

Interim analysis of the first 20 patients in a prospective clinical study evaluating Natural Matrix Protein® (NMP®) Fibers in interbody fusion

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Introduction

Autologous cancellous bone, particularly harvested from the iliac crest, remains the gold standard for spinal fusion grafting [1]. Due to the morbidity associated with autograft harvest, alternatives such as allogenic bone and synthetic substitutes have gained clinical acceptance [2]. Among these, Natural Matrix Protein® (NMP®) has shown promise. NMP is a human bone derived bioimplant which has been processed to enhance bioavailability of the native growth factors, including BMPs within its matrix. This results in a strongly osteoinductive graft that has been shown to be safe and effective clinically when used in anterior lumbar interbody fusion [3,4].

Study Design and Patient Population

This interim case series reports 12-month outcomes from the first 20 patients in the lumbar cohort of an ongoing prospective study (NCT06000319) evaluating the safety and effectiveness of NMP® Fibers as a bone void filler in cervical and lumbar interbody fusion procedures. This was a single-site study conducted by two investigators.

The cohort consisted of 13 female patients (65%) and 7 male patients (35%). Patient ages range from 44 to 79 years.

Comorbid conditions were prevalent, with hypertension (65%) and diabetes (40%) being the most common. The mean BMI was 33. Three (15%) of patients reported smoking within 30 days prior to surgery. Only 1 patient had no co-morbidities with a BMI below 30, however they were a current smoker.

The majority of patients (15) underwent single-level lumbar fusion, while 4 patients had surgery at two levels and 1 patient at three levels. A variety of surgical approaches were used, with

TLIF being the most frequent (6 patients), followed by PLIF (5 patients), XLIF (5 patients), and ALIF (4 patients). The most commonly operated spinal levels were L4/5 (10 patients), L5/S1 (7 patients), and L3/4 (6 patients), with fewer surgeries performed at L2/3 (3 patients), as shown in Table 1.

To be included in this study the patient must have had a diagnosis of degenerative disc disease (DDD), spinal stenosis, or spondylolisthesis and underwent interbody spine fusion at no more than three adjacent levels between L1-S1 using NMP Fibers. Eligible patients were required to be at least 18 years of age at the time of consent, could sign an informed consent document, maintain current contact information, and were willing to comply with follow-up visits and post-operative clinical and radiographic assessments per protocol.

Patients were excluded from participation if they were under the age of 18, were imprisoned, or experiencing a major mental illness (e.g., psychosis, schizophrenia, or major affective disorder) that, in the opinion of the investigator, could indicate symptoms of psychological rather than physical origin.

For the 20 patients analyzed, the average volume of NMP used for a single-level lumbar fusion ranged from 2.5 cc to 5.9 cc, with 2.5 cc typically used in TLIF single-level cases and 5.9 cc used in ALIF or lateral single-level cases. NMP was rehydrated prior to use with Bone Marrow Aspirate (BMA) in TLIF cases. In ALIF and XLIF cases, NMP was most often rehydrated with saline only. In 10 cases, only NMP was used where it was placed within the cage, with nothing outside the cage. In the other 10 cases, NMP was placed within the cage and locally harvested autograft was placed around the outside of the cage.

Table 1: Patient Demographics and Clinical Characteristics

ID	Age	Sex	Comorbidities	Smoker*	BMI	Op Levels	# Levels	Surg Approach	Local Autograft Used
1	60	F	Diabetes, Hypertension	Y	21.6	L3/4, L4/5	2	TLIF	Y
2	70	M	None	N	23.4	L4/5	1	PLIF	Y
3	71	M	Hypertension	N	28.7	L5/S1	1	ALIF	N
4	79	F	Diabetes	N	27.5	L4/5, L5/S1	2	TLIF	Y
5	69	F	Hypertension, GERD	N	31.8	L4/5	1	PLIF	Y
6	62	M	None	N	29.4	L2/3	1	XLIF	N
7	77	F	Diabetes, Hypertension	N	32.8	L4/5	1	TLIF	Y
8	53	F	GERD, Thyroid Dysfunction	N	21.2	L4/5	1	PLIF	Y
9	71	M	Diabetes, Hypertension	N	38.2	L5/S1	1	ALIF	N
10	44	F	Hypertension	N	48.1	L5/S1	1	PLIF	N
11	61	F	Hypertension	N	39.5	L5/S1	1	PLIF	Y

