

Performance of a Novel Nanosynthetic Bone Graft (Nano-Si-Ap) in Real World Clinical Practice: Twelve Month Results of the First 108 Patients in the Propel Spine Registry

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ABSTRACT

Background: The PROPEL prospective, multi-center, spine registry collects real-world data from the use of a novel nanosynthetic bone graft, Nano-Si-Ap, in patients undergoing spinal fusion with the objective of evaluating radiographic and clinical performance. This paper describes the results of an interim analysis including all participants with complete data at baseline and 12-month post-surgical follow-up.

Methods: 108 patients were included in this analysis from six sites; surgery dates from 25th April 2022 to 21st August 2023. Any patient, ≥21 years, requiring spinal fusion surgery for which Nano-Si-Ap was being used, was appropriate for inclusion if in the investigator's opinion, the patient was able to comply with the registry protocol requirements. The primary endpoint was assessment of fusion (bridging bone) at 12 months ± 60 days post-surgery utilizing CT or x-ray if CT unavailable. Clinical outcomes were assessed as secondary endpoints with success defined as any improvement from baseline scores for the following: Quality of Life Questionnaires (VAS and ODI/NDI (as applicable), and SF-36) and maintenance or improvement of neurological function. A safety review was also conducted of all Adverse Events (AEs).

Results: Successful fusion was achieved at 12 months in 160/181 of levels (88.4%) treated. Mean clinical outcomes all showed improvement from baseline: >3 points (0-10 scale) improvement in VAS pain scores for both back and leg pain; functional improvement (ODI/NDI score), with improvement of 23.7 points; SF-36 scores showed ≥5 point improvement for all sub-scales; there were no unexpected device-related adverse events reported.

Conclusions: The first 108 patients in the Propel registry reaching 12-month follow-up showed improvement in every category of health status measured, with no unexpected device-related adverse events, while achieving successful fusion in 88.4% of treated levels in a challenging cohort. These results provide clinical confirmation of previously reported pre-clinical and clinical data, and this study, using real-world data, continues to support its efficacy, safety and utility of using this novel nanosynthetic bone graft, Nano-Si-Ap, in spinal fusion surgery.

Keywords: Anosynthetic Bone Graft; Nano-Si-Ap; Spine; Fusion; Registry; Silicate Calcium Phosphate

Introduction

In March 2022, a prospective clinical registry was initiated known as PROPEL (prospective observational spine fusion registry for use of a novel nanosynthetic bone graft substitute (Nano-Si-Ap) in real-world clinical practice – clinicaltrials.gov ref: NCT05329129). The registry was established to collect real-world data from the use of Nano-Si-Ap bone graft in clinical practice. The objective was to monitor and assess the post-market radiographic and clinical performance of the novel nanosynthetic bone graft substitute, Nano-Si-Ap, amongst a wide range of prominent spine surgeons and their demographically varied pool of patients. This paper describes the results of an interim analysis including all participants with complete data at baseline and 12-month post-surgical follow-up. Recent trends in published literature show that the use of “real world data” (RWD) is steadily gaining acceptance, as evidenced by a marked increase of its use in orthopedic and surgical journals. Regulatory authorities like the Food and Drug Administration (FDA) have launched initiatives to highlight the use of registries to serve as a way to generate a real world view of clinical practice, patient outcomes and safety [1]. Patient registry studies may focus on a specific treatment but offer a substantial advantage over more structured clinical trials by providing necessary data on all patients regardless of profile [2,3]. Randomized, controlled, prospective trials (RCT), considered to be the “gold standard” for research, must isolate the treatment effect by restricting the patient population such that the intervention studied can be measured with minimal confounding variables. The resultant restrictive inclusion/exclusion criteria mean a substantial part of the patient population seeking treatment who are often at higher risk of a negative outcome are excluded from most RCTs [4,5]. Prospective patient registries provide a way to gather data in a structured way on this more challenging cohort resulting in enhanced post-market safety surveillance [6,7].

