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General

A retrospective review of MagnetOs Easypack Putty™ bone graft used standalone in transforaminal lumbar interbody fusion

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Background

Spinal fusion surgeries remain a successful treatment for degenerative disc disease. While autograft is considered the gold standard bone graft, synthetic bone void fillers are increasingly used to limit donor site morbidity while giving sufficient graft volume.

Methods

This retrospective clinical study evaluates MagnetOs Easypack Putty™ as a standalone graft without autograft in interbody fusion. An independent radiologist blinded to the clinical status provided evaluation of computed tomography (CT) images obtained at 12 months and graded each treated level based on the Brantigan-Steffee-Fraser (BSF) Classification. Twenty subjects were enrolled in the study. A total of 36 spinal levels were treated with an average of 1.8 levels per subject (L2-L3 to L5-S1).

Results

The primary endpoint of CT-based fusion was 94.4% (34/36 levels) based on the presence of bridging bone or locked pseudoarthrosis at 12 months. The high fusion rate was accompanied by consistent improvement in pain scores. Visual analogue scale (VAS) pain scores decreased an average of 25% from 5.3/10 pre-operatively to 2.8/10 at 12 months post-operative, and all subjects who reported pre-operative back or leg pain reported improved pain post-operatively. Although the patient population included risk factors and comorbidities, the fusion rate remained high, and no device-related adverse events (AEs) were observed.

Conclusions

The high fusion rate and favorable safety profile support the performance of MagnetOs Easypack Putty for standalone use without autograft in interbody fusion procedures.

INTRODUCTION

Autograft is considered the gold standard bone grafting material in spinal fusion surgeries. However, the morbidity associated with autograft includes chronic pain at the donor site after iliac crest harvest,[1] added operative time and blood loss, and increased infection risk due to this second operation.[2,3] Further, the volume of cancellous bone that can be harvested is limited.[4]

With these limitations, the ability of other bone grafts to serve as alternatives to autograft have been explored for spinal fusion. MagnetOs Easypack Putty consists of 65–75% tri-calcium phosphate (TCP; $Ca_3(PO_4)_2$) and 25–35% hydroxyapatite (HA; $Ca_{10}(PO_4)_6(OH)_2$) granules with a unique submicron surface topography, premixed with a synthetic polymeric binder that provides cohesion between the granules. While the polymeric binder is rapidly degraded after implantation, the granules of MagnetOs Easypack Putty guide the three-dimensional regeneration of bone in the defect site into which it is implanted. New bone is deposited throughout the graft when placed next to viable host bone, through core repair.[5] The graft resorbs and is replaced by bone during the natural process of bone remodeling.[6^]

Multiple bone void fillers have been approved for use in posterolateral fusion and are supported by animal models of posterolateral fusion while few are cleared for use in the intervertebral space. This study is a retrospective evaluation of patients with degenerative disc disease who had previously received MagnetOs Easypack Putty. A diverse cohort of patients is represented with no enrollment restrictions based on co-morbidities such as diabetes, high BMI, and heart disease. Additionally, this study does not limit subjects with risk factors for fusion such as tobacco use, fu-

Table 1. Inclusion/Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
1. Have clinical or radiological evidence of degenerative disc disease of the lumbar spine. 2. Have been treated with MagnetOs Easypack Putty between the dates of October 2022 and October 2023. 3. Be at least 22 years of age. 4. Have current contact information. 5. Be willing and able to undergo a CT scan and X-rays. 6. Be willing and able to complete patient-centered outcomes questionnaires.	1. Currently imprisoned. 2. Currently experiencing major mental illness (psychosis, schizophrenia, major affective disorder) which may indicate that the symptoms are psychological rather than of physical origin. 3. No current contact information. 4. X-rays or CT scan are contraindicated. 5. Any previous lumbar fusion or arthroplasty surgery at the index level(s).

sion of multiple levels, and prior lumbar surgeries. Cumulatively, these factors have the potential to impact the safety and success of interbody fusion procedures but are representative of the breadth of challenging patient populations that need surgery for degenerative disc disease.

