

MagnetOsTM

Global Research Summary

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1. Clinical Evidence

Efficacy of Biphasic Calcium Phosphate Ceramic With a Needle-shaped Surface Topography Versus Autograft in Instrumented Posterolateral Spinal Fusion: A Randomized Trial



Authors: Stempels H¹, Lehr M², Delawi D², Hoebink E³, Wiljouw W³, Kempen D⁴, van Susante J⁵, Kruijt M¹

Affiliations: 1) Department of Orthopaedic Surgery, University Medical Center Utrecht, Utrecht, The Netherlands; 2) Department of Orthopaedic Surgery, St. Antonius Hospital, Utrecht, The Netherlands; 3) Department of Orthopaedic Surgery, Amphia Hospital, Breda, The Netherlands; 4) Department of Orthopaedic Surgery, OLVG, Amsterdam, The Netherlands; 5) Department of Orthopaedic Surgery, Rijnstate Hospital, Arnhem, The Netherlands

Study Design: A multicenter randomized controlled noninferiority trial with inpatient comparisons

Date: June 2024

Publication: Spine

Summary: This multicenter trial was initiated to determine non-inferiority of MagnetOs™ Granules used standalone as compared to autograft in instrumented posterolateral spinal fusion. Analysis of 91 patients (128 segments) reported a MagnetOs Granules fusion rate of 79% (101/128 segments) and an autograft fusion rate of 47% (60/128 segments). Primary fusion rate analysis confirmed the non-inferiority of MagnetOs compared to autograft and even indicates the superiority of MagnetOs.

Citation: Stempels HW, Lehr AM, Delawi D, Hoebink EA; Wiljouw IAAA; Kempen DHR, van Susante JLC, Kruijt MC, Dutch Clinical Spine Research Group. Efficacy of Biphasic Calcium Phosphate Ceramic With a Needle-shaped Surface Topography Versus Autograft in Instrumented Posterolateral Spinal Fusion: A Randomized Trial. *Spine (Phila PA 1976)*. 2024;49(19):1323-1331. DOI: 10.1097/BRS.0000000000005075.

Access: Scan or [click link](#) to access the publication



Biphasic Calcium Phosphate Bone Graft With a Unique Surface Topography: A Single-Center Ambispective Study for Degenerative Disease of the Lumbar Spine



Authors: Nunley P¹, Sanda M¹, Googe H², Cavanaugh D³, Sage K⁴, Ryaby J⁵, Stone MB²

Affiliations: 1) Spine Surgery, Spine Institute of Louisiana, Shreveport, USA. 2) Spine, Spine Institute of Louisiana, Shreveport, USA. 3) Neurosurgery, Spine Institute of Louisiana, Shreveport, USA. 4) Orthopedic Surgery, Kuros Biosciences USA, Inc. 5) Spine, Kuros Biosciences USA, Inc., Atlanta, USA

Study design: This study is an ambispective evaluation and analysis of a single-center cohort

Date: April 2024

Publication: Cureus

Summary: Sixty-three patients with one- to three-level anterior (48, 76%) and lateral (15, 24%) interbody fusions with posterior instrumentation were analyzed at 12 or more months postoperative. Thirty-one participants (49%) had three or more comorbidities, including heart disease (43 participants, 68%), obesity (31 participants, 49%), and previous lumbar surgery (23 participants, 37%). The mean ODI decreased by 24. The mean SF-12 physical health and SF-12 mental health improved by a mean of 11.5 and 6.3, respectively. The mean VAS for the left leg, right leg, and back improved by a mean of 25.75, 22.07, and 37.87, respectively. Of 101 levels, 91 (90%) demonstrated complete bridging trabecular bone fusion with no evidence of supplemental fixation failure.

Citation: Nunley P, Sanda M, Googe H, Cavanaugh D, Sage K, Ryaby J, Stone MB. Biphasic Calcium Phosphate Bone Graft With a Unique Surface Topography: A Single-Center Ambispective Study for Degenerative Disease of the Lumbar Spine. *Cureus*. 2024;16(4):e58218. DOI: 10.7759/cureus.58218. PMID: 38745797; PMCID: PMC11091845.