Bone graft substitutes have substantially reduced the need for autograft harvesting from the iliac crest and its associated morbidity. Synthetic bone grafts have the added advantage of knowing the exact composition and quality of materials as opposed to allograft and autograft [8]. Synthetic bone grafts are typically osteoconductive biphasic hydroxyapatite/tricalcium phosphate ceramic substitutes [9]. Recent technical progress with newer generation synthetic bone grafts includes enhanced surface technology and nanoscale architecture similar in size and crystallinity to human bone mineral. This differs from typical sintered ceramic architecture which are many orders of magnitude greater in size [10]. The nanosynthetic silicate substituted (5.8wt% silicon) calcium phosphate bone graft substitute (Nano-Si-Ap) used in this registry, was designed such that the nano architecture and site-specific silicate substitution mimic more faithfully the scale and structure of natural bone mineral and therefore follow the healing pathways more commonly associated with autograft or biologics. Most importantly, this includes

endochondral ossification, whereby new bone is formed via a cartilaginous emplate and is crucial in fracture healing as it is not reliant on the presence of existing connective tissue to initiate the process of bone repair. As such, endochondral, or secondary, bone formation, is the dominant mechanism of bone repair where a large gap or significant micromotion is present [11]. This is in contrast to intramembranous, or primary, bone formation, whereby new bone is formed directly from existing connective tissue and is the predominant mechanism of repair where a very small bone gap is present [12] and is generally the dominant mechanism observed in previous synthetic bone graft substitute studies [13]. The use of the novel nanosynthetic bone graft substitute, Nano-Si-Ap, described in this paper, has shown encouraging results in both animal models and early clinical use. [14-17]. In recent findings, Nano-Si-Ap was shown to form mature networks of functional trabecular bone in an intramuscular implantation site. In this study, it outperformed the two other commercially-available grafts, one with a nanostructure and the other incorporating silicate substitution, demonstrating that both are required to form significant amounts of biologically functional bone in this highly challenging model. In this study, Nano-Si-Ap also demonstrated osteoclastic graft remodeling [18].

Materials and Methods

The purpose of this post-market, multi-center, prospective, observational registry was to gather information on the radiographic and clinical outcomes of the commercially available nanosynthetic bone graft (Nano-Si-Ap) known as OssDsign Catalyst® (manufactured by OssDsign AB, Uppsala, Sweden) in patients who require spinal fusion. This paper describes the results of an interim analysis including all participants with complete data at baseline and 12-month post-surgical follow-up, 108 participants were included, over six sites, spanning the surgery dates from 25th April 2022 to 21st August 2023. The registry has full ethics approval from Central or local IRBs as appropriate to participating sites and is being conducted in accordance with the principles of Good Clinical Practice, HIPAA requirements, the Declaration of Helsinki, ISO 14155 and applicable parts of FDA regulations (21 CFR Part 812, 50, 54, 56). Any patient, ≥21 years, diagnosed as requiring spinal fusion surgery for which the surgeon had decided to use Nano-Si-Ap, was appropriate for inclusion if in the investigator's opinion, the patient was psychosocially, mentally, and physically able to fully comply with the registry protocol, including the post-operative regimen and follow-up visits.

All participants included in this Spine Registry gave their written informed consent and were implanted with Nano-Si-Ap as the only synthetic bone graft used during their spine fusion surgery, and no others. The Nano-Si-Ap bone graft was mostly used alone, or in some cases mixed with local autograft or allograft. A detailed medical history was obtained including a description of prior treatment, and any relevant concurrent medical conditions (e.g., diabetes,

on-going malignancy or systemic/surgery site infection, cardio-vascular disease, renal disease, osteoporosis, other diseases which may affect metabolism and bone healing, etc.), along with current pain medications. The primary endpoint was the radiographic assessment of bone fusion at 12 months $\pm$ 60 days post-operative via CT and/or x-ray based on evidence of continuous bone bridging from the superior to the inferior vertebra or posterior elements at the target level. CT scans were used as the first tier of fusion assessment (i.e., CT Grading: no presence of bone (grade 1); presence of non-bridging trabecular bone (grade 2) and fused = presence of bridging bone (grade 3)). If no CT fusion assessment was possible (i.e., no CT scan taken or not readable), then X-rays (i.e., Anterior-Posterior (AP), neutral Lateral), were assessed for the presence of bridging trabecular bone between the superior and inferior vertebra. For multi-level fusions, all levels were assessed and scored separately according to the above criteria. Clinical outcomes were assessed as secondary endpoints with success deemed as any improvement from baseline scores for the following: Quality of Life Questionnaires (VAS and ODI/NDI (as applicable), and SF-36) and maintenance or improvement of neurological function [19,20]. A safety review was conducted by analysis of any Adverse Events (AEs) whether related to the bone graft or not (surgery or patient). An independent medical monitor reviewed all AEs. Descriptive analyses such as percentages, means and standard deviations have been applied to the data reported, as appropriate.