*Smoking last 30 days

ID	Age	Sex	Comorbidities	Smoker*	BMI	Op Levels	# Levels	Surg Approach	Local Autograft Used
12	72	F	Hypertension, Thyroid Dysfunction, Hyperlipidemia, Atrial Fibrillation	N	28.9	L2/3	1	XLIF	N
13	67	M	Diabetes, Hypertension	N	33.6	L4/5	1	PLIF	N
14	66	M	None	N	32.5	L3/4, L4/5	2	TLIF	Y
15	70	F	Diabetes, Hypertension	N	37.4	L4/5	1	TLIF	Y
16	66	F	Hypertension	N	34.5	L3/4	1	XLIF	Y
17	46	F	Diabetes	N	39.3	L3/4	1	TLIF	N
18	50	F	None	Y	26	L4/5, L5/S1	2	ALIF	N
19	65	F	Diabetes, Hypertension, Osteoporosis	N	44.4	L3/4	1	XLIF	N
20	63	M	Hypertension	Y	34.3	L3/4, L4/5, L5/S1	3	ALIF	N

Outcome Measures

Patients were prospectively followed for 12 months post-operatively with a comprehensive evaluation protocol that included:

- **Imaging assessments:** Standard and flexion-extension radiographs were obtained to assess spinal fusion and segmental stability.
- **Safety monitoring:** Adverse events were documented throughout the follow-up period.
- **Surgical outcomes:** All secondary surgical interventions—such as revisions, re-operations, hardware removals, or the need for supplemental fixation—were tracked.

Patient-reported outcomes (PROs) collected to evaluate pain and functional status included:

- Back Pain and Leg Pain using a visual analogue scale (**VAS**)
- Disability using Oswestry Disability Index (**ODI**): ODI is a validated questionnaire comprised of 10 questions around the ability of the patient to manage everyday life. A higher score on the ODI indicates more severe disability caused by low back pain.

Definition of Fusion

Fusion at 12 months was defined based on radiographic criteria provided in the FDA's "Guidance Document for the Preparation of IDEs for Spinal Systems" including:

- Less than 5° of angular motion on flexion-extension radiographs
- Absence of radiographic indicators of non-union, such as radiolucency, hardware failure, or loss of graft height

Fusion failure was defined by:

- Translational motion of ≥ 3 mm or angular motion of $\geq 5^\circ$
- Radiographic evidence of instability, pseudarthrosis, or graft-related complications.

Results

Clinical outcomes:

All 20 participants included in this interim analysis have completed a post-operative questionnaire that subjectively assessed the level of pain in the lower back, right leg and left leg as well as an ODI questionnaire that assessed disability. Overall, excellent improvements in pain levels were reported for each parameter with the average improvement being greater than minimal clinically important difference (MCID) for all reported patient reported outcomes (**Figure 1**).

MCID is defined as 12.8 for ODI, 1.2 for Back Pain and 1.6 for Leg Pain [5]. 60% of the participants achieved MCID for ODI (>12.8), 70% achieved MCID for lower back pain (>1.2), 50% for right leg pain and 55% for left leg pain (>1.6).

The mean lower back pain improved from 6.9 to 4.0, mean right leg pain improved from 5.0 to 3.6 and mean left leg pain improved from 4.6 to 3.0 from pre-op to 12-month post-op. In addition, the mean ODI score improved 15.7 points from 48.0 pre-op to 32.7 at the 12-month post-op. (**Figure 2**).

Figure 1
Mean VAS scores at Pre-Op and 12-month Follow up.
Averages are shown for all 20 patients

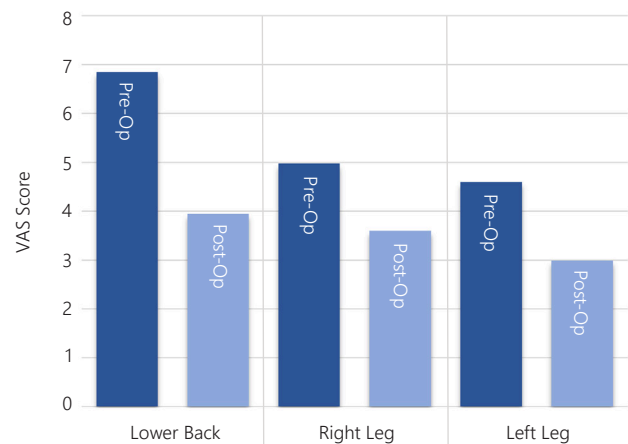
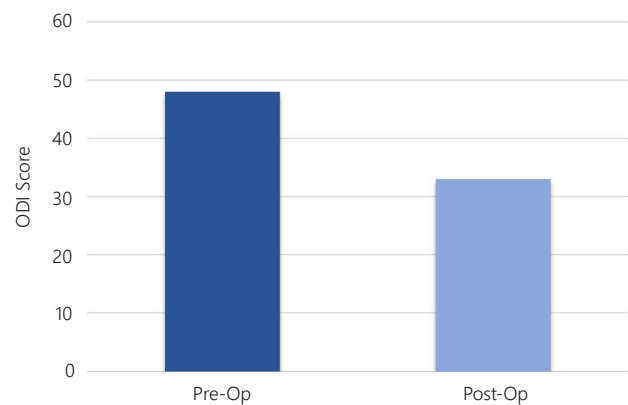


