Research Article

BIOMEDICAL Journal of Scientific & Technical Research

ISSN: 2574 -1241

DOI: 10.26717/BJSTR.2025.61.009574

Instrumented Transforaminal Lumbar Interbody Fusion Using a Novel Synthetic Bone Graft, Ossdsign Catalyst® With 24-Month Post-Surgical Follow Up

A Lazary[1], P P Varga[1], L Kiss[1], Z Szoverfi[1], J Szita[1] and R Archer[2]*

[1]*Budai Egeszsegkozpont Zrt, Investigators for Study, Hungary*

[2]*Archer Clinical Ltd, consultant to OssDsign A.B, United Kingdom*

***Corresponding author:** Rosalyn Archer, Archer Clinical Ltd, consultant to OssDsign A.B, United Kingdom

ARTICLE INFO

Received: March 29, 2025

Published: April 14, 2025

Citation: A Lazary, P P Varga, L Kiss, Z Szoverfi, J Szita1 and R Archer. Instrumented Transforaminal Lumbar Interbody Fusion Using a Novel Synthetic Bone Graft, Ossdsign Catalyst® With 24-Month Post-Surgical Follow Up. Biomed J Sci & Tech Res 61(2)-2025. BJSTR. MS.ID.009574.

ABSTRACT

Study Design: First-in-human, an open-label, prospective, single-center, clinical study using the novel synthetic bone graft, OssDsign Catalyst®, in Transforaminal Lumbar Interbody Fusion spine surgery.

Objective: To evaluate the safety and performance of OssDsign Catalyst® synthetic bone graft.

Method: TLIF surgery at one spinal level was performed on 17 enrolled patients using OssDsign Catalyst® synthetic bone graft alone, in and around the interbody cage and mixed with autograft posterior to the cage. Post-surgical follow-up visits were performed at 6 weeks, 3, 6, 12, and 24-months. CT scans were taken at 3, 6, 12, and 24-months (if not already fused at 12-months) and fusion assessments were performed by Medical Metrics Inc. Validated Patient-Reported Outcome Measures (PROMS) were completed at baseline, and each follow up visit up to 12-months, then at 24-months, only if the patient was not fused at the 12-month follow-up evaluation (i.e., ODI, VAS, SF-36, GTO/PS), along with recording adverse events (AE).

Results: By the final 24-month post-operative follow-up the fusion rate was 100% with all 14 remaining patients fused; three were withdrawn for non-device-related reasons. Previously published results reported for follow-up evaluations up to the 12-month follow-up evaluation were 29% at 3 months, 64% at 6 months, 93% at 12-months [1] and this article includes the final study results out to 24-months follow up. The PROMS (ODI, VAS, and SF-36) demonstrated progressive improvement from pre-surgical scores over the 12-month post-surgical follow up period and no reported decline at the 24-month follow-up.

Conclusions: OssDsign Catalyst® synthetic bone graft was shown to produce excellent bone fusion in all of the patients included in this first-in-human study with no adverse events related to OssDsign Catalyst® over the 24-months follow-up.

Keywords: Synthetic Bone Graft; Nano Synthetic; Silicate Enriched Calcium Phosphate; TLIF; Spine Fusion; OssDsign; Catalyst; Osteo3 ZP Putty

Abbreviations: AE: Adverse Events; TLIF: Transforaminal Lumbar Interbody Fusion; PLF: Posterolateral Fusion; ODI: Oswestry Disability Index; VAS: Visual Analog Pain Scores; GTO: Global Treatment Outcome Questionnaire; DDD: Degenerative Disc Disease; DS: Degenerative Spondylolisthesis; PS: Patient Satisfaction Scores

Introduction

Spine fusion procedures aim to facilitate the development of bridging bone between the vertebral bodies to be fused. If solid fusion is achieved, the result provides long-term stability beyond the life of any stabilizing metalwork implanted at the time of surgery. Spine fusion eliminates the motion of the vertebral bodies involved, maintains the distance between vertebral bodies, and decompresses spinal nerves, thereby relieving pain. To achieve fusion a bone graft is placed between the vertebral bodies, often within an interbody cage and/or across the transverse processes [2]. The historical 'gold standard' approach of harvesting bone from the iliac crest to be morselized for

use as a bone graft is now rarely conducted due to the extended surgical time, risks associated with performing two surgeries, and the resultant harvest site pain and morbidity [3-5]. The use of autograft harvested from around the surgical site is dependent on the quality of the patient's own bone [6] and with the greater use of minimally invasive techniques, the quantity available may be problematic, and hence require an extender of some kind to increase the amount of bone graft available. One alternative is allograft from donated human bone; however, the quality can be inconsistent, and disease transfer is a risk [3,7-10]. The use of synthetic bone graft substitutes has become more common to avoid the need to source allograft or iliac crest autograft [6,11].

