be cost-effective with a very low incidence of adverse reactions and graft-related complications.[7]

The body's natural response to spinal surgery is the upregulation of macrophages, especially the pro-inflammatory M1 phenotype.[8,9] This can lead to the formation of scar tissue and ultimately, a non-union. MagnetOs is a biphasic calcium phosphate (BCP) bone graft with a unique submicron surface topography. Its submicron needle-shaped surface features have been shown, using in vitro studies of human-derived monocytes, to promote attachment and spreading of M2 macrophages, reliably leading to the formation of bone instead of scar tissue.[10]

In preclinical studies, MagnetOs has been shown to promote bone formation; even in soft tissue, without the need for added cells or growth factors.*[11] MagnetOs is designed to mimic the porous, trabecular structure of cancellous bone. Clinically-relevant animal models demonstrate that bone formation takes place throughout MagnetOs simultaneously, leading to uniform, solid and stable fusions.*[12-14]

The purpose of this evaluation of a consecutive case series was to assess radiographic success, functional and pain outcomes following interbody fusion using a novel biphasic calcium phosphate bone graft with a unique submicron topography (MagnetOs, Kuros Biosciences, B.V.).

Methods

Two female patients with an average age at the time of surgery of 67 (62-72 years) underwent a two, or three-level interbody fusion procedure for the treatment of degenerative spine conditions using MagnetOs. Each of these cases involved a perimenopausal or a postmenopausal woman; a life stage known to negatively affect bone quality and cause concern when aiming for a successful fusion outcome.

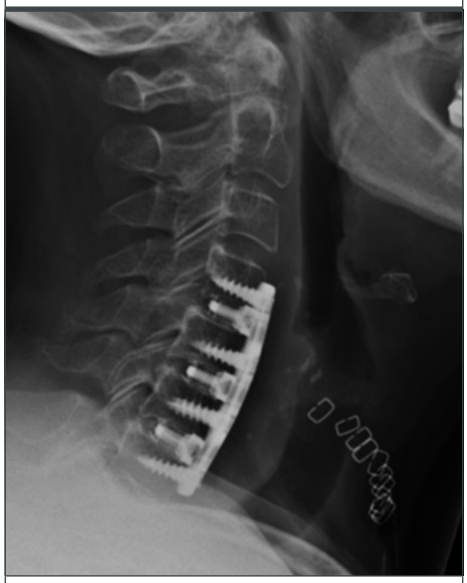
Anteroposterior and lateral radiographs, visual analog scale (VAS) for back and leg pain, Oswestry Disability Index (ODI or it's modified form NDI), and medication usage were reviewed pre-operatively and post-operatively at approximately 6, and 12 months. VAS and ODI scales were not available past 6 months; however, considering the marked improvement reported by each patient at 6 months, no significant improvement beyond this time point would be appreciated.

Case Study 1

A 72-year-old female with insufferable, 8/10 neck pain with bilateral paresthesia in her arms and poor NDI functional score of 68. Following a preoperative course of conservative care including physical therapy, facet joint injections, and a combination of oral pain medications of Tramadol and Tylenol (OTC), she was evaluated for surgical intervention. In the course of the presurgical evaluation, a bone density scan revealed a T-score of -2.5 and bisphosphonates were prescribed as part of the preoperative plan. Radiographic findings showed degeneration at C4-C7, facet arthritis C2-C5, and a SPECT scan demonstrated increased intensity at C5-C7.

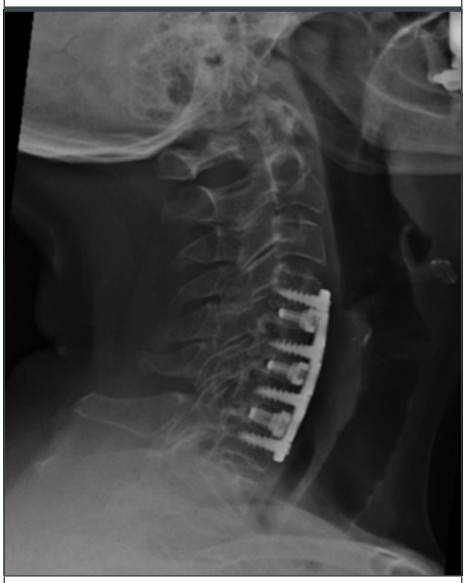
The surgical plan involved an anterior cervical discectomy and fusion (ACDF) at C4-C5, C5-C6, and C6-C7 utilising an integrated titanium/PEEK cervical fusion cages with anterior plating, packing 5cc of MagnetOs Granules inside each of the cages. Imaging at 6 months post-operative shows signs of fusion progression with early bridging bone. The patient reported complete resolution of pain with 0/10 neck pain on VAS, requiring no pain medications. Her NDI functional score dropped to 18, representing a 26% improvement. At the 12-month visit, radiographs demonstrated a complete bony fusion and pain medication remained unnecessary. Clinically, there was no need for further surgery.

