OssDsign™ Cranio PSI for skull repair

TECHNOLOGY

OssDsign™ Cranio PSI, developed by OssDsign, is a patient-specific implant for permanent cranial (skull) repair. The skull defect may be as a result of a severe head injury, skull deformity, or after surgery e.g. to remove a cranial tumour.

Cranio PSI is made of hexagonal calcium phosphate bioceramic tiles, interconnected by a thin titanium mesh, to form a mosaic-like structure.

A computerised model of the patient’s skull is produced from scans and an accurate patient-specific implant built. Anchoring points in the mesh and screws are used to attach the implant to the surrounding bone. The company states that Cranio PSI acts as a mechanical scaffold, allowing circulation of blood and tissue fluids around the implant and to encouraging the bone to heal (osteoconduction). According to the company, this calcium phosphate-based cranioplasty technique is different from other similar products, which are injectables, as it is pre-moulded and is delivered to the operator as a stable implant. The time required to attach the implant to the skull bone is between 5 to 10 minutes. The longest documented clinical follow-up with this implant technology is 30 months.

The company is planning to launch OssDsign™ Cranio PSI in the UK in 2014. OssDsign™ Cranio PSI does not require a CE mark as it is a patient-specific product. However, related off the shelf products (not patient-specific) are expected to be CE marked in early 2014.

POTENTIAL FOR IMPACT

Following severe injury to the skull, or after surgery on the skull or brain, there may be areas where bone is lost which require a prosthesis or plate to provide protection for the brain. Plates are currently made of titanium, plastics (e.g. PEEK, PMMA and polyethylene) or bone-like bioceramic materials.

Successful cranioplasty using a patient-specific implant could lead to better health outcomes for the patient. According to the company, Cranio PSI also has potential for use in patients...
where previous implants have failed, patients requiring a hemicraniectomy and in irradiated patients with weak tissues (called osteoradionecrosis).

Risks of cranioplasty with implants include infection, protrusion (where the implant becomes dislodged) and the need for subsequent removal. Hemicraniectomy is a procedure where a neurosurgeon relieves brain swelling by removing part of the skull, the bone flap, in order to allow the brain to expand. After the swelling has subsided, the patient’s autologous bone flap is normally used to fill the hole, which can take place several months after the primary procedure. The autologous bone flap sometimes however resorbs, leaving the patient with a large hole in the skull and the need for an implant.

If clinical effectiveness is demonstrated, Cranio PSI may offer an additional option for select patients requiring skull repair. The potential impact of this technology will be dependent on the comparative safety profile and the effectiveness of Cranio PSI. Additional considerations will be the long-term durability of Cranio PSI and its failure rate. The impact on the health service will be dependent on the number of patients who require and are suitable for this type of implant.

**EVIDENCE**

**PUBLISHED PAPERS AND ABSTRACTS**


**COMPLETE UNPUBLISHED STUDIES**

No complete, unpublished studies of this implant were identified for this alert.

**ONGOING STUDIES**

ClinicalTrials.gov. Bone reconstruction of the skull using a metal ceramic implant after previously failed reconstruction.


**INFORMATION FROM**

This Alert is based on information from the company and a time-limited internet search.