Commercially available synthetic bone grafts are consistent in quality and readily available [12-14] Many different types have been developed since the original ceramics and hydroxyapatites which were developed with the intent to mimic the structure of bone but would not dissolve or remodel over time [3,6] Newer synthetics aim to re-absorb or be remodelled in line with the patient's rate of bone healing and remodelling to mature lamellar bone. The ideal bone graft is osteoconductive, osteoinductive, easy to handle, and have a structure that works with the body to dissolve or remodel as the patient's bone healing occurs. One such development is the inclusion of silicon or silicate in synthetic bone grafts to increase the rate of bone development. Silicate has been extensively researched and found to be essential in bone metabolism [15-18]. Silicon is known to stimulate human osteoblasts and to secrete various bone markers of bone cell maturation and subsequent bone formation [19] and its greatest concentrations are found in immature bone [13]. An ideal synthetic bone graft will therefore have a high silicon content to aid bone formation and a honeycomb-like structure to mimic bone structure but maximize the surface area for osteoclasts to attach to and progress the natural process of bone formation [12,14]. A novel nanosynthetic, silicate-enriched calcium phosphate bone graft substitute, OssDsign Catalyst® (formerly Osteo3 ZP Putty), is designed to deliver consistent and rapid bone healing and remodeling.

The high level of substituted silicate (5.8 wt%) in the porous granules combined with the nanoscale architecture is thought to promote early bone formation. In clinically relevant animal studies [20,21] OssDsign Catalyst® has demonstrated osteoconductivity. It is 100% synthetic with no biological content. OssDsign Catalyst® contains silicate-enhanced calcium phosphate granules suspended in a resorbable gel carrier, enabling direct implantation without any further processing. The high surface area of the porous granules, along with the physical and chemical properties of OssDsign Catalyst® have shown consistent and rapid bone ingrowth, bone remodeling and cell-mediated resorption during the bone healing process. The unique scaffold of Ossdsign Catalyst® is osteoconductive and promotes bone formation on the surface of the graft. This article describes the first-in-human prospective clinical study intended to demonstrate the safety and performance of Catalyst synthetic bone graft in spine fusion surgery. The study was performed at a single-center with a small cohort of patients as this was the first time Catalyst had been used in humans. The approach used was Transforaminal Lumbar Interbody Fusion (TLIF) with instrumented posterolateral fusion (PLF), which is a minimally invasive approach that is now commonly used as it reduces the amount of retraction of the dura and nerve roots, lowering the risk of nerve damage and long-term back pain [22-30]. This article describes the results of the completed first-in-human study conducted for OssDsign Catalyst® with 24-month follow up of patients.

Materials and Methods

As previously published and described in the 12-month interim analysis [1], patients aged between 40 to 65 years old who were suffering from degenerative disc disease, lumbar spinal stenosis, or degenerative spondylolisthesis were approached to participate in this single-center study if after assessment, their surgeon had decided a one level TLIF surgery would be an appropriate treatment for their condition. Each patient must have tried and failed to relieve their symptoms through non-surgical treatment, such as bed rest, traction, drug treatments or physical therapy, for at least six months. Patients were excluded if they had already had surgery, chronic infection at the index level, a history of disease that could affect bone healing (e.g., significant bone metabolic disease, osteoporotic etc.) or other reasons which would put them at risk (e.g., known to be pregnant or breastfeeding, history of drug abuse, morbid obesity (BMI ≥40)). The clinical study was conducted at a single-center in Hungary (i.e., National Center for Spinal Disorders, Buda Health Center). The study was approved by the local and national Hungarian FDA and ethics committees (i.e., National Center for Public Health and Pharmacy) and the hospital ethics committee) and was conducted in accordance with Good Clinical Practice and the Declaration of Helsinki, ISO 14155, FDA (21CRF) and the appropriate local regulations. All patients signed written informed consent using an approved consent form before participating in the study.

A total of 17 patients were enrolled allowing for a 10% dropout rate, with the aim of leaving 15 evaluable cases. Each patient underwent a single-level TLIF procedure (L2-S1) with instrumentation including an interbody cage and two rods plus four pedicle screws across the posterolateral fusion. OssDsign Catalyst® nanosynthetic bone graft was used standalone within, and anterior (where possible) to the interbody cage and across the transverse processes, either unilaterally or bilaterally at the surgeon's choice. With the close proximity to the spinal canal, it was decided to mix the OssDsign Catalyst® in equal parts with morselized autograft taken from the facetectomy for placement posterior to the interbody cage. After gathering baseline data either on the day of surgery or before, follow-up visits were completed at 6 weeks, 3-, 6-, 12- and 24- months post-surgery. At 24-months, a full visit was conducted only if the patient was not fused at the 12-month follow-up evaluation. All patients who were al-

ready fused at 12-months were contacted by telephone at 24-months post-surgery to ask if they had experienced any adverse events since the 12-month visit. At each in-person visit the following PROMs were completed: Oswestry Disability Index (ODI), [31,32] Visual Analog pain scores (VAS), SF-36 quality of life questionnaires, [11] plus Global Treatment Outcome questionnaire (GTO), [33,34] Patient Satisfaction (PS) questionnaire, and any adverse events since the previous visit were recorded. CT scans were taken at 3, 6, and 12-months post-surgery, and additionally at 24-months post-surgery if not fused at 12-months.