Access: Scan or [click here](#) to access this publication



From Benchtop to Clinic: A Translational Analysis of the Immune Response to Submicron Topography and Its Relevance to Bone Healing



Authors: van Dijk L¹, Barrère-de de Groot F¹, Yuan H¹, Campion C¹, Patel A², Poelstra K³, de Bruijn J¹

Affiliations: 1) Kuros Biosciences 2) Northwestern Medicine 3) The Robotic Spine Institute of Las Vegas

Date: June 2021

Publication: European Cells and Materials

Summary: This translational analysis of the immune response to submicron surface topography and its relevance to bone healing introduces the concept of osteoimmunology and immunomodulation through the polarization of M2 macrophages, and how that polarization is modulated through a bone graft with submicron needle-shaped surface topography. In vitro and in vivo data are analyzed, with the authors concluding that biomaterials with specific surface structures will induce a pro-healing immune response leading to bone formation. Furthermore, material-directed bone formation is translated into reliable spinal fusion outcomes in relevant pre-clinical models and human patients.*

Citation: van Dijk LA, de Groot F, Yuan H, Campion C, Patel A, Poelstra K, de Bruijn J. From benchtop to clinic: a translational analysis of the immune response to submicron topography and its relevance to bone healing. *Eur Cell Mater.* 2021;18;41:756-773. DOI: 10.22203/eCM.v041a48. PMID: 34151417.

Access: Scan or [click link](#) to access the publication



Arthrodesis of the Subtalar Joint Using a Novel Biphasic Calcium Phosphate Bone Graft



Authors: Fusco T¹, Sage K², Rush S¹, Blom F¹, Colvin K¹

Affiliations: 1) Orthopedic Associates, Florida 2) Kuros Biosciences

Study design: Retrospective level IV study

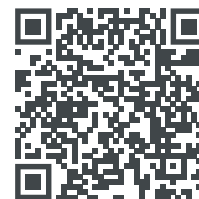
Date: January 2022

Publication: Foot & Ankle Surgery: Techniques, Reports & Cases

Summary: In this Retrospective Review, 32 consecutive patients undergoing subtalar arthrodesis surgery were evaluated: the first consecutive 15 patients were treated with various bone grafts including Demineralized Bone Matrices (DBM or Fibers), Bone Morphogenetic Protein (BMP), Cell Based Allograft (CBA), and Platelet Derived Growth Factor (PDGF), while the next consecutive 17 patients underwent fusion with MagnetOs™ Putty either as a standalone bone graft or mixed with BMA. The MagnetOs Putty group had a complete fusion rate of 70%, while the control group had a complete fusion rate of 46%, measured via plain radiograph (3 views) at twelve weeks.

Citation: Fusco TA, Sage K, Rush S, Blom F, and Colvin K. Arthrodesis of the subtalar joint using a novel biphasic calcium phosphate bone graft. *Foot & Ankle Surgery: Techniques, Reports & Cases*. 2022;2(1):100150.

Access: Scan or [click link](#) to access the publication



A Retrospective Review of MagnetOs™ Easypack Putty Bone Graft Used Standalone in Transforaminal Lumbar Interbody Fusion



Authors: Davis J¹, Everist B¹, Butrico C², Sage K²

Affiliations: 1) The University of Kansas Health System, Kansas City, KS, USA. 2) Kuros Biosciences, Atlanta, GA, USA

Manuscript Submitted

Summary: In this Retrospective Review, twenty subjects receiving a transforaminal lumbar interbody fusion from L2-L3 to L5-S1 with standalone MagnetOs Easypack Putty were evaluated. The average BMI was 32.30 and thirteen (65%) patients were considered obese with a BMI > 30.0. Seven (35%) patients were diabetics and six (30%) patients had previous lumbar surgery. The primary endpoint was radiographic fusion at 12 months post-surgery with each level graded on CT-based Brantigan-Steffee-Fraser (BSR) Classification by an independent, blinded physician. Of the thirty-six levels treated, thirty-four (34/36 levels, 94.6%) were considered fused at twelve months post-surgery. A 25% reduction in VAS pain scores were also recorded at 12 months post-surgery.

MagnetOs Easypack Putty is only commercially available in U.S.

