One-year launch of OssDsign® Catalyst in U.S. – Preliminary Post-market Safety Review

Abstract

In recent years there has been a growing interest from surgeons in the use of synthetic bone graft substitutes to avoid the need of sourcing allograft or iliac crest autograft for use in spinal fusion procedures. A novel nanosynthetic calcium phosphate bone graft substitute, OssDsign Catalyst, has been designed to deliver consistent, rapid bone healing and remodeling. The combination of the highest level of incorporated silicate (5.8 wt%) with a nanoscale structure appears to be of benefit for bone formation.

In this report, we describe the preliminary post-market safety data consisting of Adverse Events and Complaints following the sale of 511 units of OssDsign Catalyst between August 1, 2021 - August 31, 2022, and preliminary clinical data from PROPEL, the U.S.-based multi-center prospective spinal fusion registry. Zero device-related complications have been reported for Catalyst during the period covered by this report.

Introduction

Degenerative disc disease and spinal stenosis are two of the major spine pathologies prevalent in today's society[1], resulting in low back and leg pain as well as functional limitations. When symptoms are not responsive to conservative care, surgery may be recommended. Spinal fusion was initially introduced for the management of spinal deformity and has, in more recent decades, been used to relieve pain and restore function in patients diagnosed with degenerative disc disease. One of the objectives of spinal fusion is to eliminate motion of the vertebral segment and thereby relieve pain[2]. Spinal fusion is a common procedure. 1.6M spinal fusions were performed by surgeons in 2019 with most procedures using a bone graft material[9].

Several types of bone grafting material can be used: i) autograft, the clinical gold standard for bone grafting (patient's own bone), ii) allograft (donor bone), iii) processed allograft (demineralized bone matrix, DBM), iv) xenograft (bone graft derived from another species), v) growth factor bone grafts (based on bone morphogenetic proteins, BMPs) and vi) synthetic bone graft substitutes[4,5]. Over the last 10 years, there has been a move away from the use of iliac crest autograft (ICBG) due to the complications associated with a second surgical procedure to harvest the bone and limited supply, and allografts, due to variability in tissue quality and potential risks of disease transmission and rejection. During this time there was a considerable uptake in the use of growth factor bone grafts, particularly in the U.S., but the high cost and the reporting of significant side effects, led to a decline in their use[4]. As a result of the limitations of these various materials, there is increased interest in synthetic bone graft substitutes.

OssDsign Catalyst® (formerly called Osteo^3 ZP Putty) is a new nanosynthetic Calcium Phosphate bone graft substitute, containing the highest level of substituted silicate (5.8 wt%) in any bone graft available on the market. It is osteoconductive, resorbable, porous and 100% synthetic without the need for adding any biological materials or natural proteins[8]. OssDsign Catalyst contains silicate-substituted calcium phosphate granules suspended in a resorbable polymer gel, which enables direct implantation from the packaging without any further preparation, saving time in the operating room. OssDsign Catalyst can be combined with autograft for use as a bone graft extender[8] in line with common practice. The high surface area of the porous granules has been designed to deliver rapid and reliable bone ingrowth and cellular remodeling, during the bone healing process, as shown in clinically relevant, challenging, pre-clinical studies[6,7]. These studies[6,7] showed that OssDsign Catalyst achieves fusion success rates comparable to iliac crest bone graft (the traditional 'gold standard').

Under the evaluation period of this report, a total of 511 units were sold in the U.S.

Materials and methods

Post-market safety data collection is continuously performed by OssDsign in order to ensure patient safety and to confirm the performance of the OssDsign Catalyst device.

The presented data are sales data of first year after launch, between August 2021 and August 31, 2022.

The preliminary clinical data presented herein are from U.S Registry PROPEL. PROPEL is a post-market, prospective, observational, multicenter registry for up to 10 U.S. study sites. The purpose is to gather information on the clinical outcomes and real-world use of commercially available bone graft substitutes manufactured by OssDsign® AB, in patients who require spinal fusion.

The safety data reported also includes data collected from the OssDsign complaints database.

Results

This data presents the outcome of 511 units of OssDsign Catalyst Putty shipped in the various sizes (2.5 cc, 5 cc and 10 cc) during the period under evaluation.

For the general cohort of 511, population data is not available. For the sub-cohort of the PROPEL Registry more data is available and is reported herein.

Study population – PROPEL Registry

The preliminary data reported are for the first cohort of patients recruited within the report evaluation period.

The primary diagnosis in the overall population was degenerative disc disease (87%), stenosis (6%), spondylolisthesis (6%), and deformity (1%). For most patients (34%), their surgery involved one vertebral level; (20%) of patients had two involved levels and (46%) had three or more involved levels. The most frequently involved levels were L4-L5 (55%) and L5-S1 (52%) of patients.

Safety

No device-related adverse events have been reported. A total of four (4) non-device related adverse events were reported in the Registry and were recorded as complaints.