The CT scans were provided to Medical Metrics Inc for independent radiological analysis of fusion. Successful fusion was defined as: 'evidence of bridging bone (contiguous bony connection from the superior vertebral body to the inferior vertebral body, in the posterolateral gutter, in front of (anterior) or within the interbody cage' [35]. The CT scans were each reviewed by two independent experienced radiologists with appropriate experience, with an additional third radiologist review if the original two did not agree; all remained blind to the patient and results of the others during their assessment.

Results

Patient Demographics

A total of 115 patients were screened to recruit the 17 needed for the study. The main reasons for exclusion (Figure 1) were having had previous surgery at the index level (20/115; 17%) or being outside the age range selected for inclusion (40/115; 35%). Three patients had to be withdrawn from the study and were excluded from the data analyses (i.e., one death due to cancer; two had revision surgery in which the bone graft was removed after misaligned instrumentation during the index surgery), leaving 14 who completed the study to 24-months post-surgical follow up. Table 1 shows the demographics of the patients who completed the study. By chance alone, 13 of the 14 (93%) of the patients in this cohort were female. The median age of 48 years with BMI of 29.7, and only one smoker. All of the patients were diagnosed with degenerative disc disease (DDD) and/or degenerative spondylolisthesis (DS) or spinal stenosis, and one had all three. None of the patients had co-morbidities which were thought to have affected the subjects' bone fusion. TLIF surgery was performed at one of two levels (i.e., 6 (43%) at L4-L5 and 8 (57%) at L5-S1). In all cases the surgical site was stabilized using a PEEK interbody cage and two titanium rods plus four pedicle screws across the posterolateral transverse processes.

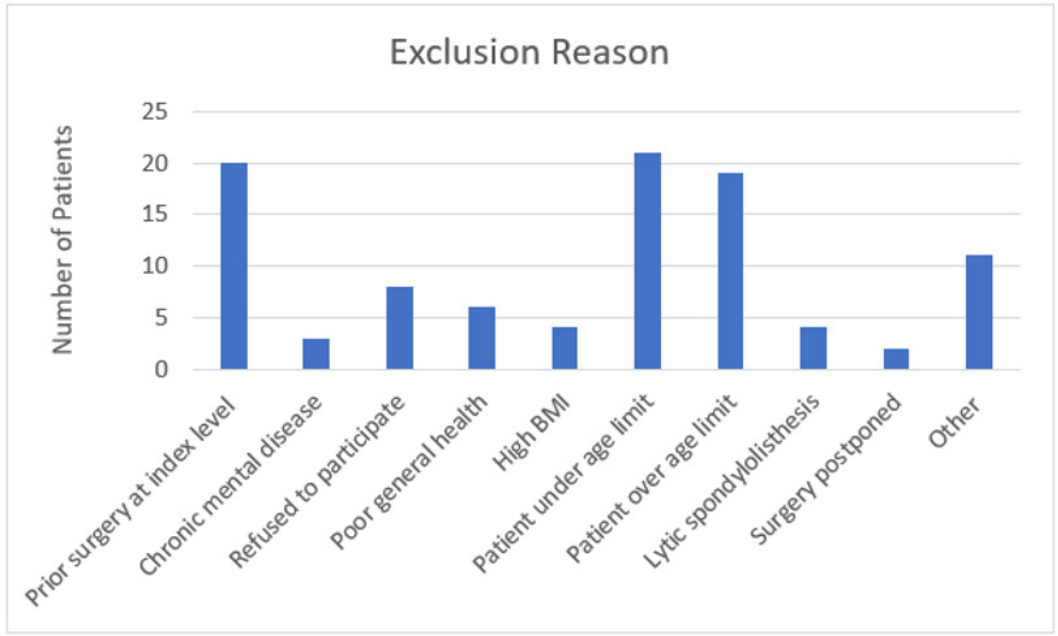

Figure 1: Screen Failure Reasons.

Table 1: Demographics.

