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REVIEW

Infection rates following custom-made cranioplasty using heterologous materials: insights from a systematic review on 3260 patients with a focus on follow-up length

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Abstract

Introduction Custom-made cranioplasty can be performed using various heterologous materials, each associated with a distinct complication profile. This systematic review focuses on infections, the most common complication following cranioplasty.

Materials and methods A systematic review of the available literature was conducted to identify infection and explantation rates associated with materials used in custom-made heterologous cranioplasty. A comprehensive search of PubMed/MEDLINE, Scopus, and Embase databases yielded 3437 articles. After screening, 43 articles met the inclusion criteria and data on study parameters, patient populations, and infection characteristics were extracted.

Results Forty-three articles were selected and included in this review, analyzing a total of 3260 implanted cranioplasties, divided by material as follows: 931 titanium, 1227 hydroxyapatite, 680 PMMA, 379 PEEK, and 143 composites. The cumulative infection and explantation rates were: 8.2% and 3.7% for titanium, 6.7% and 5.3% for hydroxyapatite, 14.9% and 6.1% for PMMA, 11.1% and 3.8% for PEEK, and 4.2% and 6.2% for composites. Importantly, the follow-up duration varied significantly among materials. Studies involving titanium and composites had the shortest follow-up, potentially underestimating infection rates, while studies on PMMA and hydroxyapatite had the longest follow-up, providing more robust estimates.

Conclusions This review confirms general trends in infection rates among cranioplasty materials and emphasizes the critical role of follow-up duration in interpreting complication rate. Differences in study design and reporting standards limit direct comparison between materials. Future research should adopt standardized follow-up thresholds and uniform outcome definitions to enable reliable cross-material comparisons.

Keywords Cranioplasty · Heterologous material · Cranioplasty complication · Infection · Explantation

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Introduction

Cranioplasty is a common neurosurgical procedure performed to restore normal cerebral function and improve both neurological and aesthetic outcome. Despite its benefits, it is associated with a high risk of complications, the most frequent and concerning of which is infection [12]. Post-cranioplasty infections often require reintervention with device explantation, leading to poorer patient outcomes and prolonged recovery.

Infections can be categorized by their timing and depth. Early infections occur within the first six weeks following the procedure, while late infections develop more than six weeks post-surgery [9].

Early infections are typically caused by highly virulent pathogens such as *Staphylococcus aureus*, streptococci, or *Enterococcus*, and are often acquired perioperative. In contrast, late infections occur beyond 6 weeks and may result from hematogenous seeding or the proliferation of low-virulence organisms such as *Staphylococcus epidermidis* or *Cutibacterium acnes* [18]. Pathophysiologically, early infections are generally attributed to direct intraoperative contamination, while late infections often involve the formation of mature bacterial biofilms on implant surfaces. These biofilms act as barriers to host immune responses and antibiotics, allowing bacteria to persist in a dormant state and cause delayed complications [8].

These infections can also be classified by the layers affected: superficial infections involve the subcutaneous or subgaleal layers, while deep infections involve the implant site, epidural or subdural regions.

While the most commonly used material for cranioplasty is autologous bone, several studies have demonstrated that safer or more effective alternatives exist [3, 14]. Autologous bone grafts are not always viable, particularly in cases of prior fracture, bone resorption, or infection, which can compromise the integrity of the graft. In such instances, surgeons turn to a variety of synthetic and heterologous materials, each with its own infection risks and benefits.