Fusion Rate of Biphasic Calcium Phosphate Bone Graft with Needle-Shaped Submicron Topography in Interbody Lumbar Fusion for Degenerative Disc Disease: A Single-Center Retrospective Review



Authors: Wakelin S¹, Cobourn K², Stirrat T¹, Sage K³, Ryaby J³, Sandhu FA²

Affiliations: 1) Georgetown University Medical Center, Washington, DC, USA. 2) MedStar Georgetown University Hospital, Washington, DC, USA. 3) Kuros Biosciences, Atlanta, GA, USA

Manuscript Submitted

Summary: In this retrospective, single-center review, patients that underwent lumbar interbody arthrodesis for degenerative disc disease with MagnetOs™ were evaluated for fusion outcome 12 months post-operatively. Fusion was determined by an independent neuroradiologist assessing CT and using an alphanumeric classification based on bridging bone. Secondary outcomes included VAS, length of stay (LOS), and fusion of all treated levels. Fifty-five patients were assessed with a total of 93 levels treated. Procedures included anterior lumbar interbody fusion (52 levels, 55.91%), transforaminal lumbar interbody fusion (22 levels, 23.66%), and lateral lumbar interbody fusion (19 levels, 20.43%). Patients averaged 3 comorbidities including obesity (50.91%), previous lumbar surgery (49.09%), arthritis (41.82%), and heart disease (23.64%). Results indicated that 95.70% of all levels treated demonstrated bony ingrowth or trabecular bony fusion without supplemental fixation failure. Fifty-one patients (92.73%) demonstrated bony fusion of all treated levels at 12 months. Moreover, no statistical difference was observed between procedure types or when using MagnetOs as an extender compared to standalone. Six-month post-operative VAS improved by a mean of 25.10 and no statistical difference was observed in LOS.

2. Case Series and Case Studies

Effective Use of a Novel Biphasic Calcium Phosphate with Submicron Surface Topography in Posterolateral Spine Fusion



Author: Jones A

Affiliation: Spire Cardiff Hospital

Study Design: Case Series

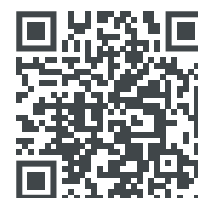
Date: April 2021

Publication: Juniper Online Journal of Case Studies

Summary: In this case series, four female patients underwent a single or a two- level posterolateral lumbar fusion procedure for the treatment of degenerative spondylolisthesis or deformity. In all cases, MagnetOs™ Granules was used on label in the posterolateral spine. All four patients had predictable fusion on imaging post-operatively, as well as improvement in functionality and decrease in Oswestry Disability Index scores.

Citation: Jones A. Effective use of a novel biphasic calcium phosphate with submicron surface topography in posterolateral spine fusion. *JOJ Case Stud.* 2021;12(2):555834. DOI: 10.19080/JOJCS.2021.12.555834.

Access: Scan or [click link](#) to access the publication



Posterior Thoracolumbar Hemivertebra Resection and Fusion with a Biphasic Calcium Phosphate Bone Graft with a Novel Submicron Surface Topography



Author: Sandhu FA

Affiliation: Georgetown University Hospital

Study Design: Case Study

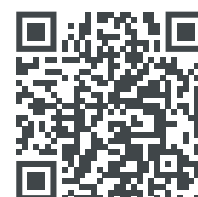
Date: December 2021

Publication: Juniper Online Journal of Case Studies

Summary: This case reports a 54-year-old female who underwent resection of a segmented T12 hemivertebra and T8-L3 fusion. Six weeks post-operatively, the patient had a sterile seroma requiring surgery, and the fusion mass was evaluated via second look surgery. At that time, the surgeon found robust bone formation and solid fusion mass with no granule migration.

Citation: Sandhu FA. Posterior thoracolumbar hemivertebra resection and fusion with a biphasic calcium phosphate bone graft with a novel submicron surface topography. *JOJ Case Stud.* 2021;12(2):555831. DOI:10.19080/JOJCS.2021.12.555831.

Access: Scan or [click link](#) to access the publication



Clinical, Radiographic, and Histologic Outcomes of Ankle Arthrodesis in a Diabetic Patient using a Biphasic Calcium Phosphate Bone Graft with a Novel Submicron Needle-shaped Surface Topography



Authors: Fusco T¹, van Dijk L², Sage K²

Affiliations: 1) Orthopedic Associates, Florida 2) Kuros Biosciences

Study Design: Case Study

Date: February 2022

Publication: Juniper Online Journal of Case Studies

Summary: This case details a patient with uncontrolled diabetes who underwent an uncomplicated ankle arthrodesis using MagnetOs™ Putty. Twelve-weeks post-operatively, the patient developed Charcot collapse of the subtalar joint and the fusion was converted to a tibiotalocalcaneal nail. On revision surgery, the ankle arthrodesis was palpated and visually inspected, and the surgeon found robust fusion mass and solid arthrodesis with no granule migration. Furthermore, histology taken from the fusion site confirmed mature lamellar bone at the arthrodesis and continued resorption of the bone graft at twelve-weeks post-operatively.