Age, yrs: mean ± SD (Range)	49 ± 6 (40 - 62)
Median (IQR)	48 (46 – 52)
Gender	13 Females; 1 Male
BMI (mean ± SD) (Range)	30.0 ± 4.4 (22.4 – 39.0)
Median (IQR)	29.7 (27.2 – 33.0)
Vertebral levels: n	L4-L5: 6; L5-S1: 8
Primary diagnosis:	
Degenerative spondylolisthesis	11
Degenerative disc disease	11
Stenosis	2
Co-morbidities:	
Hypertension	5
Thyroid	2
Pulmonary Disease	1
Thrombosis/Embolic Disease	1
Smoker	1 (20 cigarettes/day)

Radiographic Outcomes

The previously published [1] fusion results assessed by CT scans at the 3, 6 and 12-month post-surgical follow-ups are shown in Figure 2, along with the result for the one patient who returned for a 24-month in-person evaluation; the results for those fused at 12-months follow-up were imputed to the 24-months post-surgical follow-up. Where Catalyst was used as a stand-alone bone graft (i.e., in the interbody cage, anterior to the cage and across the transverse processes) the post-surgery fusion results were 4/14 (29%) after 3 months, 9/14 (64%) after 6 months, 13/14 (93%) after 12-months and 14/14 (100%) after 24-months.

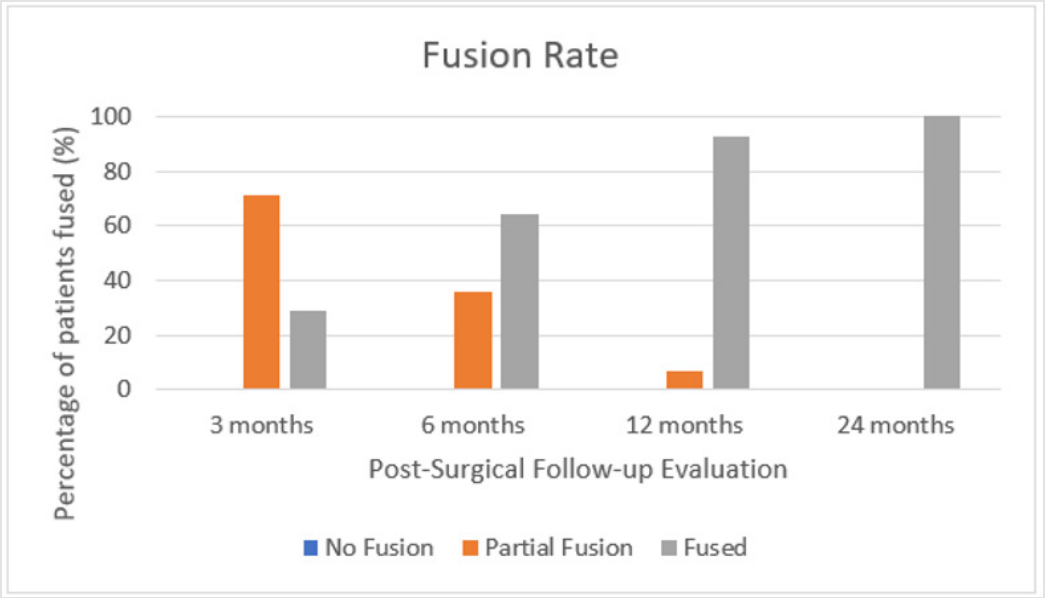

Figure 2: Rates of Successful Fusion (%).

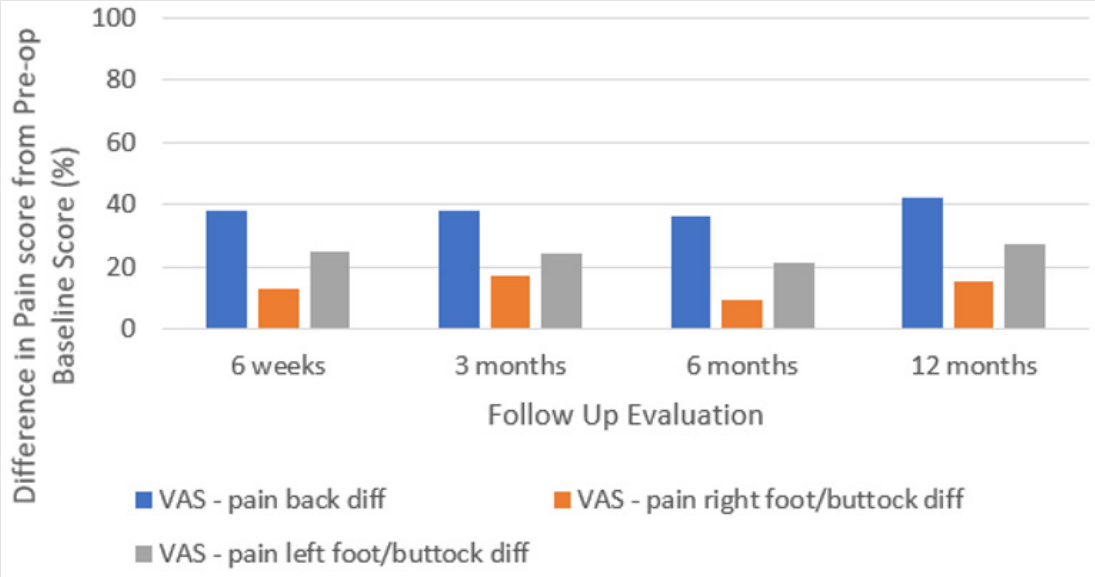

Figure 3: VAS Improvement from Pre-Op Baseline.