MATERIALS AND METHODS

This clinical study was conducted at a single center, in accordance with the protocol, the ethical principles that have their origin in the Declaration of Helsinki, and Good Clinical Practice and applicable regulatory requirements including IRB review and approval. This study was a single-arm, retrospective evaluation of patients who received MagnetOs Easypack Putty standalone without mixing with autograft as part of an interbody fusion surgery.* The charts of enrolled subjects were reviewed to collect information about the interbody fusion procedure. Subjects were considered to have concluded the study after completing the physical exam, patient-centered outcome questionnaires, X-rays, and CT scan (approximately 12 months post-operative). All subjects who met the inclusion criteria and did not meet the exclusion criteria were included in the study (**Table 1**). The study was designed to enroll up to 20 subjects.

The study consisted of a retrospective review of subjects' medical records, collection of available imaging (CT scans and X-rays), and patient-reported outcomes questionnaires. Patient charts were reviewed for visual analog scales (VAS) for pain, radiographs, MRIs, CT scans, demographics, medical history, social history, surgical history, and post-surgical care to collect data regarding complications, determine factors that may affect the performance of MagnetOs Easypack Putty, and determine clinical and radiologic outcomes as previously described. Collected X-rays and CT scans were interpreted by an independent physician who was not involved in the subjects' clinical care, blinded to the clinical status of the patients.

The primary endpoint of this study was radiographic fusion at 12 months post-surgery. Each level was graded on the CT-based Brantigan-Steffee-Fraser (BSF) Classification by an independent and blinded physician. The BFS scores were used to determine whether each level was "Fused" or "Not Fused".[7] Grade 1 of the BSF Classification is considered "Not Fused" because it corresponds to pseudoarthrosis, collapse of the loss of disc height, vertebral slip, broken screws, displacement of the cage, or significant resorption of the bone graft with lucency around the periphery of the graft or cage. Grades 2 and 3 were both considered "Fused", capturing solid construct bridging the two vertebrae.

Secondary outcomes assessed included baseline to post-operative change in the VAS for pain and change or maintenance of neurologic status from baseline compared to post-operative visits. Duration of hospitalizations, number of patients with complications considered to be related to the subject device within 12 months post-surgery, and number of patients that underwent revision/reoperation within 12 months post-surgery were monitored.

Adverse events (AE), including adverse device effects, were collected. An AE was defined as any undesirable deviation from the subject's baseline condition to include all new conditions or symptoms or worsening of the pre-existing condition or symptoms regardless of the cause. The intensity of the AE was determined by the investigator using the following definitions and was not necessarily the subject's interpretation: mild indicated the AE was commonly asymptomatic or caused minimal symptoms and did not require active intervention; moderate indicated the AE caused discomfort and required treatment but did not pose any significant or permanent risk to harm the subject; severe indicated incapacitating event with inability to perform usual activities, necessitating medical or surgical intervention to preclude permanent disability.

ETHICAL CONSIDERATIONS

This clinical study was conducted at a single center, in accordance with the protocol, the ethical principles that have their origin in the Declaration of Helsinki, and Good Clinical Practice and applicable regulatory requirements including IRB review and approval at The University of Kansas Health System. Patient consent was waived due to the retrospective and de-identified data collection.

RESULTS

Twenty subjects met the inclusion/exclusion criteria and were enrolled in the study (**Table 2**). Of the 20 subjects, 11

Table 2. Demographics and Comorbidities

Number of Subjects	N=20
Sex	11 Female, 9 Male (55% Female)
Age	67.2 years [range: 42-78]
Body Mass Index (BMI)	BMI Average: 32.30 [range: 19.77 – 47.55] BMI >30.0: 13/20 (65%)
Tobacco Use	Never smoked: 9/20 (45%) Former smoker: 9/20 (45%) Current smoker: 2/20 (10%)
Previous Lumbar Surgery	6/20 (30%)
Diabetes	7/20 (35%)

Table 3. Fusion Surgical Procedures

Fusion Procedure	Frequency
Interbody Fusion	20/20 subjects (100%)
Total Fusion Levels	36 levels in 20 subjects
Average Fusion Level	1.8 fusions per subject
L2-L3	3/36 levels (8.3%)
L3-L4	12/36 levels (33.3%)
L4-L5	19/36 levels (52.8%)
L5-S1	2/36 levels (5.6%)
Interbody Fusion Only	17/20 subjects (85%)
Interbody and Posterolateral Fusion	3/20 subjects (15%; all open surgeries)

were females (55%) and 9 were males (45%) with an average age of 67.2 years. The average body mass index (BMI) for the study population was 32.30 (range 19.77 to 47.55) and 65% were considered obese with a BMI greater than 30.0. An equal number of subjects never smoked (9/20; 45%) or were former smokers (9/20; 45%), and 2 of 20 subjects (10%) were current smokers. Seven of the 20 subjects (35%) had diabetes (**Appendix 1**).

