Improving Outcomes In Cranioplasty – Clinical Results From 1480 Cranioplasties Using OssDsign® Cranial PSI

Abstract

Reconstruction of cranial defects can be a complex surgical procedure associated with an underestimated morbidity. This report describes the outcome of 1480 cranioplasties using OssDsign Cranial PSI, a patient-specific implant made from a calcium phosphate material reinforced with 3D printed titanium. All data was collected as part of post-market surveillance following introduction of the product in Europe, US and selected Asian markets in compliance with MEDDEV 2.7/1 rev.4 and MDR 2017/745. At a median follow up time of 22 months (range, 0-82 months) 53 implants (3.6%) had been explanted; whereof 24 (1.6%) of the implants were explanted due to early postoperative infections, 20 (1.4%) due to persistent wound dehiscence, 1 (0.1%) due to unsatisfactory aesthetical outcome and 8 (0.5%) due to other reasons, such as tumor recurrence.

Histological analysis of several implants explanted ≥ 9 months following surgery revealed bony integration between the implant and the native bone, as well as new bone formation within and around the remaining calcium phosphate material.

Introduction

Cranioplasty is sometimes perceived as a straightforward procedure, however literature confirms the opposite. Reconstruction of the cranium, especially involving large cranial defects, has high morbidity, regardless of the choice of reconstructive material. Autologous bone flaps have been the gold standard for a long time but rates of bone resorption and infection are high[1,2]. Use of inert alloplastic materials such as titanium or PMMA, tailored to the patients defect anatomy can be used but these materials may be less than optimal as their use is correlated to high rates of implant exposure, infection and ultimately implant removal[3,4]. Known risk factors of implant failure include irradiation, previous cranioplasty failures, thin and fragile soft tissue, exposed sinus cavities, age, and previous infections[5].

OssDsign Cranial PSI is, currently (2021), the only patient-specific cranial implant that combines mechanical performance with long-term bone integration and remodelling. The implant consists of a 3D printed medical-grade titanium mesh skeleton, encased in a calcium phosphate material with clinical and pre-clinical evidence of bone regenerative characteristics. OssDsign Cranial PSI is designed to be used for non-load bearing applications in patients where cranial growth is complete, and for use with an intact dura with or without duraplasty. The device is custom-made to fit each patient-specific cranial defect.

To date (September 2021), a total of 1495 devices have been delivered to 119 European hospitals, 14 Asian hospitals, 80 hospitals in the USA and 1 hospital in Central America.

Materials and methods

Post-market surveillance data collection as part of regulatory requirements has been continuously performed by OssDsign in compliance with MEDDEV 2.7/1 rev.4 and MDR 2017/745. Specific patient-related information, such as age, sex and underlying pathology is not applicable, as this is not revealed during the normal implant ordering process. This data presents the outcome of 1480 cases of cranial reconstruction using OssDsign Cranial PSI with dimensions ranging between 7 and 239 cm^2 (Table 1). 15 of the 1495 devices originally ordered

TABLE 1.

Device size (cm^2)	Number of devices (%)
≤ 50	239 (16)
51-100	307 (21)
101-150	598 (40)
151-200	305 (21)
201-250*	31 (2)
Total	*1480 (100)*

Size distribution of OssDsign Cranial PSI in clinical use.
**Devices shipped to Europe and Israel.*

were not implanted for patient-specific reasons, none of which were device-related.
Of the 1495 OssDsign Cranial devices originally delivered, 76.4% (1142/1495) were ordered by university hospitals with a high-level trauma unit (Table 2).

TABLE 2.

Hospital type	Number of hospitals (%)
University Hospital	135 (63)
General Hospital	70 (33)
Army Hospital	1 (0.5)
Veteran Hospital	1 (0.5)
Private Hospital	7 (3)
Total	*214 (100)*

Hospital systems using OssDsign Cranial to date (September 2021).

One patient experienced a tumor recurrence 31 months following reconstructive surgery. This allowed for explantation of the implant and subsequent preparation of histological samples for analysis of bone formation.

Results

As of 30th September 2021, a total of 1480 OssDsign Cranial PSI devices had been successfully implanted in US, European, Central American, and Asian patients. At a median follow up time of 22 months (range 0-82 months), 53 implants (3.6%) had been explanted; whereof 24 (1.6%) of the implants were explanted due to early postoperative infections, 3 (0.2%) due to tumor recurrence, 20 (1.4%) due to persistent wound dehiscence, 3 (0.2%) due to early postoperative hematomas, 1 (≤0.1%) due to a non-device related dura rift post-op, 1 (≤0.1%) due to progression of autologous bone flap resorption and 1 (≤0.1%) due to unsatisfactory aesthetical outcome. (Table 3). None of the explantations were performed due to complications that were determined to be device-related by the operating surgeon. Peer-reviewed data from a subpopulation of the material has shown similar figures in terms of device explantation due to infection[6].

