

<b>Title</b>	A Detailed Study of Infection Following Custom-Made Porous Hydroxyapatite Cranioplasty: Risk Factors and How to Possibly Avoid Device Explantation
<b>Journal</b>	Journal of Clinical Medicine
<b>Authors</b>	Mannella FC, Faedo F, Pallud J, Chibbaro S, Fumagalli M, Norata GD, Zaed I, Servadei F.
<b>Study type</b>	Biomaterial characteristics (association white antibiotics)
<b>Product</b>	CustomBone Service (CBS), Fin-Ceramica Faenza, S.p.A.
<b>Objective(s)</b>	Treatment strategies used to manage infections and avoid cranioplasty porous hydroxyapatite (PHA) explantation.
<b>Method of Analysis</b>	Retrospective multicenter analysis clinical data.
<b>POINTS</b>	
<b>1) Method</b>	This retrospective multicenter analysis included 984 patients who underwent PHA cranioplasty as part of a post-market clinical follow-up. Clinical data included demographics, surgical characteristics, infection features, microbiological results, infection management strategies, and outcomes. Associations with infection risk and implant explantation were assessed using chi-square tests.
<b>2) Results</b>	Seventy-six patients (7.7%) developed postoperative infections. Infection risk was significantly associated with second-line procedures ( $p = 0.011$ ) and implant location ( $p = 0.037$ ). Most infections were superficial (92.1%) and early-onset ( $\leq 2$ months from the surgery, 61.9%), with <i>Staphylococcus</i> spp. as the predominant pathogens. Explantation occurred in 77.6% of infected cases. The infection management strategy—whether initial conservative treatment with antibiotics alone ( $n = 18$ of which 11.1% explanted) or surgical reoperation ( $n = 58$ of which 93.8% explanted)—along with surgical cleaning and local (in situ) antibiotic use alone, was significantly associated with explantation outcomes (all $p < 0.001$ ). Among 18 patients treated with systemic antibiotics alone, 88.9% retained their implants. Notably, all successful cases had received broad-spectrum antibiotics for at least 4 weeks. Local antibiotic therapy was administered in 13 patients; no explants occurred among those who also received prolonged systemic treatment. Pathogen type was not significantly associated with the risk of explantation.
<b>3) Conclusions</b>	Prolonged systemic antibiotic therapy, especially when combined with local treatment, may allow implant retention in selected infections, supporting individualized, conservative management strategies.
<b>ADDITIONAL COMMENTS / POINTS TO STRESS / POINTS OF STRENGTHNESS</b>	
<ul style="list-style-type: none"> <li>• Postoperative infection is a significant complication following cranioplasty procedures;</li> <li>• In case of late infections, the patient can be treated with systemic antibiotics, in order to try to avoid the removal of the prosthesis;</li> <li>• Porous hydroxyapatite is a valid biomimetic material: in particular patient implanted with the custom made device, CustomBone Service, and treated with prolonged systemic treatment avoid explant of the prosthesis.</li> </ul>	