All subjects in the study had transforaminal lumbar interbody fusion (TLIF) spine surgery. All but 3 subjects had minimally invasive surgeries (MIS) (17/20; 85%). Three subjects received a concurrent posterolateral fusion, necessitating an open surgery (3/20 subjects; 15%). All subjects enrolled in the study had an interbody fusion procedure with a total of 36 levels treated in the study (average of 1.8 levels per subject; **Table 3**). The fusion levels ranged from L2-L3 to L5-S1 (**Appendix 2**).

Consistent with the inclusion/exclusion criteria, all subjects received MagnetOs Easypack Putty for interbody fusion. MagnetOs Easypack Putty was used standalone and not mixed with autograft in all 20 subjects.* The average amount of MagnetOs Easypack Putty used in interbody fusion ranged from 1.125 to 3.3 cc (average of 2.0 cc, **Appendix 2**). Subjects who also received a posterolateral fusion all received a MagnetOs bone graft in the posterolateral space.

The primary endpoint for this study was fusion at 12 months as determined by CT imaging. An independent radiologist not involved in the subjects' clinical care and blinded to clinical status evaluated each fusion level with the CT-based BSF classification. Fusion for each level was classified from grade 1 to 3. CT imaging was obtained at an average of 12.6 months post-operative with a range of 12 to 14 months. Of the 36 treated levels, 34 levels (94.4%) were considered fused, and 2 levels (5.6%) were considered not fused at 12-14 months (**Table 4** and **Appendix 3**). A representative pre-operative MRI and X-ray reveal degenerative disc disease of the lumbar spine (**Figure 1A-C**). CTs 1-year post-operative reveal complete bridging bone and consolidation of MagnetOs Easypack Putty in the intervertebral disc space (**Figure 1D-F**).

Table 4. Fusion Results

Fusion Status	Per Fusion Level
Average Time of CT Scan	12.6 months [12-14 months]
Fused	34/36 (94.4%)
Not Fused	2/36 (5.6%)

Pain was assessed in subjects using the Visual Analogue Scale (VAS) and binary presence/absence evaluation. The average VAS pain score was 5.3/10 pre-operative, decreased to 3.3/10 at 3 months post-operative, and advanced to 2.8/10 at 12 months post-operative (**Appendix 3**). This represents a 2.5/10 or 25% reduction in VAS pain scores over 12 months. Most subjects (19/20; 95%) experienced pre-operative back pain. Seventeen of 20 subjects (85%) experienced pre-operative left leg pain, and 12 of 20 subjects (60%) ex-

perienced right leg pain. Of the subjects with pre-operative pain, all reported improvement in their back (19/19), left leg (17/17), and right leg (12/12) pain.

Of the 20 subjects, 13 remained in hospital for 1 or 2 days with the maximum hospital stay recorded at 13 days (single subject). Subjects with the open TLIF approach and concurrent posterolateral fusion were more likely to have an extended hospital stay compared to subjects with those only needing an interbody fusion with MIS TLIF. Three AEs were reported in 3 subjects: one infection, one report of transient foot weakness, and one durotomy. Both the infection and durotomy required intervention, and all 3 resolved. All 3 AEs were determined by the investigator to be related to the surgical procedure and not related to the subject device. One secondary surgical procedure was noted during the retrospective chart review due to infection.

