

OssDsign Catalyst[®] Bone Graft Performance in a Three-Level Extreme Lateral Interbody Fusion (XLIF[®])

KB Strenge¹, R Archer^{2*} and SM Czop³

¹Consultant Surgeon, Strenge Spine Center, United States ²Senior Consultant to OssDsign A.B, Archer Clinical Ltd, United Kingdom

³Director of Medical Affairs, OssDsign A.B, United States

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

ARTICLE INFO	ABSTRACT
Received: i → May 21, 2024 Published: june 03, 2024	Minimally invasive interbody fusion techniques such as eXtreme Lateral Interbody Fusion (XLIF®) using anterolateral approaches have been developed along with new nanosynthetic bone grafts designed to instruct bone formation. A challenging 60-year-old patient underwent a three-level XLIF® with Catalyst® Bone Graft

Citation: KB Strenge, R Archer and SM Czop. OssDsign Catalyst[®] Bone Graft Performance in a Three-Level Extreme Lateral Interbody Fusion (XLIF[®]) . Biomed J Sci & Tech Res 56(5)-2024. BJSTR. MS.ID.008906. Minimally invasive interbody fusion techniques such as eXtreme Lateral Interbody Fusion (XLIF®) using anterolateral approaches have been developed along with new nanosynthetic bone grafts designed to instruct bone formation. A challenging 60-year-old patient underwent a three-level XLIF® with Catalyst® Bone Graft Substitute, a new silicate-enriched calcium phosphate bone graft with a nanoscale structure resembling bone. At 6-month post-operative follow-up, all three levels were successfully fused, and the patient was generally pain-free with significantly improved function. No peri-operative or post-operative complications were encountered, and the fusion status was confirmed at 12-month follow-up. This patient's outcome in a multi-level XLIF with challenging comorbidities (i.e., obesity, two previous spine surgeries, endocrine disorder) provides support for the use of this bone graft substitute in more challenging patient scenarios.

Keywords: Nano Synthetic Bone Graft; Catalyst; Silicate; Calcium Phosphate; XLIF; Interbody Fusion

Abbreviations: ALIF: Anterior Lumbar Interbody Fusion; BMI: Body Mass Index; CT: Computed Tomography Scan; DDD: degenerative disc disease; MRI: Magnetic Resonance Imaging; ODI: Oswestry Disability Index; PLF: Posterolateral Lumbar Fusion; OLIF: Oblique Lumbar Interbody Fusion; TLIF: Transforaminal Lumbar Interbody Fusion; VAS: Visual Analogue Score for Pain; XLIF: Extreme lateral interbody fusion

Introduction

Spinal fusion is commonly performed in patients with a variety of pathologies when conservative treatment fails resulting in continued pain and functional limitations. These symptoms decrease the quality of life for an individual to the extent that surgery may be indicated [1]. Minimally invasive interbody fusion techniques using anterolateral approaches such as Extreme lateral interbody fusion (XLIF®, NuVasive, Inc., San Diego, CA) have been developed to avoid disruption of the posterior spinal column, while permitting wide exposure of the disc space, use of larger interbody cages, shorter operating times, less blood loss, and indirect nerve root decompression [2,3]. The use of synthetic bone grafts has become mainstream in recent years with advances in nanoscale architecture, microporosity, and ionic substitution designed to amplify signaling pathways to instruct bone formation [4,5]. A new silicate-enriched (5.8 wt% silicon) calci-

um phosphate bone graft substitute (Catalyst®, OssDsign A.B.) with nanoscale architecture is gaining popularity among spine surgeons in the US. The following is a report on the use of Catalyst in a challenging three-level XLIF case.

Case Description

This case reports the results of a 60-year-old male (BMI 32.3) with a prior history of high blood pressure and endocrine disease who presented with severe back and leg pain causing severe disability (Visual Analogue Score (VAS) for pain: VAS Back - 8.5/10, VAS Right Leg-5.5/10, VAS Left Leg 8.5/10, and Oswestry Disability Index (ODI) score 76%). He had several lumbar decompression (laminectomy) procedures in the past along with an uninstrumented L5-S1 postero-lateral (PLF) fusion and a C3-C7 cervical fusion (ACDF). Pre-operative X-rays (Anterior-Posterior (AP) and Lateral) of the lumbar spine are

shown in Figure 1. Magnetic Resonance Imaging (MRI), clinical, and radiographic examination revealed degenerative disc disease (DDD) at 3 levels (L2-L3, L3-L4, and L4-L5). After 6 months of conservative treatment and administration of both narcotic and anti-inflammato-ry medications, the patient chose to have surgery after having been informed of the potential risks and benefits. The surgery was performed in a staged fashion in May 2022 and consisted of a three-level, minimally invasive, XLIF[®] at L2-L5 using three PEEK interbody cages,

one at each level, approved for use with Catalyst[®] Bone Graft. Each cage was filled with 8cc of Catalyst, totaling 24cc. The second stage was done two days later adding posterior instrumentation with pedicle screws and rods with local autograft placed in the lateral gutters. There were no intraoperative complications seen in either procedure. The patient returned for follow-up examinations at 3, 6, and 12 months.