Post-op



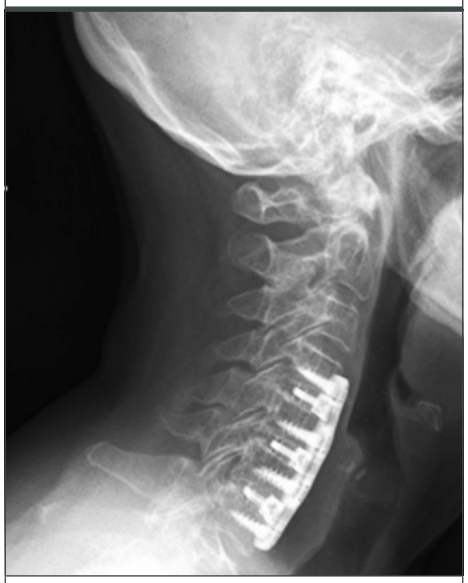
Early post-procedure signs of graft integration within the interbody cages

6 month Post-op



Signs of fusion progression with early bridging at 6 months post-procedure

12 month Post-op



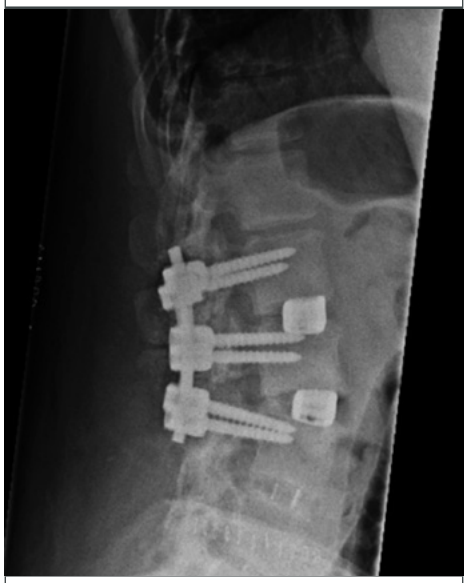
Observable complete transition from MagnetOs Granules to solid bony fusion at 12 months post-procedure

Case Study 2

A 62-year-old female with back pain, bilateral leg pain, and paresthesia. She required the use of a wheelchair to ambulate and has resultant paraspinal muscle atrophy. She had lumbar fusion surgery at L4-5, L5-S1 10 years prior. Patient reported pre-operative 10/10 back pain, 9/10 leg pain, and a very poor ODI function score of 78. Conservative care included physical therapy and pain medication through a combination of Duragesic, Duloxetine, and Amitriptyline. MRI and plain radiographs showed degeneration at L2-3, degenerative spondylolisthesis at L3-4, and a fusion L4-S1 with loss of lordosis. The surgical plan involved extending the posterior fusion above the previous fusion levels and decompression at L3-4. A 2-level posterolateral fusion with fixation at L2-3, L3-4 placing MagnetOs Granules mixed with local bone in the intertransverse process area was performed in combination with extreme lateral interbody fusion (XLIF) at the same levels.