DISCUSSION

Compared to posterolateral fusion procedures, interbody fusion procedures provide a robust and consistent response associated with corresponding improvements in pain.[7] This is consistent with the clinical and radiographic outcomes from the use of MagnetOs Easypack Putty in TLIF procedures. This study captures the use of MagnetOs Easypack Putty with broad inclusion criteria and does not restrict enrollment based on co-morbidities such as diabetes, high BMI, and heart disease. Additionally, this study does not limit subjects with risk factors for fusion, such as tobacco use, fusion of multiple levels, and prior lumbar surgeries. Cumulatively, these clinical fusion and VAS outcomes data have the potential to impact the safety and success of interbody fusion procedures.

The Food and Drug Administration (FDA) recently began clearing bone void fillers for use in the intervertebral disc space. However, there are limited data on the efficacy and safety of these products for use in the interbody space. This study provides clinical and radiographic outcomes data for the use of a bone void filler in the intradiscal space. Published literature includes reports of a variety of bone grafting materials assessed for interbody fusion outcomes, including autograft, allograft, demineralized bone matrices, cellular bone allografts, bone morphogenetic protein 2 (BMP-2), and synthetics. A single peer-reviewed journal publication reports on the use of a similar device, SIGNAFUSE™, in interbody fusion procedures for 8 subjects. The 8 subjects had 11 total levels fused and 87.4% were deemed fused at 1 year post-operative.[8] Clinical data also supports the use of AttraX Putty™ and Fibergraft™ in the intervertebral disc space.[9,10] Thirteen subjects (18 levels) were treated with AttraX Putty, which led to an 83% interbody fusion rate at a mean follow-up time of 34.5 months post-operative (12-62 months).[9] Fibergraft led to a 96.4% fusion rate in eXtreme Lateral Interbody Fusion (XLIF) procedures at 24 months post-operative in a cohort of 30 patients.[10] A range of interbody fusion rates are documented with autograft as low as 77.8% and extending to 100% at 12 months post-operative.[11-13]

Sun et al. reported variation in fusion rate based on changes to the ratio of average autologous bone graft area to average endplate area, with higher ratios (i.e. proportionally more bone graft) having higher fusion rates.[12] This suggests that the volume plays a critical role in fusion suc-

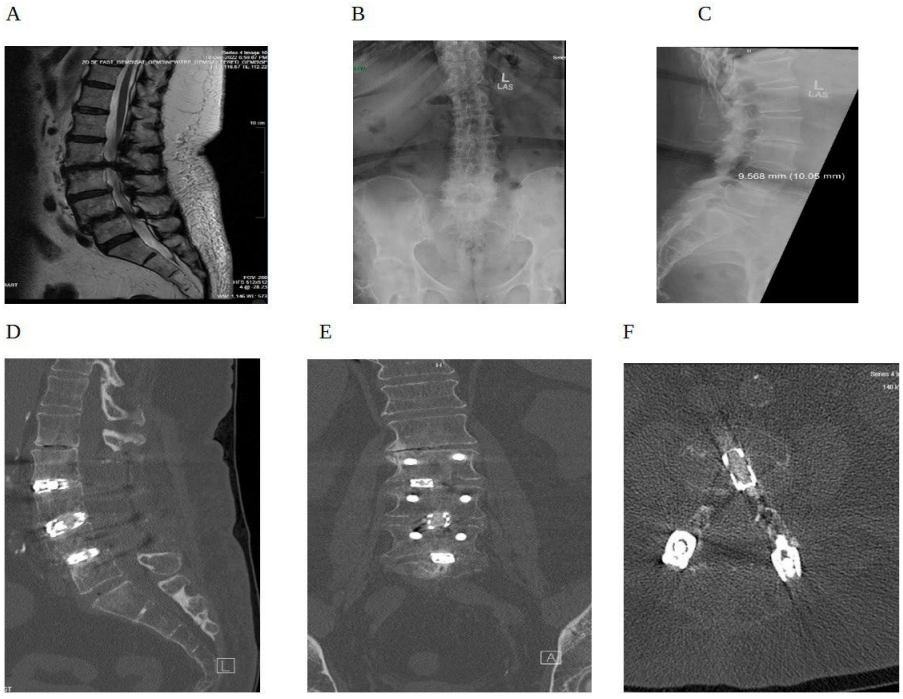

Figure 1. Pre-operative MRI (A), anterior-posterior X-ray (B), and lateral X-ray (C) reveal degenerative disc disease. Post-operative sagittal (D), coronal (E), and axial (F) CTs demonstrate complete bridging bone at 1-year post-operative.