Figure 1:

- (A) Anterior-Posterior (AP) pre-operative X-rays.
- (B) Lateral pre-operative X-rays of the lumbar spine.

Results

At 3-month follow-up, plain X-rays (AP and lateral images) revealed the instrumentation to be intact and well-positioned. VAS Pain Scores and ODI improved significantly from the pre-operative scores (VAS Back-2/10, VAS Right Leg-1/10, VAS Left Leg 1/10, ODI 46%). At 6-month follow-up, pain, and function further improved and radiographic findings, both X-Ray (Figure 2) and CT scan (Figure 3),

showed complete interbody fusion at all three levels. At the 12-month follow-up, the patient was generally pain-free (using only occasional over-the-counter pain relief, Figures 4 & 5) with significantly improved function (VAS Back-1/10, VAS Right Leg-0/10, VAS Left Leg 0/10, ODI 30%). Radiographic findings, both X-ray (Figure 6) and CT scan (Figure 7) at 12 months confirm complete interbody fusion at all three levels. There were no post-operative complications seen during the follow-up period.



Figure 2: Post-operative X-ray at 6 months.



Figure 3: CT scan at 6 months.







Figure 6: Post-operative X-ray at 12 months.



Figure 7: CT scan at 12 months.

Discussion

Recent studies have shown minimally invasive multi-level interbody procedures such as XLIF and others (e.g, OLIF, ALIF and TLIF) to be comparable with respect to fusion rates and global sagittal alignment [6-8]. Catalyst bone graft was shown previously to provide consistent and rapid bone healing in one-level TLIF patients with significantly improved VAS and ODI scores8. The case described here finds earlier than expected interbody fusion at 6 months with corresponding clinical and functional improvement, which was confirmed at the 12-month follow-up visit. This patient's outcome in a multi-level XLIF with challenging comorbidities (i.e., obesity, multiple previous spine surgeries, endocrine disorder) provides support for the use of this bone graft substitute in more challenging patient scenarios.

Acknowledgement

We particularly thank the Clinical Study Coordinator, Rebekah Vinson, who enabled the recruitment and all the data collection for this Case Study and the OssDsign Spine Registry through which the data has been collected.

References

- Mobbs RJ, Phan K, Malham G, Seex K, Rao PJ, et al. (2015) Lumbar interbody fusion: techniques, indications and comparison of interbody fusion options including PLIF, TLIF, MI-TLIF, OLIF/ATP, LLIF and ALIF. J Spine Surg (1): 2-18.
- 2. Xu DS, Walker CT, Godzik J, Turner JD, Smith W, et al. (2018) Minimally invasive anterior, lateral, and oblique lumbar interbody fusion: a literature review. Ann Transl Med 6(6): 104.
- Ozgur BM, Aryan HE, Pimenta L, Taylor WR (2006) Extreme Lateral Interbody Fusion (XLIF): A novel surgical technique for anterior lumbar interbody fusion. Spine J 6(4): 435-443.
- 4. Grauer JN, Beiner JM, Kwon BK, Vaccaro AR (2003) Bone graft alternatives for spinal fusion. Bio Drugs 17(6): 391-394.
- 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. Spine J 21(11): 1925-1937.
- 6. Yoon J, Choi HY, Jo DJ (2023) Comparison of Outcomes of Multi-Level Anterior, Oblique, Transforaminal Lumbar Interbody Fusion Surgery: Impact on Global Sagittal Alignment. J Korean Neurosurg Soc 66(1): 33-43.
- Lazary A, Varga PP, Kiss L, Szoverfi Z, Czop S, 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).
- Palacios P, Palacios I, Palacios A, Gutiérrez JC, Mariscal G, et al. (2024) Efficacy and Safety of the Extreme Lateral Interbody Fusion (XLIF) Technique in Spine Surgery: Meta-Analysis of 1409 Patients. J Clin Med 13(4): 960.

ISSN: 2574-1241

DOI: 10.26717/BJSTR.2024.56.008906

Rosalyn Archer. Biomed J Sci & Tech Res

(cc)

(i) (i) This work is licensed under Creative Commons Attribution 4.0 License

Submission Link: https://biomedres.us/submit-manuscript.php



Assets of Publishing with us

- Global archiving of articles
- Immediate, unrestricted online access
- **Rigorous Peer Review Process** •
- Authors Retain Copyrights •
- Unique DOI for all articles •

https://biomedres.us/