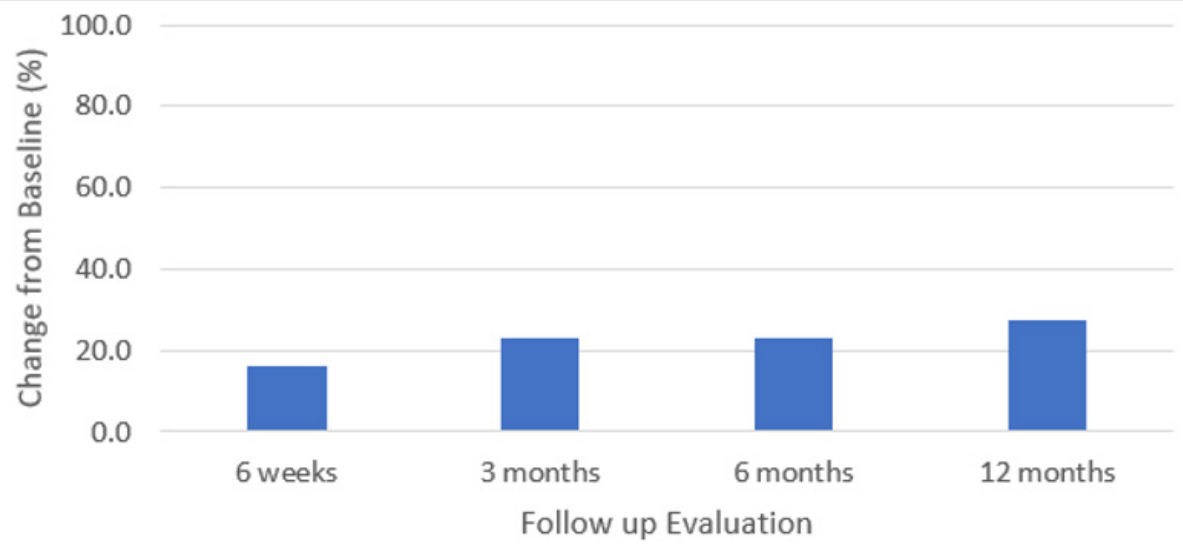

Figure 4: Mean Improvement in ODI Scores (%) from Pre-Op Baseline.

Clinical Outcomes

Evaluating the difference between pre-surgical scores and follow-up scores for VAS (Figure 3) and ODI (Figure 4) showed a decrease in pain and improvement in quality of life, at all follow-up visits up to 12-months when compared to the pre-surgical baseline scores. At the 24-month telephone follow-up and for the one patient who had the in-person visit no deterioration in clinical outcome was reported. The results from the SF-36 quality of life questionnaire (Figure 5) showed significant improvement in all categories and the overall assessment of their Physical and Mental Health. All patients were pleased with the outcomes of their surgery which were assessed using the Global Treatment Outcome score (GTO) and patient satisfaction scores (PS). All patients reported the surgery had 'helped', or 'helped a lot' (GTO of 4.8/5 (96%)), and that they were 'very satisfied' (PS of 4.9/5 (98%)) with the results.