cess. Fusion outcomes are also influenced by the surgical approach, radiographic assessment, and time to post-operative assessment. The inclusion and exclusion criteria for each study introduce additional variables, such as limiting to a single fusion level or excluding subjects who use tobacco. Taken together, MagnetOs Easypack Putty leads to robust interbody fusion rates as a standalone graft in patients including those without favorable fusion characteristics.*

The patient population in this retrospective study represents real-world use of the MagnetOs Easypack Putty. Subjects in this cohort had multiple co-morbidities such as diabetes (35%), high BMI (65%), tobacco use (55% former or current smokers), fusion of multiple levels (60% with two or more levels), and/or previous lumbar surgeries (30%). These comorbidities may impact both the safety and success of interbody fusion procedures. This study reports a high fusion rate at 12 months with no device-related AEs. Based on the range of fusion rates reported for other cleared synthetic bone void fillers and autograft, these clinical data support that MagnetOs Easypack Putty promotes fusion when used standalone in interbody procedures.*

CONCLUSION

MagnetOs Easypack Putty demonstrated high fusion rates at 12 months with 94.4% of treated levels being classified as either exhibiting bony bridging or locked pseudoarthrosis. Levels that were not fused (pseudoarthrosis) had contributing factors that likely impacted the fusion including infection. The high fusion rate was accompanied by a consistent improvement in pain scores. VAS pain scores decreased an average of 25% from 5.3/10 pre-operatively to 2.8/10 at 12 months post-operative, and all subjects who reported post-operative back or leg pain reported improved pain post-operatively. The device was well-tolerated with 3 adverse events observed in the study, all of which were resolved. These data support the performance of MagnetOs Easypack Putty used standalone in the intervertebral space to promote spinal fusion†.

^Results from in vivo or in vitro laboratory testing may not be predictive of clinical experience in humans.

*When used in intervertebral body fusion procedures, MagnetOs Easypack Putty must be used with an intervertebral body fusion device cleared by the FDA for use with a bone void filler.

†Please refer to the Instructions for Use (IFU) specific to your territory for approved indications, contraindications, and warnings

LIST OF ABBREVIATIONS

AE – Adverse event
BMI – Body mass index
BMP – Bone morphogenetic protein
BSF – Brantigan-Steffee-Fraser
CT – Computed tomography
FDA – Food and Drug Administration
TLIF – Transforaminal interbody fusion
MIS – Minimally invasive surgery
VAS – Visual analog scale

ACKNOWLEDGMENTS

Not applicable.

AUTHOR CONTRIBUTIONS

JD generated the data and wrote and reviewed the manuscript, BE completed a blind review of the radiographic outcomes, and CH and KS reviewed the data and wrote the manuscript. All authors reviewed the manuscript.

POTENTIAL CONFLICTS OF INTEREST

JD and BE are consultants for Kuros Biosciences, and CH and KS are employees of Kuros Biosciences.

FURTHER INFORMATION

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APPENDICES

Appendix 1. Patient demographics and comorbidities

Subject Number	Sex	Age at surgery	BMI	Obesity	Smoking Status	Diabetes	Previous Surgery	Previous Lumbar Surgeries	Arthritis
1	M	74	34.73	Yes	Former	Yes	Yes, multiple	No	No
2	F	69	38.17	Yes	No	Yes	Yes, multiple	Yes	Yes
3	M	66	32.59	Yes	No	No	Yes, multiple	Yes	Yes
4	M	72	37.88	Yes	Former	Yes	Yes, multiple	Yes	Yes
5	F	77	28.51	No	Former	Yes	Yes, multiple	No	No
6	F	69	28.35	No	Former	Yes	Yes, multiple	No	No
7	M	42	28.89	No	No	No	Yes, multiple	Yes	No
8	F	61	47.55	Yes	Current Smoker	No	Yes, multiple	No	No
9	M	53	28.23	No	Current Smoker	No	Yes	No	Yes
10	M	68	24.73	No	No	No	Yes, multiple	No	Yes
11	F	68	30.91	Yes	No	No	Yes, multiple	No	Yes
12	F	68	28.43	No	No	No	No	No	No
13	M	64	19.77	No	Former	No	Yes, multiple	No	Yes
14	F	72	38.74	Yes	No	No	No	No	No
15	F	76	34.18	Yes	Former	No	Yes, multiple	No	Yes
16	F	53	30.29	Yes	Former	No	Yes, multiple	Yes	Yes
17	M	78	34.52	Yes	Never	Yes	No	No	Yes
18	F	66	34.18	Yes	Former	No	Yes, multiple	No	Yes
19	F	74	30.32	Yes	Never	No	Yes, multiple	No	Yes
20	M	74	34.97	Yes	Former	Yes	Yes, multiple	Yes	Yes