A summary of the complaint incidents from the OssDsign Registry PROPEL is presented in Table 1.

TABLE 1.

Total number of complaints	Total number of device-related complications	Total number of reportable events	Number of complaints per unit sold (%)
4	*0*	*0*	*0.008 (0.8 %)**

Number of complaints.
**4 events per 511 units sold*

One (1) patient had a superficial wound infection requiring conservative treatment and one (1) patient suffered a deep infection requiring surgical drainage and conservative treatment. Both events were attributed to the procedure.

The other two (2) events were user-related and not related to the device. In these patients, the device was used after the expiration date without adverse clinical outcomes or patient harm.

A computer tomography (CT) image of a patient treated with OssDsign Catalyst for posterior lumbar fusion (PLF) surgery in L4-L5 (Figure 1) showed bone fusion after 6 months.

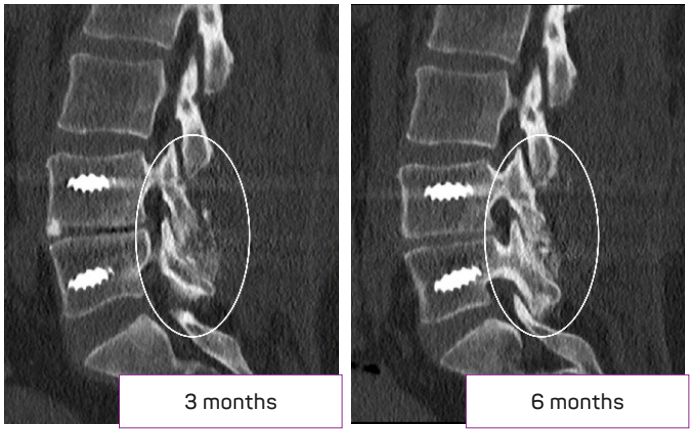

Figure 1. CT images at 3 and 6 months

Image disclaimer: This image is from a European clinical study and the use may differ from the cleared indications for use in other regions. Please refer to your local OssDsign representative for information on cleared indications for use in your country.

Early CT follow-up data supports that the clinical performance of Catalyst is similar to the performance reported in pre-clinical studies.

Conclusion

In the period under evaluation, no safety or performance issues were reported. This, along with the preliminary clinical data from the U.S. Registry PROPEL adds to the body of knowledge from preclinical studies, supporting the safety and performance outcomes of OssDsign Catalyst.

References

1. Katz, J. N. Lumbar spinal fusion. Surgical rates, costs, and complications. Spine (Phila Pa 1976) 20, 78S-83S (1995).
2. Weiner, B. K. & Fraser, R. D. Lumbar Interbody Cages. Spine (Phila Pa 1976) 23, 634–640 (1998).
3. Brandoff, J. F., Silber, J. S. & Vaccaro, A. R. Contemporary alternatives to synthetic bone grafts for spine surgery. Am J Orthop (Belle Mead NJ) 37, 410–4 (2008).
4. Vaccaro, A. R. et al. Bone grafting alternatives in spinal surgery. The Spine Journal 2, (2002).
5. Ehrler, D. M. & Vaccaro, A. R. The Use of Allograft Bone in Lumbar Spine Surgery. Clin Orthop Relat Res 371, 38–45 (2000).
6. Sirakoss (Unpublished). Osteo3 ZP Putty Preclinical Results From 510(k), internal report, dated 20 June 2018 (2018).
7. Conway, J. C. et al. The efficacy of a nanosynthetic bone graft substitute as a bone graft extender in rabbit posterolateral fusion. The Spine Journal 21, 1925–1937 (2021).
8. 2021-2225 OssDsign Catalyst IFU.
9. Becker's Healthcare: Becker's Spine Review. c2022; [accessed 2022 Oct]. https://www.beckersspine.com/spine/45273-surgeons-perform-1-62m-instrumented-spinal-fusions-per-year-in-the-us-5-things-to-know.html.

About OssDsign Catalyst

OssDsign Catalyst nanosynthetic bone graft putty is designed to engage dual bone formation pathways resulting in rapid and reliable bone formation at early time points throughout the entire fusion mass:

- A combination effect of engineered nanotechnology with silicate chemistry.
- Instructs bone formation in both vascular and avascular environments including the hypoxic center of the fusion mass where non-unions are known to occur.
- Rapid bone remodeling across entire fusion mass as soon as 6 weeks in a proven spine model.
- FDA cleared for use standalone or as an extender depending on indication[8].

About OssDsign

OssDsign's vision is to provide regenerative solutions to all patients with cranial or spinal bone defects, so they can be restored and healed as naturally as possible. Driven by a commitment to give patients back the lives they deserve, OssDsign collaborates with surgeons to engineer better healing by integrating biomaterials with clinical design. Headquartered in Sweden, OssDsign supplies hospitals worldwide with implants for use in cranial reconstruction and other orthopedic surgery applications.

REF. 2022-2305 Rev01