The choice of material used for the cranioplasty plays a significant role in the risk of post-operative infection [1]. Among the various materials used for custom-made heterologous cranioplasty, each exhibits distinct physicochemical and biological properties that may influence the risk of post-operative infection. Titanium, for example, offers excellent mechanical strength and biocompatibility, but lacks osteoconductivity and tissue integration, potentially leaving dead space at the bone–implant interface that can predispose to bacterial colonization [6]. In contrast, hydroxyapatite closely mimics the mineral component of bone and supports osteointegration, potentially reducing infection risk through enhanced vascular ingrowth and reduced biofilm formation [16]. Polymethylmethacrylate (PMMA) is chemically inert and widely used, but its smooth surface and poor integration with surrounding tissue may allow for biofilm development and impair immune clearance [6, 11]. Similarly, PEEK is valued for its inertness and elastic modulus similar to bone, yet its low porosity and lack of osteointegration may favor persistent bacterial adherence [11]. These intrinsic material characteristics, particularly surface roughness, porosity, and integration potential, are increasingly recognized as contributing factors in the development and persistence of implant-associated infections [6, 11]. Newer materials, such as composites (e.g. titanium-calcium phosphate implants) and fiberglass, offer additional options for cranioplasty, though their use remains less widespread [7].

The primary goal of this systematic review is to evaluate and compare the infection rates associated with different materials used in heterologous cranioplasty and to provide a detailed characterization of infections based on timing and depth. By doing so, the review aims to assist clinicians in selecting the most safe, appropriate, and patient-specific material for cranioplasty procedures.

An additional important aspect addressed by this review is the variability in the length of follow-up across different studies. The duration of follow-up is not standardized in the literature, which may significantly impact on the reliability of reported infection rates [9]. Studies with shorter follow-up periods may fail to capture late-onset infections [4, 7] and complications, skewing the overall assessment of a material's safety. This review also considers study quality by examining factors such as multicenter versus single-center design and retrospective versus prospective methodology.

Materials and methods

Search strategy

This systematic review was conducted following the Meta-analysis of Observational Studies in Epidemiology (MOOSE) guidelines and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA). The primary goal of this review was to evaluate infection rates following custom-made cranioplasty using heterologous materials, with a specific focus on how follow-up duration may influence the reported infection rates.

A systematic search of the literature was performed to gather published articles reporting infection rates after cranioplasty using heterologous materials.

The search was carried out in PubMed/MEDLINE, Scopus, and Embase databases, using the following keywords: "cranioplasty," "cranioplasty infection," "cranioplasty

complications," "cranioplasty heterologous materials," "cranioplasty hydroxyapatite," "cranioplasty titanium," "cranioplasty PEEK," "cranioplasty PMMA," "cranioplasty material," and "cranioplasty custom-made." The search was restricted to articles published over the past seven years, from January 2018 to January 2025. The exact search string for each database is available in the Supplementary Materials.

Study selection

Two authors (F.F. and I.Z.) screened all potentially relevant articles for eligibility, with full-text articles reviewed when necessary. The inclusion criteria were as follows: studies reporting infection rates following heterologous custom-made cranioplasty, using three-dimensional (3D) modelling or reconstruction techniques, restricted to adult populations, and with a minimum follow-up of six months. Eligible study designs included case series, case-control studies, retrospective studies, and clinical trials. Case reports, technical notes, letters, and editorials were excluded. Meta-analyses and systematic reviews were thoroughly screened for potential inclusion.

Studies that included cranioplasty performed after non-decompressive craniectomy (e.g., osteomyelitis) or craniotomy with simultaneous replacement of the autologous bone flap with a heterologous implant (e.g., resection of a bone-invading tumor) were included. Infection was defined as any complication requiring treatment with antibiotics or removal of the cranioplasty implant.

The exclusion criteria were:

- Studies published in a language other than English.
- Studies that did not differentiate infection rates among different materials.
- Case series with fewer than 10 patients.
- Studies on pediatric populations or those that did not differentiate infection rates between pediatric and adult populations (pediatric was defined as any patient under 14 years of age, or as indicated in the studies).
- Non-custom-made cranioplasties.
- Follow-up periods of less than six months.

Data extraction

The following data, if clearly reported, were collected: year of publication, type of study, material used for cranioplasty, number of neurosurgical centers involved (single or multicenter study), number of patients, epidemiological data (sex, average age), size of bone defect (in cm^2), average follow-up duration (in months), timing of cranioplasty, use of antibiotic prophylaxis before cranioplasty, number of infections, time interval between cranioplasty and the occurrence of infection (early < 6 weeks or late > 6 weeks post-cranioplasty), type of infection (superficial, such as subcutaneous infection, or deep, such as implant or epidural infection), and number of explants due to infection.