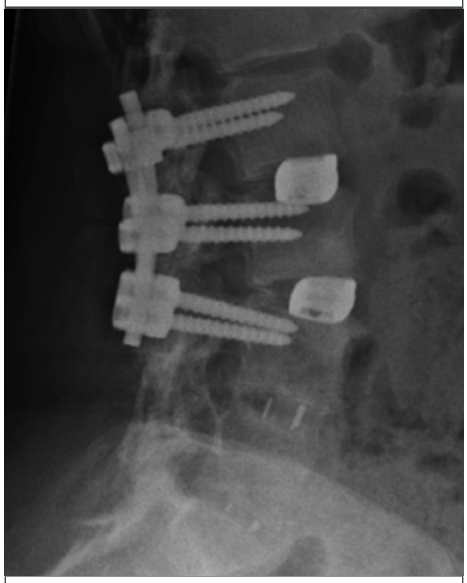
MagnetOs Granules were packed into both interbody cages. Radiographs at 5 months demonstrated fusion progression, good incorporation of MagnetOs into the fusion bed and graft resorption evidenced by the change from granular to more trabecular appearance. The patient was still rehabilitating but reported significantly improved pain and function scores. There was a 60% reduction in back pain with the patient-reported score dropping from 10/10 to 4/10 on the VAS. Leg pain, improved 88%, with a patient-reported decreased from 9/10 to 1/10. The patient achieved a 51% improvement in ODI score with a drop from 78 to 40. Pain medication usage reflected the reported improvement in pain. At 9 months, the radiographs revealed a solid fusion bilaterally and medication had been reduced to only Tramadol 50 mg, as needed.

Post-op



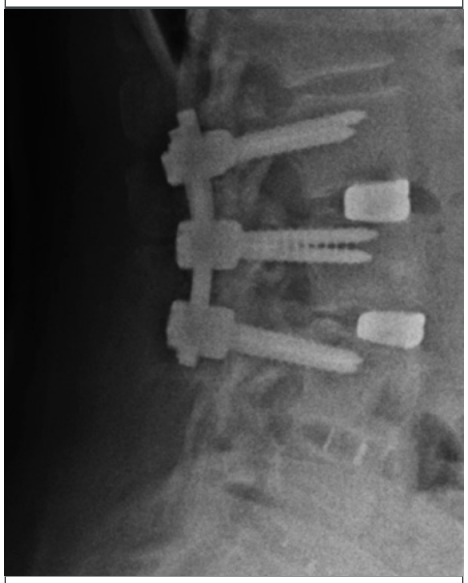
Early post-operative incorporation at 2 months post-procedure

5 month Post-op



Fusion progression at 5 months post-procedure

9 month Post-op



Complete fusion evidenced by the solid bone formation at 9 months post-procedure

Discussion

In the 1950s the first interbody device developed was the bone dowel graft, which was often obtained from the iliac crest. The comorbidities associated with iliac crest bone harvest are well documented in the literature. While autograft is still considered the 'gold standard', in 1988 the first cylindrical-shaped interbody fusion cage allowing for bony ingrowth was developed.[13] However, the donor-site pain and other related autograft harvest complications drove the ongoing search for viable alternatives to autograft. This ultimately led surgeons to look to allograft and newly developed synthetic materials. Historically, conventional synthetic bone grafts, such as β-TCP, have underperformed when compared to autograft in spinal fusion.[14,15] The cases described herein clearly demonstrate the effective use of a biphasic calcium phosphate with a novel submicron surface topography in achieving fusion in the intervertebral spine. This cohort includes two (2) women of menopausal age at risk for diminished host bone quality, one prescribed a bisphosphonate for known osteopenia/osteoporosis. MagnetOs Granules were packed inside the interbody cages with full consideration of the comorbidities known within the older population, such as hypertension, diabetes, and osteopenia/osteoporosis.

Radiographically each case reported successful outcomes whilst pain and function scores also improved. Regular follow-up X-rays showed the integration of the graft with trabecular bone over time. Significant pain and function improvements were demonstrated with an 80% average (60%-100%) improvement in back/neck pain. The function scores improved an average 44 points (range 38-50 points) representing a 38.9% average score improvement. Prescribed pain medication usage was dramatically reduced or eliminated. There were no device-related adverse events reported and neither 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 interbody fusion, worthy of future clinical research.

Conclusion

This case series review demonstrates successful fusion results in an aged and bone density challenged group. It shows that MagnetOs directs bone formation early in the healing process and the graft resorbs at a physiologically balanced rate, thus supporting the transition from woven to trabecular bone and the development of a uniform, stable and solid fusions. These outcomes further substantiate the results from preclinical studies that MagnetOs is an ideal bone graft for use in spine fusion.

References

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* Results from in vitro or in vivo 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, warnings and precautions.

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