Figure 2
Mean ODI scores at Pre-Op and 12-month Follow up.
Averages are shown for all 20 patients



Radiographic Outcomes

Radiographic assessments conducted by the study investigators on the 20 lumbar interbody fusion cases showed evidence of successful fusion in 18 subjects (90%). Representative images of fusion at 12 months are found in Figures 3, 4, 5 and 6.

Of the two non-fused patients, one patient (a 79-year-old female with diabetes and a BMI of 27.5 who underwent a 2-level TLIF between L4 and S1) demonstrated signs of delayed fusion (limited bridging bone on CT scan). There were also hardware-related findings noted which included an L4 screw halo and screw migration. Despite these radiographic findings, the patient experienced significant clinical improvement, with marked reductions in pain and notable gains in functionality.

The remaining patient (a 71-year-old male with diabetes, hypertension and a BMI of 38.2 who underwent a single level ALIF at L5/S1) was found to have pseudoarthrosis on CT imaging, along with a broken screw, and is expected to require reoperation.

Table 2: Summary of Radiographic Outcomes

ID	Bridging Bone on X-ray	Translational Motion	Angular Motion	Fused (Yes/No)	Comment
1	Yes	0	0°	Yes	
2	Yes	0	0°	Yes	
3	Yes	0	0°	Yes	
4	Yes	Not available	Not available	Delayed	Limited bridging bone on CT
5	Yes	0	0°	Yes	
6	Yes	0	0°	Yes	
7	Yes	0	0°	Yes	
8	Yes	0	0°	Yes	
9	No	0	0°	No (CT-scan)	Broken screw
10	Yes	0	0°	Yes	

ID	Bridging Bone on X-ray	Translational Motion	Angular Motion	Fused (Yes/No)	Comment
11	Yes	0	0°	Yes	Confirmed CT-scan
12	Yes	0	0°	Yes	
13	Yes	0	0°	Yes	
14	Yes	0	0°	Yes	
15	Yes	0	0°	Yes	
16	Yes	0	2°	Yes	
17	Yes	0	0°	Yes	Confirmed CT-scan
18	Yes	0	0°	Yes	
19	Yes	0	1°	Yes	
20	Yes	0	0°	Yes	

Figure 3

Representative radiographic images at 1, 6, and 12 months postoperatively demonstrating progressive and successful spinal fusion at 12 months in a 69-year-old female patient following a one-level (L4/L5) PLIF procedure. Patient was diagnosed with degenerative disc disease, degenerative spondylolisthesis and spinal stenosis. She had several comorbidities: hypertension, sleep apnea and GERD. Patient's BMI is 31.8.

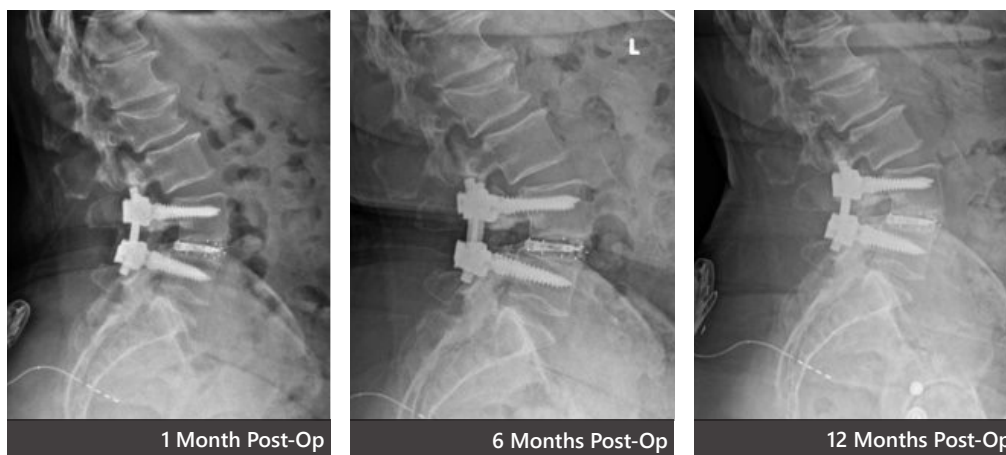


Figure 4

Representative radiographic images at 1, 6, and 12 months postoperatively demonstrating progressive and successful spinal fusion at 12 months in a 46-year-old female patient following a one-level (L3/L4) TLIF procedure. The patient was diagnosed with degenerative disc disease, adjacent segment disease and spinal stenosis. She is diabetic and her BMI is 39.3.