Results

The demographic profile of the 108 patients included in this interim analysis of participants having completed their post-surgery 12-month follow-up describes a challenging patient population with a mean age of 63.2 years (range 31-88) with a mean BMI of 31.9 (obese). As shown in Table 1, there was a relatively high percentage of active smokers (23%), in addition to a further 25% with a previous history of smoking. Primary diagnosis was, in most cases, degenerative disc disease (76%), spinal stenosis (11%), or spondylolisthesis (10%). There were 181 total levels treated in the 108 patients with the vast majority of the levels involving lumbar interbody fusion (ALIF, TLIF, XLIF). Three levels in two patients were treated with posterolateral fusion only, without an interbody component. There were 14 cervical interbody (ACDF) levels in seven patients (Table 1). In 11 patients (12 levels) the Nano-Si-Ap was mixed with allograft or autograft and in the remaining 97 patients (169 levels) it had been used alone. All lumbar interbody fusions had additional posterior instrumentation. There was a high percentage of several prominent surgical and patient risk factors (Table 2). In addition to age, smoking, and BMI as previously mentioned, 13 patients (12.0%) presented with diabetes and seven (6.4%) with osteoporosis. Previous spine surgery was also prevalent (decompression 17/108 (15.7%) patients) and previous fusion surgery (54/108 (50.0%)

patients) either at the operated level or adjacent levels. In addition, 22 of the 108 (20.3%) patients had fusion performed at three or more levels. Patient comorbidities are listed in Table 3A and categorized by the number of these per patient in Table 3B.

Table 1: Demographics and Surgical Approach.

Patients (levels)	108 (181)
Age, yrs	
Mean $\pm$ SD, (Range)	63.2 $\pm$ 12.0, (31-88)
Sex, n (%)	
Male	47 (43.5%)
Female	61 (56.5%)
BMI	
Mean $\pm$ SD, (Range)	31.9 $\pm$ 6.1 (19.7-46.5)
Smoking, n (%)	
Active smokers	25 (23%)
Ex-smokers	27 (25%)
Primary diagnosis, n (%)	
Cervical Myelopathy	1 (1%)
Degenerative Disc Disease	82 (76%)
Herniated Nucleus Pulposus	1 (1%)
Instability	1 (1%)
Spinal Stenosis	12 (11%)
Spondylolisthesis	11 (10%)
Surgical Approach* (by Levels)	181 (Total Levels)
ALIF	48 (26.5%)
TLIF	11 (6.0%)
XLIF	99 (54%)
PLF	9 (4.7%)
ACDF	14 (7.4%)

Note: *All lumbar interbody procedures had additional posterior instrumentation.

Table 2: Risk Factors for Spine Fusion.

Direct Surgical Risk Factors	N (%)	Patient Surgical Risk Factors	N (%)
Previous Spine Surgery (decompression only)	17 (15.7%)	Age > 65 years old	57 (52.7%)
		BMI > 30	65 (60.1%)
Previous Spine Fusion	54 (50.0%)	Active Smokers	25 (23.1%)
		Previous Smoking History	27 (25.0%)
Number of Levels to be fused is 3 or greater	22 (20.3%)	Diabetes (Type 1 or 2)	13 (12.0%)
		Osteoporosis	7 (6.4%)

Table 3:

A. Patient Comorbidities.

B. Number of Comorbidities per Patient.

Comorbidities	N (%)
A	
Thyroid/Lymph Disease	7 (6.5%)
Cardiovascular Disease	35 (32.4%)
Hypertension	65 (60.1%)
Pulmonary Disease	16 (14.8%)
Gastrointestinal Disease	17 (15.7%)
Metabolic Disease	4 (3.7%)
Renal Disease	6 (5.6%)
Hepatic disease	1 (0.9%)
Hematological	4 (3.7%)
Neurological	17 (15.7%)
Urogenital	5 (4.6%)
Endocrine Disease	7 (6.5%)
Immunological	6 (5.6%)
Multiple Joint Disorder	4 (3.7%)
Substance Dependence	1 (0.9%)
Mental Disorder	14 (12.9%)
Thrombosis/Embolic Disease	3 (2.8%)
Cancer History	13 (12.0%)
B	
Number of Comorbidities	N (%)
None	7 (6.4%)
One	20 (18.5%)
Two	29 (26.8%)
Three or More	52 (48.1%)