Citation: Fusco T, van Dijk L, Sage K. Clinical, Radiographic, and Histologic Outcomes of Ankle Arthrodesis in a Diabetic Patient using a Biphasic Calcium Phosphate Bone Graft with a Novel Submicron Needle-shaped Surface Topography. *JOJ Case Stud.* 2022;13(2):555857. DOI: 10.19080/JOJCS.2022.13.555857.

Access: Scan or [click link](#) to access the publication



Early Radiographic and Clinical Outcomes of Five Patients Undergoing Open Instrumented Posterolateral Fusion Surgery with MagnetOs™ Flex Matrix



Authors: Goodmanson R¹, Butrico C², Sage K²

Affiliations: 1) McLaren Hospital 2) Kuros Biosciences

Study Design: Case series

Date: October 2023

Publication: Juniper Online Journal of Case Studies

Summary: In this case series, five patients underwent lumbar or cervical posterolateral spinal fusion. These cases included a challenging patient population including revision surgeries, comorbidities, and cancer. All patients received MagnetOs Flex Matrix on-label in the posterolateral spine. Each patient had radiographic imaging with multiple imaging modalities and at various time points. Post-operative imaging revealed a consistent remodeling of bone and resorption of bone graft resulting in trabecular bone formation and loss of granular graft appearance as early as six weeks.

Citation: Goodmanson R, Butrico C, Sage K. Early Radiographic and Clinical Outcomes of Five Patients Undergoing Open Instrumented Posterolateral Fusion Surgery with MagnetOs Flex Matrix. *JOJ Case Stud.* 2023; 14(3): 555886. DOI: 10.19080/JOJCS.2023.14.555886.

Access: Scan or [click link](#) to access the publication.

MagnetOs Flex Matrix is only commercially available in U.S.



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



Authors: Elia C¹, Brais M¹, Butrico C², Sage K²

Affiliations: 1) Spine and Brain Surgery Specialists 2) Kuros Biosciences

Study Design: Case series

Date: March 2024

Publication: Juniper Online Journal of Case Studies

Summary: 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 four clinical cases where MagnetOs Easypack Putty was used on-label in the posterolateral spine. Radiographic fusion and patient reported outcomes demonstrate favorable outcomes using MagnetOs Easypack Putty.

Citation: Elia C, Brais M, Butrico C, Sage K. Early Radiographic and Clinical Outcomes of Three Patients Undergoing Open Instrumented Posterolateral Fusion Surgery with MagnetOs Easypack Putty. *JOJ Case Stud.* 2024; 14(4): 555895. DOI: 10.19080/JOJCS.2024.14.555895.

Access: Scan or [click link](#) to access the publication

MagnetOs Easypack Putty is only commercially available in U.S.



3. Pre Clinical Evidence*

Biphasic Calcium Phosphate with Submicron Surface Topography in an Ovine Model of Instrumented Posterolateral Spinal Fusion



Authors: van Dijk L^{1,2}, Duan R^{1,3}, Luo X¹, Barbieri D¹, Pelletier M⁴, Christou C⁴, Rosenberg A², Yuan H^{1,5}, Barrère-de Groot F¹, Walsh W⁴, de Bruijn J^{1,6}

Affiliations: 1) Kuros Biosciences 2) Department of Oral and Maxillofacial Surgery, University Medical Center, Utrecht 3) Biomaterial Science and Technology University of Twente Enschede 4) Surgical and Orthopedic Research Laboratories, Prince of Wales Clinical School University of New South Wales, Sydney 5) MERLIN Institute for Technology-inspired Regenerative Medicine, Maastricht University 6) School of Materials and Science Engineering, Queen Mary University of London

Date: November 2018

Publication: Journal of Orthopedic Research Spine

Summary: This study evaluated the performance of MagnetOs™ Granules and MagnetOs Putty used in posterolateral spine fusion against the gold standard of autograft in a clinically relevant, validated ovine model. Multiple endpoints were measured including manual palpation, range of motion, X-ray, CT, histology, and histomorphometry. The authors concluded that the MagnetOs Granules and MagnetOs Putty fusions developed complete bridging bone which was equivalent to autograft.