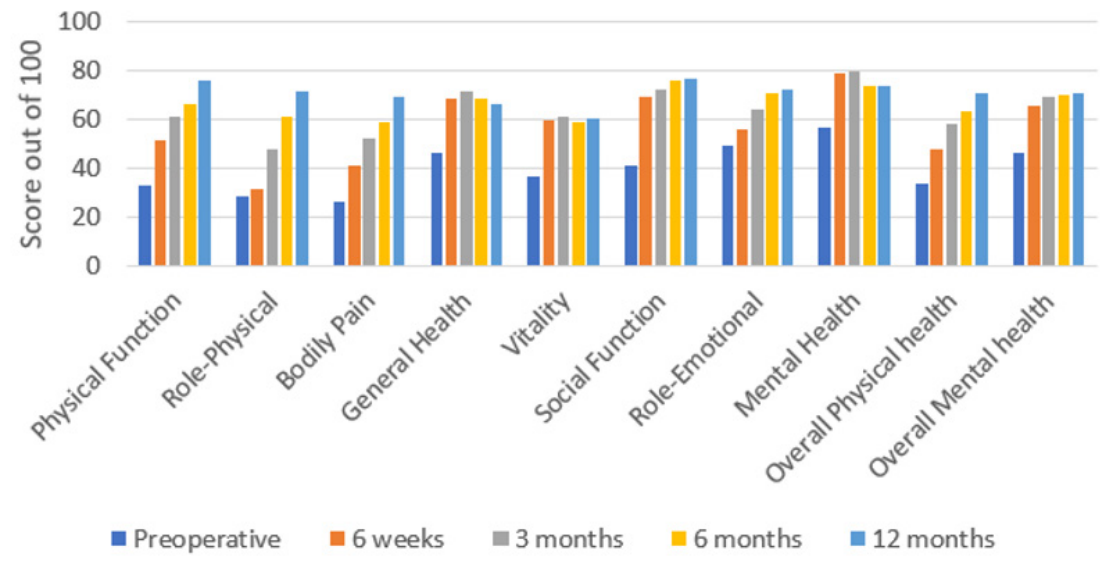

Figure 5: Mean SF-36 Quality of Life scores.

Adverse Events

There were no adverse events related to the OssDsign Catalyst® bone graft reported during the 24-month post-surgical follow-up period. Although twelve adverse events were reported during the study [1] in the 'safety population' including all 17 patients originally recruited, none were assessed as 'related', or 'possibly related' to the investigational device (i.e., Catalyst). Of the adverse events, four were unrelated to both the device or procedure (i.e., stroke, cancer, back pain after a fall and gallstones). The remaining were related to the procedure and consisted of three wound infections, one seroma in the subcutaneous fat, one case of radiculitis, and three instrumentation failures (i.e., two sub-optimal pedicle screw placements; one resulting in a L5 pedicle fracture). Three patients were withdrawn from the study before the 3-month follow-up evaluation; one was diagnosed with a pancreatic head tumor, and two had revision surgery due to problems with sub-optimal pedicle screw placement and had the bone graft removed during their revision surgery.

Discussion

The first 14 human subjects to receive OssDsign's Catalyst® nanosynthetic bone graft were all found to have successfully fused after 24-months post-surgical follow-up when assessed via CT scans. Previous results reported for this study reported fusion rates of 64% (n=9/14) at 6-months follow-up and 93% (n=13/14) at the 12-month post-surgical follow-up evaluation.1 The final patient showed good fusion at the 24-months post-surgical follow-up after showing fusion progressing well at 12-months post-surgery; hence a final result of 100% fusion rate in this first, but small cohort of patients. These results compare favorably with other state-of-the-art synthetic bone grafts using the same TLIF surgical approach, which have reported post-surgical 12-month fusion rates ranging from 77% to 100% [23-31]. The 6-month post-surgical fusion rate of 64% (assessed via CT) is comparable to the 6-month early fusion rate of 62.5% (assessed via x-ray) reported by vonderHoeh, et al. [23] for Iliac crest bone graft, the accepted 'gold standard' for bone graft, and are better than the 83% fusion rate (assessed via CT) reported at 12-months. Clinical outcomes data from PROMS produced significant clinical improvements. The higher the ODI or VAS score between 0-100, the greater the indication of functional disability, or pain [36]. When compared to baseline scores a minimally clinically significant difference (MCID) is accepted as a movement of 15 points (30%) when a 0-100 scoring scale is used such as for ODI and VAS where pre-surgical scores started at >40% [32,35-37].

In this study, although there was significant improvement measured at all visits, particularly in reduction in back pain in VAS, the ODI failed to a reach 30% difference from the mean baseline score but did reach a difference of 23 and 27% improvement from baseline at 6 and 12-months follow-up from a mean pre-surgical score of 42%, which was more than the ≥22% improvement identified by van Hooff [38] in his review of 1288 spine fusion patients as indicating the achievement of an acceptable symptom state and can hence be used as a criterion of treatment success alongside the other commonly used outcome measures. Clinical outcome results which included VAS, ODI, and SF-36 showed significant symptom relief which remained at 24-month follow-up and were evident at each previous follow-up evaluation1. Patients with 24-month post-surgical follow-up reported no adverse

events signifying a lack of clinical outcome deterioration. This study adds significant value to current literature regarding nanosynthetics and their safety and efficacy in spinal fusion and provides an update to previously published data from the 12-month interim analysis of the study [1,39].

Limitations of the Study

In this first-in-human study, the number of patients was low and the study was conducted at a single- center. OssDsign Catalyst® performed well but it is recognized that in this study the patient selection was targeted to certain physical health, and only one level of lumbar surgery. A larger multi-center registry study has now commenced to compare these results with real-world all-comers data for OssDsign Catalyst® in surgical use as an extender or replacement bone graft.