A few cases where the mosaic structure of the OssDsign Cranial PSI is visible through the skin have been reported. These patients have in general thin and fragile soft tissue.

Histological analysis of one retrieved implant (Figure 1-2) showed that the calcium phosphate was partly transformed into new, well-vascularized osteonal bone after 31 months, indicating that the triphasic calcium phopsphate composition has osteoconductive properties and that new bone growth can bridge between the ceramic tiles. This is consistent with earlier published data on use of the exact same calcium phosphate composition for cranial reconstruction[6,7,8]. The regenerative features of the material have also been confirmed in several preclinical studies.

TABLE 3.

Primary cause of explantation	Number of patients (%)
Infection (Early post-op)	24 (1.6)
Tumor Recurrence	3 (0.2)
Persistant Wound Dehiscence	20 (1.4)
Hematoma (Early post-op)	3 (0.2)
Non-device Related Dura Rift	1 (≤0.1)
ABF Resorption	1 (≤0.1)
Aesthetic	1 (≤0.1)
Total	*53 (3.6)*

Reasons for explantation of OssDsign Cranial PSI.

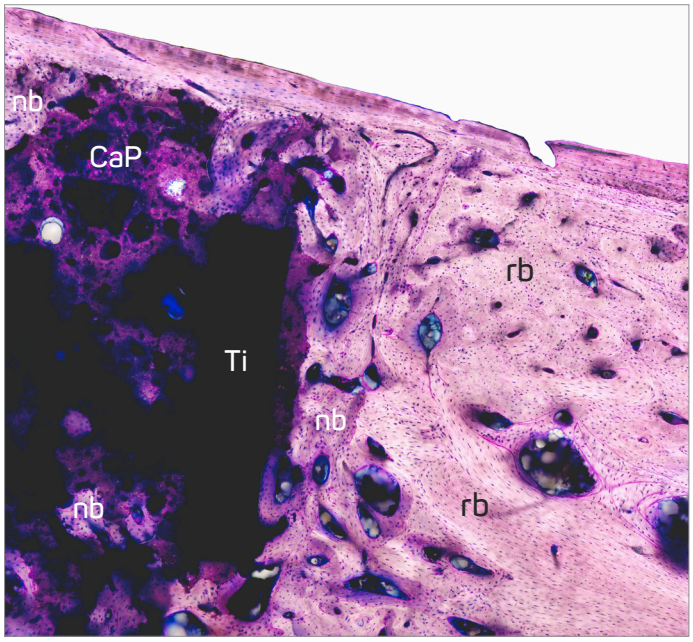

Figure 1. Histological evidence of bone formation at 31 months post-implantation. *Paragon-stained sectioning of OssDsign Cranial PSI shows bony integration between the implant and the recipient bone (rb) as well as new bone formation (nb) within, and around the remaining calcium phosphate material (CaP) and supporting titanium structure (Ti).*