Citation: van Dijk LA, Duan R, Luo X, Barbieri D, Pelletier M, Christou C, Rosenberg AJWP, Yuan H, Barrère-de Groot F, Walsh WR, de Bruijn J. Biphasic calcium phosphate with submicron surface topography in an Ovine model of instrumented posterolateral spinal fusion. *JOR Spine*. 2018;28;1(4):e1039. DOI: 10.1002/jsp2.1039. PMID: 31463454; PMCID: PMC6686792.

Access: Scan or [click link](#) to access the publication



Efficacy of a Synthetic Calcium Phosphate with Submicron Surface Topography as Autograft Extender in Lapine Posterolateral Spinal Fusion



Authors: van Dijk L^{1,2}, Barbieri D¹, Barrère-de Groot F¹, Yuan H^{1,3}, Oliver R⁴, Christou C⁴, Walsh W⁴, de Bruijn J^{1,5}

Affiliations: 1) Kuros Biosciences 2) Department of Oral and Maxillofacial Surgery, University Medical Center, Utrecht 3) MERLIN Institute, Complex Tissue Regeneration, Maastricht University 4) Surgical and Orthopedic Research Laboratories, Prince of Wales Clinical School University of New South Wales, Sydney 5) School of Materials and Science Engineering, Queen Mary University of London

Date: December 2018

Publication: Journal of Biomedical Materials Research: Part B Applied Materials

Summary: This study evaluated the performance of MagnetOs™ Granules and MagnetOs Putty against the gold standard of autograft in a lapine model. Multiple endpoints were measured including manual palpation, range of motion, radiography, histology, and histomorphometry. The authors concluded that the MagnetOs Granules and MagnetOs Putty are effective autograft extenders for posterolateral fusion.

Citation: van Dijk LA, Barbieri D, Barrère-de Groot F, Yuan H, Oliver R, Christou C, Walsh WR, de Bruijn J. Efficacy of a synthetic calcium phosphate with submicron surface topography as autograft extender in lapine posterolateral spinal fusion. *J Biomed Mater Res B Appl Biomater*. 2019;107(6):2080-2090. DOI: 10.1002/jbm.b.34301. Epub. 2019 Jan 7. PMID: 30614621; PMCID: PMC6690075.

Access: Scan or [click link](#) to access the publication



Accelerated Bone Formation by Biphasic Calcium Phosphate with a Novel Sub-Micron Surface Topography



Authors: Duan R^{1,2}, van Dijk L^{2,3}, Barbieri D², de Groot F², Yuan H^{2,4}, de Bruijn J^{2,5}

Affiliations: 1) Biomaterial Science and Technology University of Twente Enschede 2) Kuros Biosciences 3) Department of Oral and Maxillofacial Surgery, University Medical Center, Utrecht 4) MERLIN Institute, Complex Tissue Regeneration, Maastricht University 5) School of Materials and Science Engineering, Queen Mary University of London

Date: January 2019

Publication: European Cells and Materials

Summary: In this study, four calcium phosphate bone grafts with different surface features and composition were implanted via blunt dissection into the soft tissue paraspinalis muscles in a canine model. The scientists found that calcium phosphates with submicron surface topography were able to form bone without added cells or growth factors, and that MagnetOs™ Granules with its needleshaped surface features led to accelerated bone formation. The authors concluded that surface feature size has the most impact on bone growth in soft tissues, followed by the surface feature morphology.

Citation: Duan R, van Dijk LA, Barbieri D, de Groot F, Yuan H, de Bruijn J. Accelerated bone formation by biphasic calcium phosphate with a novel sub-micron surface topography. *Eur Cell Mater.* 2019;28;37:60-73. DOI: 10.22203/eCM.v037a05. PMID: 30687909.

Access: Scan or [click link](#) to access the publication



MagnetOs™, Vitoss, and Novabone in a Multi-Endpoint Study of Posterolateral Fusion: A True Fusion or Not?