The primary outcomes were infection and explantation rates. The secondary outcomes included the characterization of infection based on timing (early vs. late) and depth (superficial vs. deep), as well as an assessment of study quality. This qualitative assessment considered parameters such as follow-up duration (as the primary criterion), number of patients included, single-center vs. multicenter design, and prospective vs. retrospective study design.

Data analysis

Data were extracted from all eligible sources using a pre-specified electronic data collection form. Statistical averages, relative percentages, and 95% confidence intervals were calculated when appropriate. All studies that reported infection rates as one of the primary outcomes were included. However, not all studies provided detailed information on specific patient subsets, particularly regarding the timing and depth of infection, thereby limiting the scope of comparative analyses.

Due to the substantial heterogeneity across studies, including differences in patient populations, definitions of infection and explantation, follow-up durations and reporting formats (mean, median, range, or undefined), and the overall completeness of key data, neither formal meta-analysis nor meta-regression could be conducted. The lack of methodological and reporting standardization made valid statistical comparisons unfeasible. Moreover, relevant variables required for stratified analysis (such as surgical technique, antibiotic prophylaxis, or the indication for cranioplasty) were inconsistently reported or missing entirely, further precluding meaningful subgroup analyses.

To address inconsistencies in follow-up reporting, we categorized studies according to minimum reported follow-up duration. Studies were divided into groups based on the minimum follow-up reported. Four follow-up groups were defined: greater than 6 months, 12 months, 24 months, and 32 months. This classification allowed us to analyze infection rates while taking into account the effect of follow-up duration as the primary analytic focus, ensuring that each group contained studies with a consistent minimum duration, though this approach did not account for the maximum follow-up duration and limited the use of statistical synthesis. This binning strategy enabled more homogeneous comparisons of infection rates across materials, recognizing that shorter follow-ups may underrepresent late-onset infections. Although this approach limited statistical synthesis

and data granularity, it provided the best available method for interpreting outcomes across heterogeneous studies.

Statistical comparisons of infection rates among materials were performed using the Chi-square test for independence. A p-value < 0.05 was considered statistically significant.

Results

The results of the literature review are presented in the PRISMA flow diagram (Fig. 1). The search yielded 3437 articles (810 from PubMed, 1409 from Scopus, and 1218 from Embase). A total of 314 articles were excluded using automation tools (filters applied were "English language", "human studies", "full-text availability"). One hundred thirty-three articles were duplicates. Subsequently, 2990 articles were screened for relevance, and 214 articles were retrieved for further assessment (131 from PubMed, 57 from Scopus, and 26 from Embase); thirteen articles were not retrievable. Articles evaluated for eligibility were 201.

After applying the exclusion criteria, 158 studies were excluded, leaving 43 studies included in the final review.

The reasons for exclusion were as follows: 15 articles did not report infection rates; 61 articles did not differentiate infection rates by material; 8 articles included pediatric populations; 32 articles had case series with fewer than 10 patients; 23 articles had a follow-up shorter than six months or did not report follow-up duration; and 19 articles included non-custom-made cranioplasties.

A list of all the included studies is available for consultation in the Supplementary Materials.