Conclusion

This prospective series indicated OssDsign Catalyst®, a new nanosynthetic calcium phosphate bone graft substitute, demonstrates consistent and rapid bone healing and remodeling, with corresponding good patient outcomes.

Acknowledgments

The authors would like to recognize the study co-ordinators, Julia Szita and Edit Pap for all their considerable efforts to ensure this study ran smoothly, with good complete datasets and no missed patient visits.

References

1. A Lazary, PP Varga, L Kiss, Z Szoverfi, S Czop, et al. (2024) First-In- Human Study with a Novel Synthetic Bone Graft, OssDsign Catalyst®, in Transforaminal Lumbar Interbody Fusion with Instrumented Posterolateral Fusion. Biomed J Sci & Tech Res 54(4): 46078-46085.
2. Weiner BK, Fraser RD (1998) Lumbar Interbody Cages. Spine (Phila Pa 1976) 23(5): 634–640.
3. Nagineni VV, James AR, Alimi M, Hofstett C, Shin BJ, et al. (2012) Silicate-Substituted Calcium Phosphate Ceramic Bone Graft Replacement for Spinal Fusion Procedures. Spine 37(20): E1264-E1272.
4. Goulet JA, Senunas LE, DeSilva GL, Greenfield ML (1997) Autogenous iliac crest bone graft Complications and functional assessment. Clin Orthop Relat Res 339: 76-81.
5. Seiler JG, Johnson J (2000) Iliac crest autogenous bone grafting: donor site complications. J South Orthop Asso Summer 9(2): 91-97.
6. Jenis LG, Banco RJ (2010) Efficacy of Silicate-Substituted Calcium Phosphate Ceramic in Posterolateral Instrumented Lumbar Fusion. SPINE 35(20): E1058-E1063.
7. Barriga A, Díaz de Rada P, Barroso JL, Alfonso M, Lamata M, et al. (2004) Frozen cancellous bone allografts: positive cultures of implanted grafts in posterior fusions of the spine. Eur Spine J 13(2): 152-156.
8. McCann S, Byrne JL, Rovira M, Shaw P, Ribaud P, et al. (2004) Outbreaks of infectious diseases in stem cell transplant units: a silent cause of death for patients and transplant programmes. Bone Marrow Transplant 33(5): 519-529.
9. McAllister DR, Joyce MJ, Mann BJ, Vangsness CT Jr (2007) Allograft update: the current status of tissue regulation, procurement, processing, and sterilization. Am J Sports Med 35(12): 2148-2158.
10. Ehrler DM, Vaccaro AR (2000) The Use of Allograft Bone in Lumbar Spine Surgery. Clin Orthop Relat Res 371: 38-45.
11. Ware JE, Kosinski M, Dewey JE (2001) How to score Version 2 of the SF-36 Health Survey. Lincoln RI Quality Metric Incorporated.
12. Brandoff JF, Silber JS, Vaccaro AR (2008) Contemporary alternatives to synthetic bone grafts for spine surgery. Am J Orthop (Belle Mead NJ) 37(8): 410-414.
13. Waked W, Grauer J (2008) Silicates and bone fusion. Orthopedics 31(6): 591-597.
14. Vaccaro AR, Kazuhiro C, Heller JG, Patel TC, Thalgott JS, et al. (2002) Bone grafting alternatives in spinal surgery. The Spine Journal 2(3): 206-215.
15. Carlisle E (1974) Silicon as an essential element. Fed Proceed 33: 1758–1766.
16. Gibson I, Hing K, Revell P (2002) Enhanced *in vivo* response to silicate substituted hydroxyapatite. Key Eng Mater 218: 203-206.
17. Muller W, Boreiko A, Wang X, Anatoli Krasko, Werner Geurtsen, et al. (2007) Morphogenetic activity of silica and biosilica on the expression of genes controlling biomineralization using SaOS-2 cells. Calcif Tissue Int 81(5): 382-393.
18. Guth K, Buckland T, Hing H (2006) Silicon dissolution from micro porous silicon substituted hydroxyapatite and its effect on osteoblast behavior. Key Eng Mater 309: 117-120.
19. Reffitt DM, Ogston N, Jugdaohsingh R, Cheung HF, Evans BA, et al. (2003) Orthosilicic acid stimulates collagen type 1 synthesis and osteoblastic differentiation in human osteoblast-like cells *in vitro*. Bone 32(2): 127-135.
20. Sirakoss (Unpublished) (2018) Osteo3 ZP Putty Preclinical Results From 510(k). internal report.
21. Conway JC, Oliver RA, Wang T, Wills DJ, Herbert J, et al. (2021) The efficacy of a nanosynthetic bone graft substitute as a bone graft extender in rabbit posterolateral fusion. The Spine Journal 21(11): 1925-1937.
22. Precision brain spine and pain center (2020) Transforaminal lumbar interbody fusion (TLIF).
23. VonderHoeh NH, Voelker A, Heyde CE (2017) Results of lumbar spondylodeses using different bone grafting materials after transforaminal lumbar interbody fusion (TLIF). Eur Spine J Nov 26(11): 2835-2842.
24. Rapan S, Jovanović S, Gulan G (2010) Transforaminal lumbar interbody fusion (TLIF) and unilateral transpedicular fixation. Coll Antropol 34(2): 531-534.
25. Poh SY, Yue WM, Chen LTJ, Guo CM, Yeo W, et al. (2011) Two-year outcomes of transforaminal lumbar interbody fusion. J Orthop Surg (Hong Kong) 19(2): 135-140.
26. Wang HW, Hu YC, Wu ZY, Wu HR, Wu CF, et al. (2017) Minimally Invasive Transforaminal Lumbar Interbody Fusion and Unilateral Fixation for Degenerative Lumbar Disease. Orthop Surg 9(3): 277-283.
27. Yoo JS, Min SH, Yoon SH (2015) Fusion rate according to mixture ratio and volumes of bone graft in minimally invasive transforaminal lumbar interbody fusion: minimum 2-year follow-up. Eur J Orthop Surg Traumatol 25 Suppl 1: S183-S189.
28. Challier V, Boissiere L, Obeid I, Vital JM, Jean Etienne Castelain JE, et al. (2017) One-Level Lumbar Degenerative Spondylolisthesis and Posterior Approach: Is Transforaminal Lateral Interbody Fusion Mandatory?:

A Randomized Controlled Trial With 2-Year Follow-Up. Spine (Phila Pa 1976) 42(8): 531-539.

29. Wu WJ, Li Y, Hou TY, Cheng P, Zhang ZH, et al. (2019) Application of New Allogeneic Lumbar Fusion Cage (Biocage) in Single-Segment Lumbar Degenerative Disease: A Prospective Controlled Study with Follow-Up for ≥2 Years. World Neurosurg 126: e1309-e1314.
30. Mura PP, Costaglioli M, Piredda M, Caboni S, Casula S (2011) TLIF for symptomatic disc degeneration: a retrospective study of 100 subjects. Eur Spine J 20 Suppl 1(Suppl 1): S57-S60.
31. Fairbank JCT, Pynsent PB (2000) The Oswestry Disability Index. Spine (Phila Pa 1976) 25: 2940-2953.
32. Little DG, MacDonald D (1994) The use of the percentage change in Oswestry Disability Index score as an outcome measure in lumbar spinal surgery. Spine (Phila Pa 1976) 19(19): 2139-2143.
33. Mannion AF, Porchet F, Kleinstuck FS, Lattig F, Jeszenszky D, et al. (2009) The quality of spine surgery from the patient's perspective: Part 1. The Core Outcome Measures Index in Clinical Practice. Eur Spine J 18(3): 367-373.
34. Mannion AF, Porchet F, Kleinstuck FS, Lattig F, Jeszenszky D, et al. (2009) The quality of spine surgery from the patient's perspective: Part 2. Minimal clinically important difference for improvement and deterioration as measured with the Core Outcome Measures Index. Eur Spine J, 18(3): 374-379.
35. Sirakoss Ltd (2023) First-in-man safety and performance of Osteo3 ZP Putty in subjects undergoing transforaminal lumbar interbody fusion (Unpublished Clinical Investigation Plan 2.2, 16 Jan 2023).
36. Clopper CJ, Pearson ES (1934) The use of confidence or fiducial limits illustrated in the case of the binomial. Biometrika 26(4): 404-413.
37. Stempels HW, Lehr AM, Delawi D, Hoebink EA, Wiljouw IAAA, et al. (2024) Efficacy of Biphasic Calcium Phosphate Ceramic With a Needle-Shaped Surface Topography Versus Autograft in Instrumented Posterolateral Spinal Fusion. Spine (Phila Pa 1976) 49(19): 1323-1331.
38. van Hooff ML, Mannion AF, Staub LP, Ostelo RW, Fairbank JC (2016) Determination of the Oswestry Disability Index score equivalent to a "satisfactory symptom state" in patients undergoing surgery for degenerative disorders of the lumbar spine-a Spine Tango registry-based study. Spine J 16(10): 1221-1230.
39. Ostelo RWJG, Deyo RA, Stratford P (2008) Interpreting Change Scores for Pain and Functional Status in Low Back Pain Towards International Consensus Regarding Minimal Important Change. Spine (Phila Pa 1976) 33(1): 90-94.

ISSN: 2574-1241

DOI: 10.26717/BJSTR.2025.61.009574

Rosalyn Archer. Biomed J Sci & Tech Res