Osteoplug™
Addressing a clinical need in burr-hole reconstruction

Introduction
The burr-hole is a common surgical procedure that facilitates access to the brain for the purpose of treating various neurological symptoms and diseases. The underlying reasons for a burr-hole procedure include subdural hematoma (various types), epidural hematoma, brain cancer, hydrocephalus, and more. In more severe cases, the burr-hole may be the first step before a craniotomy or craniectomy procedure. The burr-hole may be surgically created using a variety of instrumentation systems such as perforators and high-speed drills, resulting in a variety of burr-hole sizes.

Clinical Need
Despite the burr-hole being regarded as a small bone defect, it appears to have indirect clinical consequences that significantly impact patient quality-of-life. According to a study conducted on 196 patients that underwent chronic subdural hematoma (CSDH) procedure followed by burr-hole reconstruction with and without a burr-hole cover, 73.9% of patients that had scalp depressions due to ineffective burr-hole filling reported inferiority complexes, while 62.3% reported functional handicaps. [1]

Scalp depression and bone healing
Scalp depressions are an observed phenomenon that implies incomplete or insufficient bone healing. In the study described above, Titanium burr-hole cover (BHC) or gel foam packing (GPO) was used. GPO is an absorbable gelatin sponge that was used in the study but did not sufficiently reconstruct the focal bone defect (Figure 1A). In the BHC group, the focal bone defect was expectedly present as Titanium is neither a bioresorbable biomaterial nor a regenerative solution (Figure 1B).

Figure 1 (A) Burr-hole reconstruction with GPO, showing insufficient bone regeneration (white arrow). (B) Burr-hole reconstruction with Titanium BHC. The burr-hole is clearly present and not reconstructed.[1]
Osteoplug™ as an integrating implant for burr-hole reconstruction

The Osteoplug™ is a biodegradable implant with an interconnected porous architecture that mimics the natural cancellous bone microstructure. It promotes tissue and vascular growth. It is an integrating implant that aims to restore burr-hole defects, leading to a shift in burr-hole reconstructive surgery from purely cosmesis to functional regeneration of damaged tissues. Figure 2 illustrates the regenerative capability of the Osteoplug™ through CT scans at 1 month and 12 months post-operative, demonstrating complete tissue formation and restoration of the focal bony defect.

![Figure 2](image)

**Figure 2** One-month post-operative axial CT showing burr-hole clearly. 12 month post-op axial CT showing that the burr-hole has been covered with native bone.[2]

Design and Handling Characteristics

The Osteoplug™ is fabricated with the biomaterial polycaprolactone (PCL), which is a biodegradable polymer that degrades and resorbs fully in vivo by hydrolysis, and is eventually metabolized by the body into carbon dioxide and water. It has a gradual resorption profile, depending on patient anatomy and metabolism, of approximately 18-24 months. This resorption rate is optimized to maintain mechanical integrity during the healing process, minimizing adverse host-implant and inflammatory reactions. The Osteoplug™ is designed to fit perfectly into the burr-hole defect. This ensures direct interaction between surrounding bone, allowing repair cells to use the implant as a scaffold, promoting bone tissue regeneration.

References


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