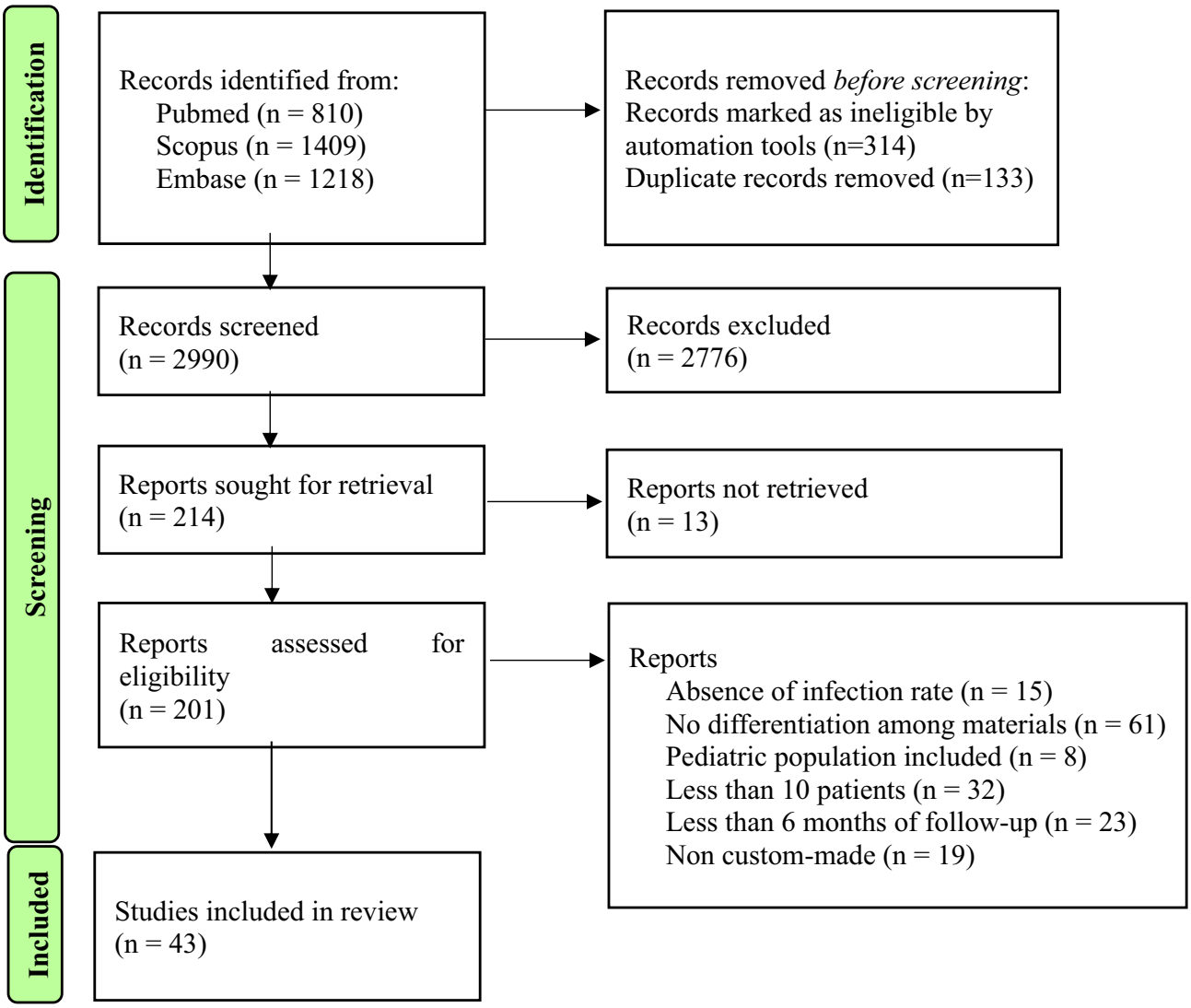

Fig. 1 PRISMA flow-diagram

Titanium

Sixteen articles included titanium cranioplasties, for a total of 931 cases. Of these 931 cases 76 developed an infection (8.2%), of which 22 required explantation of the implant (3.7%). The explantation rate was calculated using a subset of the total population ($n=595$), which included only the cranioplasties from studies that explicitly reported the number of explants. Twenty-four cases were differentiated between deep infection, 11 cases (46%), and superficial infection, 13 cases (54%). Twenty cases were differentiated between early infection, 6 cases (30%), and late infection, 14 cases (70%). Articles were divided based on minimum follow-up period: 9 articles had>6 months of follow-up, 3 articles had>12 months of follow-up, 4 articles had>24 months of follow-up, finally 0 articles had>32 months of follow-up. All studies were retrospective and only 1 study was multicentric.