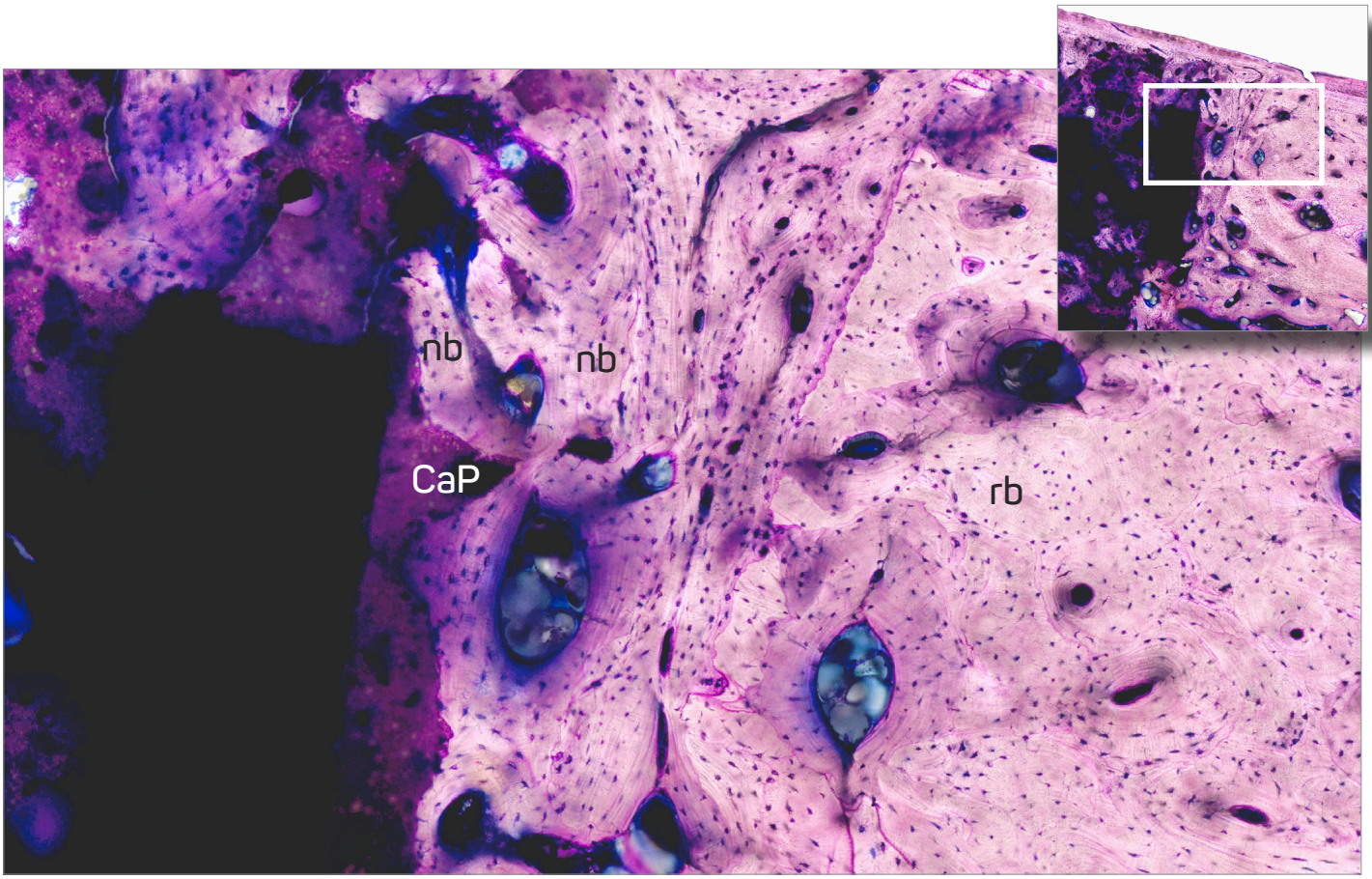

Figure 2. Magnification of interface between recipient bone and OssDsign Cranial PSI following 31 months of implantation. *The magnified picture clearly shows the viable new bone (nb) growing in and around the remnants of the triphasic calcium phosphate material (CaP) of OssDsign Cranial PSI. The interface between new bone and recipient bone (rb) shows complete integration of the implant.*

A 52-week preclinical implantation study in a sheep model revealed the same pattern of host bone integration of the implant along with new bone formation in and around the calcum phosphate material[9,10].

In conclusion, OssDsign Cranial PSI has shown exceptional performance with an infection rate warranting implant removal of 1.6% in a patient population having undergone 1480 cranioplasties at a median follow up time of 22 months.

The bone-regenerative capacity of the calcium phosphate material has been substantiated in preclinical studies and is supported by clinical experience in multiple cases.

References

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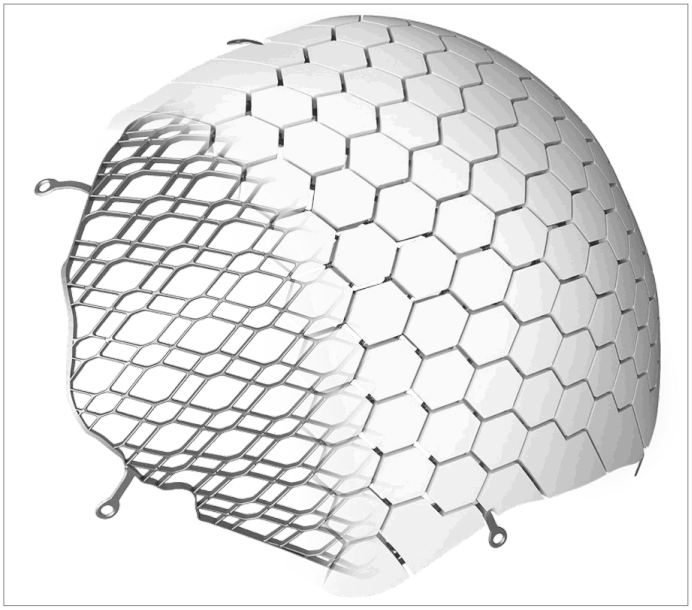
About OssDsign Cranial PSI

OssDsign Cranial is a patient-specific implant based on a biocompatible calcium phosphate composition with a strong 3D printed titanium skeleton embedded in the core of its ceramic tiles.

OssDsign Cranial PSI is intended for the reconstruction of cranial defects. It is indicated for non-load bearing applications for patients in whom cranial growth is complete, and for use with an intact dura, with or without duraplasty. Always read instructions for use which accompany the product for indications, contraindications, warnings and precautions.

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.



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