Nearly half of the patients 52/108 (48.1%) had three or more comorbidities. Successful fusion was achieved at 12 months in 160 of the 181 levels (88.4%); 147/181 (81.2%) assessed using CT scans and 34/181 (18.8%) assessed using AP/L x-rays.. Table 4 shows this high fusion success rate was consistent through patient and surgical risk factors (range 84.7%-93.4%). Clinical outcomes showed greater than 3 points (0-10 scale) improvement in mean VAS pain scores for both back and leg pain (Figure 1). Functional improvement, as measured by ODI score, showed a mean improvement of 23.5% (Figure 2). Due to the low number of cervical levels (4 patients, 14 levels), NDI/ODI, and all VAS scores have been pooled for analysis. SF-36 mean outcomes are shown in Figure 3. The subscales regarding physical function (PF), role physical (RP), and bodily pain (BP) all improved

by 5 points or greater from baseline and the physical component score (PCS) improved substantially from 32.7 at baseline to 37.8 at 12 months (5.1 points difference). Up to 12 months, no unexpected device-related serious adverse events were recorded. In all, 21 adverse events were reported representing 19.4% of participants (Table 5). There were 18 complications attributed to the surgery and three reported as pseudoarthrosis/non-union, graded as possibly, or probably, device-related by the surgeon.

Table 4: Fusion Success by Levels for Direct and Patient Surgical Risk Factors*.

Patient Surgical Risk Factor	N levels)	Fused (levels)	%
Age ≥ 65	109	96	88.10%
Age < 65	72	64	88.90%
BMI ≥ 30	114	102	89.40%
BMI < 30	67	58	86.60%
Smokers	36	32	88.80%
Previous or Non-Smokers	145	128	88.20%
Diabetes	27	23	85.10%
No Diabetes	154	137	88.90%
Osteoporosis	18	16	88.90%
No Osteoporosis	163	144	88.3%
Previous Surgery (decompression)	90	78	86.70%
No Previous Surgery	91	82	90.10%
Previous Fusion	69	59	85.50%
No Previous Fusion	112	101	90.10%
Levels Attempting Fusion are ≥3	76	71	93.40%
Levels Attempting Fusion < 3	105	89	84.70%

Note: All apparent differences in success rates are not statistically significant (p >0.10 in all cases, two sided fishers exact test, GraphPad)

Table 5: Adverse Events/Complications.

N	Adverse Event/Complication
2	Superficial wound infection
8	Failure of spinal instrumentation
1	Left leg radiculopathy/ anterior thigh weakness
1	Continued right leg radiculopathy
1	Continued lower back pain
1	Bilateral dorsiflexor weakness
1	Adjacent level disease- L1-2
3	Excessive leg pain (greater than pre-op)
3	Pseudoarthrosis/ non-union
21	Total (19.4%)