Hydroxyhapatite

Eleven articles included hydroxyapatite cranioplasties, for a total of 1227 cases. Of these 1227 cases 82 developed an infection (6.7%), of which 44 required explantation of the implant (5.3%). The number of cranioplasties from studies that reported explantation rates was 526. None of the articles including hydroxyapatite cranioplasties differentiated between deep and superficial infections. Fifty cases were differentiated between early infection, 24 cases (48%), and late infection, 26 cases (52%). Articles were divided based on minimum follow-up period: 2 articles had>6 months of follow-up, 2 articles had>12 months of follow-up, 4 articles had>24 months of follow-up, finally 3 articles had>32 months of follow-up. Seven studies were retrospective, 4 studies were prospective. Multicentric studies were 6.

PMMA

Fifteen articles included PMMA cranioplasties, for a total of 680 cases. Infection occurred in 101 cases (14.9%). A total of 311 cranioplasties were reported in studies that included data on explantation, with 19 implants removed (6.1%). Only 4 cases were differentiated between deep infection (1 case) and superficial infection (3 cases). Sixty-six cases were differentiated between early infection, 24 cases (36%), and late infection, 42 cases (64%). Articles were divided based on minimum follow-up period: 6 articles had>6 months of follow-up, 4 articles had>12 months of follow-up, 1 article had>24 months of follow-up, finally 4 articles had>32 months of follow-up. Only one study was prospective, and another study was multicentric.

PEEK

Nine articles included PEEK cranioplasties, for a total of 379 cases. Of these 379 cases 42 developed an infection (11.1%). A total of 212 cranioplasties were reported in studies that included data on explantation, with 8 implants removed (3.8%). Sixteen cases were differentiated between deep infection, 8 cases (50%), and superficial infection, 8 cases (50%). None of the articles including PEEK cranioplasties differentiated between early and late infections. Articles were divided based on minimum follow-up period: 3 articles had>6 months of follow-up, 3 articles had>12 months of follow-up, 2 article had>24 months of follow-up, finally 1 article had>32 months of follow-up. All studies were retrospective and 2 were multicentric.

Composites

Five articles included composits cranioplasties (CaP-Ti, Ce-Ti, HA-Ti), for a total of 143 cases. Infection occurred in 6 cases (4.2%). However, explantation rates were reported only for a subset of studies, for a total of 65 cranioplasties. Among these, 4 infections occurred and all required implant removal, corresponding to 6.2% of the total cases. The higher explantation rate compared to the infection rate reflects the limited number of studies reporting explantation data. None of the articles including composits cranioplasties differentiated between deep and superficial infections. Three cases were differentiated between early infection, 1 case, and late infection, 2 cases. Articles were divided based on minimum follow-up period: 1 article had>6 months of follow-up, 4 articles had>12 months of follow-up, 0 articles had>24 months of follow-up, finally 0 articles had>32 months of follow-up. All studies were retrospective and one was multicentric.

A Chi-square test for independence was performed to assess whether infection rates differed significantly among the five heterologous materials. The test revealed a statistically significant association between material type and infection occurrence ($\chi^2(4)=42.66$, $p<0.001$), indicating that the risk of infection is not equally distributed across materials.

Tables 1 and 2 summarize the main findings of the review, including infection and explantation rates for each material, with associated 95% CI, as well as key methodological characteristics of the included studies. Detailed infection and explantation data stratified by material are available in the Supplementary Materials (Supplementary Tables 2–6).