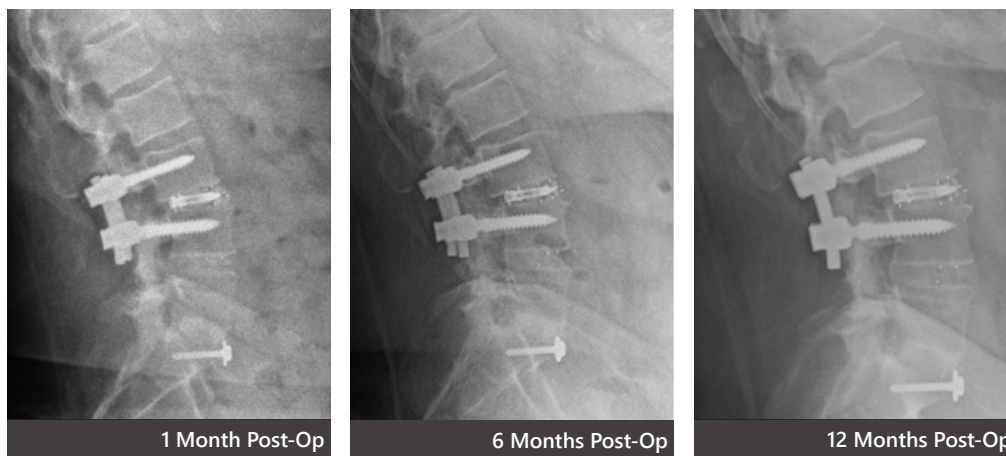


Figure 5

Representative radiographic images at 1, 6, and 12 months postoperatively demonstrating progressive and successful spinal fusion at 12 months in a 50-year-old female patient following a two-level (L4/L5-L5/S1) ALIF procedure. The patient was diagnosed with degenerative disc disease and spinal stenosis, smoker, BMI is 26.



Radiographic Outcomes (continued)

Figure 6

CT image and x-ray of a 70-year-old female with a history of diabetes and hypertension, BMI 37.4, who underwent an L4–L5 transforaminal lumbar interbody fusion (TLIF). At 12-months post-op, both CT and x-ray imaging demonstrated excellent fusion.



Summary of Adverse Events in Lumbar Interbody Fusion Cases

Adverse events were defined as “any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in participants, users or other persons, whether or not related to the use of NMP.” This definition included events related to the procedure, both expected or unexpected.

Participant medical records were reviewed, and all adverse events were documented in the Electronic Data Capture (EDC) system. The adverse events were then categorized as serious or non serious and their relationship to the investigational device (NMP) was assessed as unrelated, possibly related or reasonably causally related by the Principal Investigator (PI).

No events were classified as serious or were related to the investigational product. Among the 20 patients, 10 (50%) experienced adverse events (Table 3).

Conclusion

Preliminary radiographic and clinical data suggest that Induce NMP Fibers are effective in promoting spinal fusion in a variety of lumbar interbody fusion procedures, even in patients with significant comorbidities. High rates of fusion—both radiographic and clinical—were observed at 12 months. Additionally, there was a significant reduction in pain and disability compared to preoperative levels. These early findings support the continued use and further investigation of NMP in interbody fusion procedures. Final outcomes from the full 200-patient cohort will provide deeper insight into long-term efficacy and safety.

References

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Table 3: Adverse Event Breakdown by Category

Category	# of Occurrences
Incision Related	1
Wound Drainage	1
Pain	7
Pain - Lumbar	2
Pain - Remote transverse process fracture	1
Pain - Hip	1
Pain - Fall	2
Pain - Paraspinal pain	1
Neurological	1
Neurological - Dural Pinhole Tear	1
Implant/Hardware Issues	1
Total	10

Disclosures

NMP grafts are intended for use as a bone void filler for filling voids and gaps in the skeletal system that are not intrinsic to the stability of the bony structure.

Please see the NMP IFU for a complete list of indications, contraindications, warnings, precautions, and other important medical information.

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