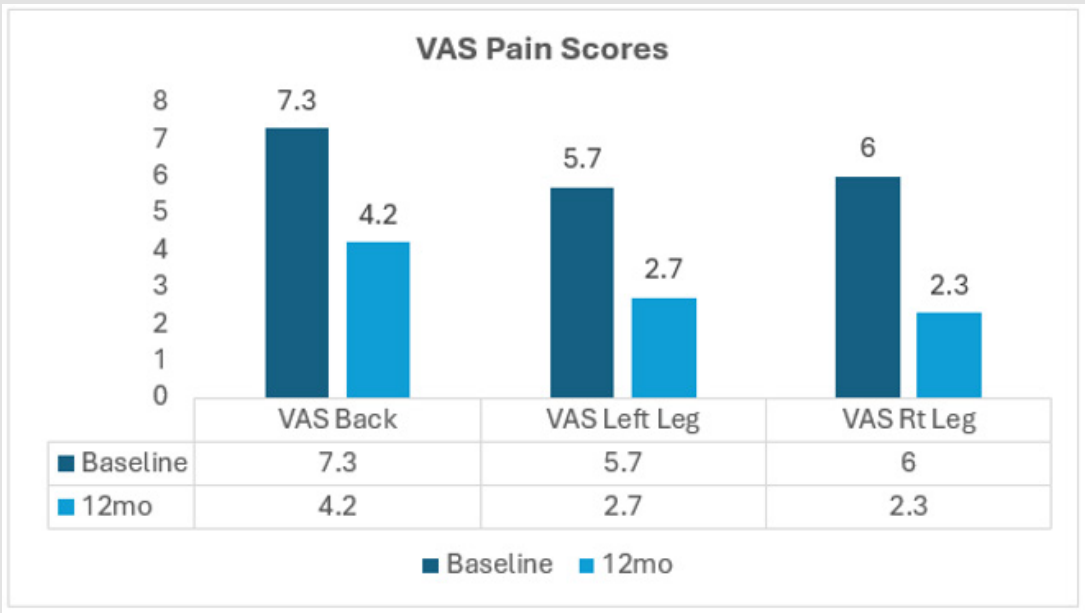


Figure 1: Mean Visual Analog Scale (VAS) Pain Scores at baseline and 12-month follow-up.

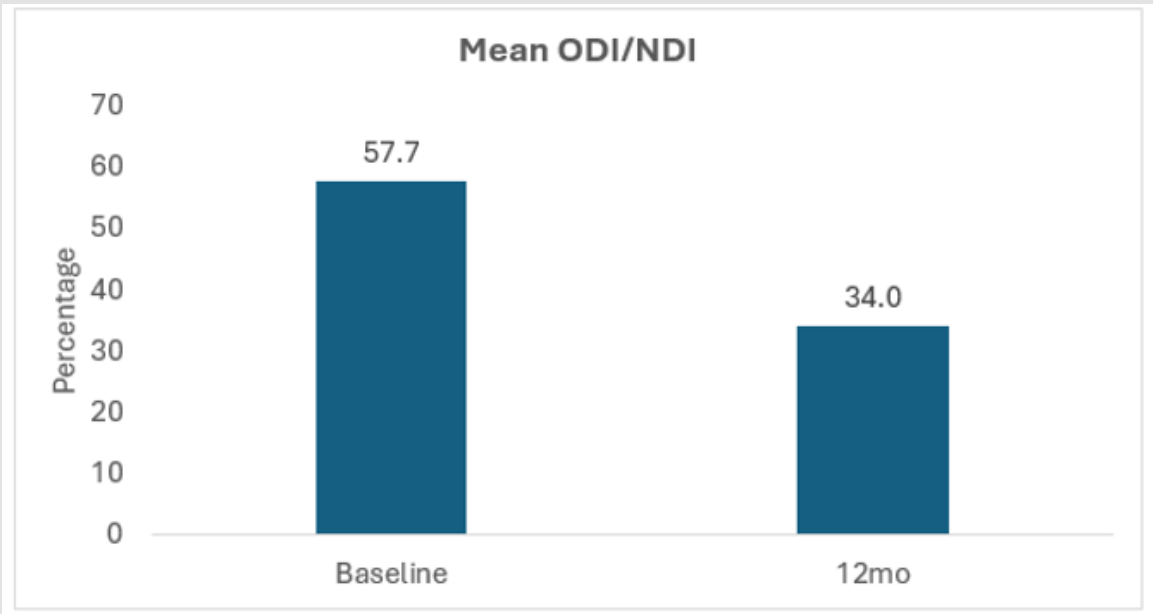


Figure 2: Mean Oswestry Disability Index (ODI) and Neck Disability Index (NDI) score at baseline and 12-month follow-up.