Authors: van Dijk L^{1,2}, Barrère-de Groot F¹, Rosenberg A², Pelletier M³, Christou C³, de Bruijn J^{1,4}, Walsh W³

Affiliations: 1) Kuros Biosciences 2) Department of Oral and Maxillofacial Surgery, University Medical Center, Utrecht 3) Surgical Orthopedic Research Laboratories, Price of Wales Clinical School 4) School of Engineering and Materials Science, Queen Mary University of London

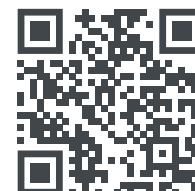
Date: July 2020

Publication: Clinical Spine Surgery

Summary: This study compared autograft, MagnetOs Putty, Vitoss BA2X, and Novabone in a clinically relevant, validated ovine model for posterolateral spine fusion. Multiple endpoints were measured including manual palpation, range of motion, X-ray, CT, histology, and histomorphometry. The study revealed clear differences in efficacy between commercially available bone grafts and demonstrated the efficacy of MagnetOs Putty, as this was the only material that showed equivalent performance to autograft in achieving spinal fusion.

Citation: van Dijk LA, Barrere-de Groot F, Rosenberg AJWP, Pelletier M, Christou C, de Bruijn J, Walsh WR. MagnetOs, Vitoss, and Novabone in a Multi-endpoint Study of Posterolateral Fusion: A True Fusion or Not? *Clin Spine Surg.* 2020;33(6):E276-E287. DOI: 10.1097/ BSD.0000000000000920. PMID: 31977334;PMCID: PMC7337107.

Access: Scan or [click link](#) to access the publication



Physico-Chemical Characteristics and Posterolateral Fusion Performance of Biphasic Calcium Phosphate with Submicron Needle-Shaped Surface Topography Combined with a Novel Polymer Binder



Authors: Belluomo R¹, Arriola-Alvarez I², Kucko N¹, Walsh W³, de Bruijn J^{1,4}, Oliver R³, Wills D³, Crowley J³, Wang T³, Barrère-de Groot F¹

Affiliations: 1) Kuros Biosciences 2) Tissue Engineering Group 3) Surgical Orthopedic Research Laboratories, Price of Wales Clinical School 4) School of Engineering and Materials Science, Queen Mary University of London

Date: February 2022

Publication: Materials

Summary: This study evaluated the performance of MagnetOs™ Easypack Putty against the gold standard of autograft in a posterolateral fusion lapine model. Multiple endpoints were measured including manual palpation, range of motion, radiography, histology, and histomorphometry. The authors concluded that MagnetOs Easypack Putty polymer hydrolyzes in physiological conditions, with the MagnetOs Granules exposed to lapine tissue after 3 days of implantation. The authors also found similar fusion rates between autograft bone and MagnetOs Easypack Putty after 12 weeks of implantation, with no migration of the Granules or adverse reactions.

Citation: Belluomo R, Arriola-Alvarez I, Kucko NW, Walsh WR, de Bruijn J, Oliver RA, Wills D, Crowley J, Wang T, Barrere-de Groot F. Physico-Chemical Characteristics and Posterolateral Fusion Performance of Biphasic Calcium Phosphate with Submicron Needle-Shaped Surface Topography Combined with a Novel Polymer Binder. *Materials (Basel)*. 2022;11;15(4):1346. DOI: 10.3390/ma15041346. PMID: 35207887;PMCID: PMC8880136.

Access: Scan or [click link](#) to access the publication

MagnetOs Easypack Putty is only commercially available in U.S.



Preclinical Evaluation of Synthetic Bone Graft Materials in an Instrumented Sheep Posterolateral Lumbar Spinal Fusion Model



Authors: Kucko N¹, Barrère-de Groot F¹, Wills D², Wang T², Pelletier M², de Bruijn J¹, Walsh W²

Affiliations: 1) Kuros Biosciences BV, Bilthoven, The Netherlands; 2) Surgical and Orthopaedic Research Laboratories, Prince of Wales Clinical School, University of New South Wales, Sydney, New South Wales, Australia

Manuscript accepted for review

Publication: Clinical Spine Surgery

Summary: This study evaluated the efficacy of MagnetOs™ Flex Matrix, i-FACTOR Putty®, OssDsign® Catalyst Putty and FIBERGRAFT® BG Matrix in a clinically relevant instrumented sheep posterolateral spinal fusion (PLF) model. The performance was measured after 12 weeks implantation using a comprehensive range of assessment tools including manual palpation, radiograph and μ CT imaging (based on the Lenke scale), non-destructive range-of-motion mechanical testing, histological and histomorphological evaluation.

The results show distinct differences in the fusion performance between the different synthetic bone graft substitutes, highlighting the importance of utilizing clinically relevant animal models with robust, multi-endpoint analyses to evaluate their efficacy. Specifically, MagnetOs Flex Matrix achieved superior fusion rates compared to three commercially-available synthetic bone grafts when used standalone, further demonstrating its enhanced bone-forming ability *in vivo*.