Discussion

The results obtained in our study shows a substantial agreement with the data available in the literature. Regarding titanium, our study found an infection rate of 8.2%, similar

Table 1 Comparison of infection and explantation rates among materials

	No. of patients	No. of infections	Infection rate (95% CI)	No. of explant	Explantation rate (95% CI) (*)
Titanium	931	76	8.2% (6.6%–10.1%)	22	3.7% (2.5%–5.5%)
Hydroxyapatite	1227	82	6.7% (5.4%–8.2%)	28	5.3% (3.7%–7.6%)
PMMA	680	101	14.9% (12.4%–17.7%)	19	6.1% (3.9%–9.3%)
PEEK	379	42	11.1% (8.3%–14.6%)	8	3.8% (1.9%–7.3%)
Composits	143	6	4.2% (1.9%–8.9%)	4	6.2% (2.4%–14.8%)

(*) explantation rates were calculated using as denominator the total number of patients from studies that explicitly reported the number of explants. The exact number of patients included in this calculation is specified in the text for each material. This justifies why, in some cases, the explantation rate May appear higher than the overall infection rate, as it reflects a subset of the total cohort

Table 2 Study characteristics relevant to quality assessment: follow-up duration, type of study and no. of centers involved

	Follow-up				Type of study		No. of centers	
	>6 months	**>12 months**	**>24 months**	**>36 months**	**R**	**P**	**Mono**	**Multi**
Titanium	9	3	4	0	16	0	15	1
Hydroxyapatite	2	2	4	3	7	4	4	6
PMMA	6	4	1	4	14	1	13	1
PEEK	3	3	2	1	9	0	7	2
Composits	1	4	0	0	5	0	4	1

Type of study: *r* retrospective, *p* prospective, *no. of centers mono* monocentric, *multi* multicentric

to that reported by *Zhu et al.* [17] (7%) and by *Oliver et al.* [11] (6%). For hydroxyapatite, *Henry et al.* [6] reports an infection rate of 6%. Our data show similar values, with 6.7% for infections and 5.5% for explantation. Regarding PMMA, *Oliver et al.* [11] reports an infection rate of 7.9%, whereas our study shows an higher value of 14.9%. Finally, for PEEK, our data report an infection rate of 11.1%, higher than that documented by *Punchak et al.* [13] (6%) and by *Oliver et al.* [11] (6.8%). Regarding the explantation rate, *Punchak et al.* [13] indicate a value of 9%, while our study does not show significant differences in this parameter. In their 2023 meta-analysis, *Cerveau et al.* [2] reported infection rates of 7.5% for autologous implants and 8.1% for allogenic implants, with a mean follow-up duration of approximately 11 months for both groups. Overall, our study confirms general trends already reported in the literature but highlights some differences in infection and explantation rates, particularly for PMMA and PEEK.

Unfortunately, the planned analysis of infection depth and timing yielded limited insights due to the small number of studies that reported these variables. *Yeap et al.* [15] found that infections in titanium cranioplasty were predominantly late (70%) compared to early (30%). In contrast, hydroxyapatite showed more varied results: *Amendola et al.* [1] reported an even distribution, *Di Rienzo et al.* [4] observed mostly late infections, while *Moles et al.* [10] found infections to be predominantly early. Differentiating infection timing in future studies could be crucial, as early and late infections may have distinct mechanisms, involve different pathogens, and most importantly, influence the optimal duration of follow-up monitoring. Understanding these differences would help refine post-operative management and improve long-term outcomes.

These claims have been recently addressed by a study by *Zaed et al.* [16] conducted on specimen of hydroxyapatite cranioplasties; authors have been able to conclude that under Dynamic Contact Conditions it can be seen that hydroxyapatite cranioplasty appears to inhibit exponential growth by inducing bacterial stasis in the early hours of contact. Further similar studies are suggested also with different materials to better define the evidences.

The same applies to deep and superficial infections, as deep infections often require explantation, whereas superficial infections can typically be managed with antibiotics [4]. Although the available data was very limited, it did not indicate a clear prevalence of either type for different materials. However, there was a slight predominance of superficial infections in PMMA [5].