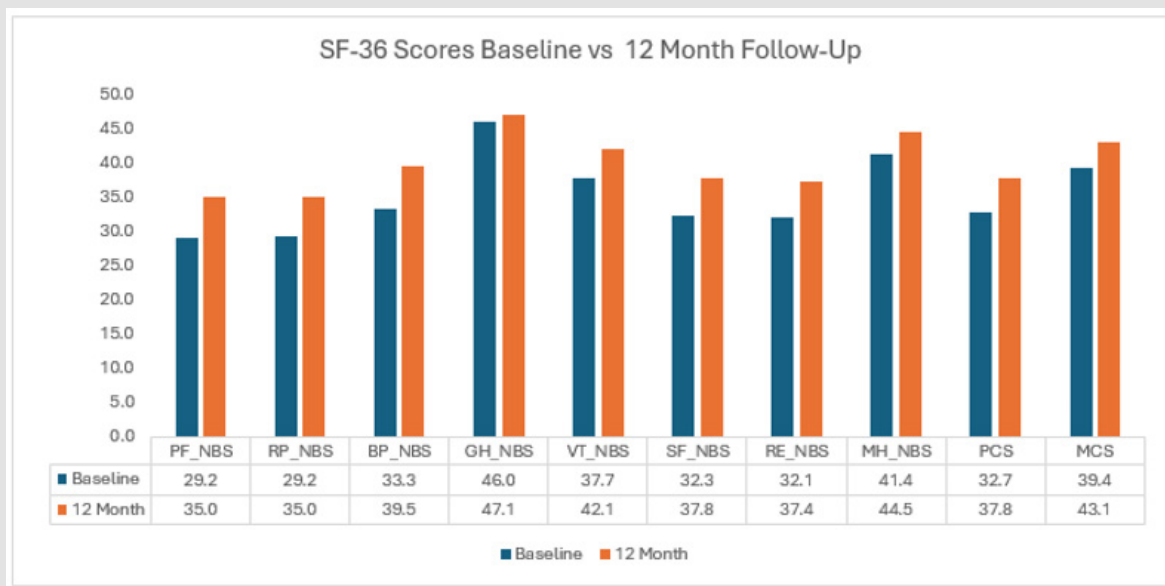


Figure 3: Short Form 36 Health Survey Questionnaire (SF-36).

Discussion

The demand for lumbar fusion surgery in older and more medically complex patients is increasing as the population ages, and treatment of aging patients with debilitating degenerative conditions will become more frequent for spine surgeons [21]. Advancing age, smoking status, and multiple level pathologies have been shown to be direct risk factors for fusion failure [21]. Multiple patient comorbidities can increase the likelihood of complications and may result in poor clinical outcomes [22]. Revisions to fusion surgery have consistently been associated with a high rate of failure and reoperation [23-25]. The choice of bone graft used to obtain fusion, among other factors, is a critical element to obtain radiographic and clinical success. These real-world data demonstrate that this novel nanosynthetic bone graft, Nano-Si-Ap, (a 100% synthetic bone graft), can reliably achieve fusion (88.4% of all levels, and 84.7%-93.4% in high-risk subgroups reaching 12-month follow-up) even in an inclusive complex patient population, where typical alternatives may include rhBMP-2 with its acknowledged attendant risks. [4,5]. Other bone grafts such as rhBMP-2 and Peptide enhanced bone grafts have shown fusion rates of 92.8 and 89%, respectively, for 24 months follow-up in RCTs which is comparable to our 12-month real-world data. These are two examples for bone grafting where the surgical technique and approach were closely defined along with an extensive list of other inclusion-exclusion criteria were used to determine the treatment effect, as anticipated for randomized, controlled, prospective trials [4,5]. Registries, on the other hand, are less selective and consequentially represent the surgeons' standard cohort of patients and more realistic population fusion rates. Only three of the reported Adverse Events,

described as pseudoarthrosis/non-union, were graded as possibly, or probably, device-related by the surgeon. Pseudoarthrosis is unavoidable in spinal fusion surgery, but our data suggest very strong results in a medically diverse and complex population.

Limitations of the Study

Limitations of this interim analysis are acknowledged with the numerous surgical techniques, varied number of levels, and other factors which at this point do not allow for all clinically relevant subgroup analysis. As the registry progresses with increasing numbers of patients, more robust statistical methods (logistic regression, odds ratios, etc.) will be employed to provide surgeons with additional information for their treatment choices. The outcomes in this registry verified the increasing challenge for spine surgeons as patients present with increasing medical and surgical complexity. The radiographic and clinical results presented thus far show that the surgeons participating in this registry have relied on the use of synthetic bone graft as an adjunct to surgical decision-making and technique in this higher risk population.

Conclusion

The first 108 patients reaching 12-month follow-up in the Propel registry showed improvement in every category of health status measured, with no unexpected device-related adverse events achieving successful fusion in 88.4% of treated levels in a challenging cohort. These results provide clinical confirmation of previously reported pre-clinical and clinical data, and this study using RWD continues to support its efficacy, safety and utility of using Nano-Si-Ap in spinal fusion surgery.

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Conflict of Interest

All of the authors are either Investigators involved in the Registry or working for Ossdsign, the Study sponsor.

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