Citation: Kucko NW, et al. Accepted for review. *Clinical Spine Surgery*. 2025.

MagnetOs Flex Matrix is only commercially available in U.S.

4. Scientific Evidence*

Calcium Phosphate with Submicron Topography Influences Primary Human Macrophage Response, Enhancing Downstream Angiogenesis and Osteogenesis in Vitro



Authors: van Dijk L^{1,2,4}, Utomo L^{2,3}, Yuan H¹, Barrère-de Groot F¹, Gawlitta D^{2,4}, Rosenberg A², de Bruijn J¹

Affiliations: 1) Kuros Biosciences 2) Department of Oral and Maxillofacial Surgery, University Medical Center, Utrecht 3) Department of Clinical Sciences, Faculty of Veterinary Medicine, Utrecht University, Utrecht 4) Regenerative Medicine Center Utrecht 5) Queen Mary University of London

Date: January 2023

Publication: Journal of Immunology and Regenerative Medicine

Summary: In this in vitro study, the response of primary human macrophages to different calcium phosphate bone graft substitutes was assessed. Human immune cells were seeded on two different calcium phosphate materials. The first material had a submicron topography of needle-shaped crystals (BCPμm, MagnetOs™) while the second material had no submicron topography (TCP). Macrophage phenotype characterization indicated stronger macrophage activation and phenotypic skewing toward the M2 phenotype on BCPμm vs TCP. Furthermore, macrophages cultured on BCPμm resulted in enhanced in vitro angiogenic tube formation (vascular supply) and osteogenic differentiation of mesenchymal stromal cells when compared to macrophages cultured on TCP. Altogether, these findings suggest a potential role of M2 macrophage upregulation in the bone-induction mechanism of calcium phosphates with submicron surface topography.

Citation: van Dijk LA, Utomo L, Yuan H, Barrere-de Groot F, Gawlitta D, Rosenberg AJWP, de Bruijn J. Calcium phosphate with submicron topography influences primary human macrophage response, enhancing downstream angiogenesis and osteogenesis in vitro. *Journal of Immunology and Regenerative Medicine*. 2023; 19 (2023) 100070. DOI: 10.1016/ j.regen.2023.100070.

Access: Scan or [click link](#) to access the publication



5. Whitepapers

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



Authors: The Orthopedic Surgery Department

Affiliation: The University of California, San Diego

Study Design: Case Series

Date: April 2022

Publication: Clinical Whitepaper

Summary: This whitepaper details the use of MagnetOs™ Putty used as a bone graft extender in two challenging revision cases. Both subjects had predictable fusions and reduction in pain scores post-operatively.

Access: Scan or [click link](#) to access the publication



6. Ongoing Clinical Studies

Post Marketing Study of MagnetOs™ Putty Compared to Demineralized Bone Matrix (DBM or Fibers) in Patients Undergoing Posterolateral Lumbar Fusion (PROOF)



ClinicalTrials.gov Identifier: NCT04679844

Study Design: Prospective, randomized, intra-patient controlled, multi-center study

Summary: A prospective, randomized, multi-center study of MagnetOs Easypack Putty compared to DBM or Fibers mixed with autograft in patients undergoing 2-level instrumented posterolateral lumbar fusion.

Access: Scan or [click link](#) for ClinicalTrials.gov

MagnetOs Easypack Putty is only commercially available in U.S.



MagnetOs™ Flex Matrix Compared to a Cellular Based Allograft (CBA) in Patients Undergoing up to Four-level Instrumented Posterolateral Fusion (PRECISE)



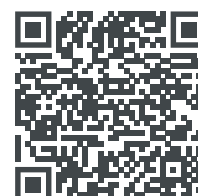
ClinicalTrials.gov Identifier: NCT05037968

Study Design: Prospective, randomized, multi-center study

Summary: A prospective, randomized, multi-center study to assess the performance of MagnetOs Flex Matrix compared to a cell based allograft in patients undergoing up to 4-level instrumented posterolateral lumbar fusion.

Access: Scan or [click link](#) for ClinicalTrials.gov

MagnetOs Flex Matrix is only commercially available in U.S.



*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, precautions and warnings. For important safety and intended use information please visit kurosbio.com. MagnetOs is not cleared by the FDA or TGA as an osteoinductive bone graft.

Manufactured by **Kuros Biosciences BV**

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kurosbio.com

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