Appendix 2. Surgical procedures

Subject Number	Surgical Approach	Levels	Fusion Levels	PLF	Easypack Putty (cc)	Average per level (cc)
1	MIS TLIF	L3-L5	2	No	3	1.5
2	MIS TLIF	L3-L5	2	No	3	1.5
3	Open TLIF	L2-pelvis	4	Yes	4.5	1.125
4	MIS TLIF	L2-L4	2	No	3	1.5
5	MIS TLIF	L4/L5	1	No	1.5	1.5
6	MIS TLIF	L3-L5	2	No	3	1.5
7	MIS TLIF	L3-L5	2	No	2.5	1.25
8	MIS TLIF	L4/L5	1	No	2.5	2.5
9	MIS TLIF	L4/L5	1	No	2.5	2.5
10	Open TLIF	L3-L5	2	Yes	2.5	1.25
11	MIS TLIF	L4/L5	1	No	2.5	2.5
12	MIS TLIF	L3-L5	2	No	2.5	1.25
13	MIS TLIF	L4/L5	1	No	2.5	2.5
14	MIS TLIF	L3-L5	2	No	5	2.5
15	MIS TLIF	L4/L5	1	No	2.5	2.5
16	MIS TLIF	L4/L5	1	No	2.5	2.5
17	MIS TLIF	L3-L5	2	No	5	2.5
18	Open TLIF	L2-L5	3	Yes	10	3.3
19	MIS TLIF	L3-S1	3	No	7.5	2.5
20	MIS TLIF	L4/L5	1	No	2.5	2.5

Appendix 3. Pain scores and radiographic fusion assessment

	VAS Pain Scores			Radiographic Fusion Assessment						
Subject Number	**Pre-op**	**3-month Post op**	**12 month Post-op**	**CT Imaging (months after surgery)**	**Evaluated Level**	**L1-2**	**L2-3**	**L3-4**	**L4-5**	**L5-S1**
1	3/10	0/10	5/10	12	L3-L5	-	-	3	3	-
2	5/10	6/10	5/10	14	L3-L5	-	-	2	2	-
3	7/10	4/10	7/10	12	L2-S1	-	1	3	3	3
4	2/10	0/10	0/10	13	L2-L4	-	2	2	-	-
5	6/10	5/10	6/10	14	L4/L5	-	-	-	3	-
6	1/10	3/10	0/10	13	L3-L5	-	-	1	2	-
7	3/10	3/10	0/10	13	L3-L5	-	-	3	3	-
8	8/10	6/10	-	12	L4/L5	-	-	-	3	-
9	7/10	3/10	5/10	13	L4/L5	-	-	-	2	-
10	8/10	7/10	4/10	12	L3-L5	-	-	2	2	-
11	7/10	4/10	4/10	12	L4/L5	-	-	-	3	-
12	7/10	0/10	0/10	12	L3-L5	-	-	3	3	-
13	0/10	0/10	0/10	12	L4/L5	-	-	-	3	-
14	6/10	2/10	0/10	13	L3-L5	-	-	3	3	-
15	9/10	6/10	0/10	13	L4/L5	-	-	-	3	-
16	7/10	5/10	5/10	13	L4/L5	-	-	-	3	-
17	4/10	4/10	4/10	13	L3-L5	-	-	3	3	-
18	3/10	3/10	5/10	12	L2-L5	-	3	3	3	-
19	5/10	0/10	0/10	12	L3-S1	-	-	3	3	2
20	8/10	5/10	4/10	12	L4/L5	-	-	-	2	-
					Totals	**0**	**3**	**12**	**19**	**2**