One of the most critical aspect is the duration of follow-up, as it directly influences the reliability of infection and explantation rate assessments. Late-onset infections can manifest up to two or more years post-cranioplasty [4, 7], underscoring the inadequacy of follow-up periods shorter than six months (the authors excluded such studies from this review, but they are not excluded in most published papers). Even a follow-up of 6–12 months remains suboptimal; an ideal duration would be at least 12 months, with 24 or even 36 months being preferable.

Analysis of the data reveals that PMMA cranioplasties exhibit a relatively high infection rate of 14.9%; however, this finding is supported by long follow-up durations, indicating the presence of high-quality studies. In contrast, studies investigating composite cranioplasties (CaP-Ti, Ce-Ti,

HA-Ti) report a notably low infection rate of 4.2%, yet these studies also have the shortest follow-up periods and the lowest methodological quality, rendering the data less reliable.

Infection rates for cranioplasties utilizing PEEK, titanium, and hydroxyapatite are 11.1%, 8.2%, and 6.7%, respectively. Titanium cranioplasty is generally associated with shorter follow-up durations, while hydroxyapatite cranioplasty is supported by three studies with follow-ups exceeding 36 months.

Another consideration concerns the presence of multicentric and prospective studies. Four prospective studies were identified, all of which focused on hydroxyapatite cranioplasties. The materials with the highest number of multicentric studies were hydroxyapatite (five studies) and PEEK (two studies). Regarding the total number of patients analyzed, studies on titanium and hydroxyhapatite cranioplasties included the largest patient cohort overall with 931 patients for titanium and 1227 for hydroxyhapatite. Even if we are probably still searching the best material for cranial reconstruction a deeper inside view of the published papers is required before making straight foreword comparisons.

Study limitation

Despite the authors' best efforts, this systematic review presents several limitations. The first limitation is given by the heterogeneity of included studies because of which a meta-analysis was not performed.

Another limitation is given by the variability in follow-up duration for which it seems that shorter follow-up periods may lead to underreporting of late-onset infections and long-term complications.

This study is also limited by the broad infection definition: infections were defined as any complication requiring antibiotic treatment or implant removal, which, while clinically relevant, may have introduced variability in what different studies classified as infection.

At last, the absence of stratified analysis should be pointed out: although stratification by variables such as surgical technique or antibiotic prophylaxis could have enhanced the analysis, it was not feasible due to inconsistent or missing data across studies. Given this limitation, a non-stratified but systematically structured approach was considered the most appropriate.

Conclusion

This systematic review confirms general trends in infection rates among cranioplasty materials, with higher rates for PMMA and PEEK and lower rates for hydroxyapatite, titanium, and composites. However, these findings must be interpreted cautiously due to significant variability in follow-up duration and the inconsistency of infection definition and classification.

By grouping studies based on minimum follow-up duration, we aimed to reduce this bias and provide a more meaningful comparison across materials. Our findings emphasize the critical role of adequate follow-up in accurately assessing complication rates.

The lack of standardized reporting on infection characteristics, such as timing and depth, and study design further limits direct comparisons. Future research should adopt consistent definitions, longer follow-up thresholds (ideally > 24 months), and improved methodological rigor to enable more reliable inter-material comparisons. Until then, inter-material differences should be interpreted with caution.

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Author contributions All authors contributed to the study conception and design. Literature search was performed by Francesca Faedo and Ismail Zaed. Data collection and analysis were performed by Francesca Faedo. The first draft of the manuscript was written by Francesca Faedo and all authors commented on previous versions of the manuscript. Critical revision and editing of the manuscript was performed by Franco Servadei. All authors read and approved of the final manuscript.

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Data availability No datasets were generated or analysed during the current study.

Declarations

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of Emory University IRB and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Consent for publication Informed consent for publication was waived as all patients' information was de-identified.

Consent to participate Informed consent was waived given the retrospective nature of the study.

Competing interests Authors F.F., A.P. and C.I. declare no competing interests. Authors F.S. and I.Z. have received consultancy fees from Finceramica Faenza S.p.a. Author FS has received also consultancy fees from Integra-Life.

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