Neurosurgical Review (2025) 48:659
https://doi.org/10.1007/s10143-025-03832-3

RESEARCH

Cranioplasty complications in severe traumatic brain injury: implications of timing of surgery, implant material and incidence of vetriculomegaly versus Post-Traumatic hydrocephalus

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Received: 25 February 2025 / Revised: 14 July 2025 / Accepted: 6 September 2025

Abstract

Background Despite the increasing number of decompressive craniectomy (DC) in neurotrauma, the optimal timing for elective cranioplasty (CP) is still debated. Little is known about the CP complications related to surgery, implant material, and post-traumatic hydrocephalus. Objectives To explore the correlation between CP timing, implant material, and the incidence of postoperative complications in patients undergoing CP after DC for severe head injuries. Materials and methods A retrospective multicenter study was conducted from January 2010 to December 2021 across 9 European neurosurgical centers. A cohort of 4007 patients who underwent CP following DC for severe head injury was analyzed. Timing was categorized as: *ultra-early* (<30 days), *early* (31–90 days), *late* (>90 days). Complications were defined according to Clavien-Dindo classification, requiring revision surgery and/or hospital readmissions. Results Among the 4007 patients, 352 (8.8%) had ultra-early CP, 1627 (40.5%), and 2028 (51.7%) had early and late CP respectively. Cerebrospinal fluid (CSF) derangement was more frequently associated with large defects and the incidence of Sinking Skin Flap Syndrome (SSFS). SSFS was more frequently diagnosed in patients undergoing late surgery whereas hydrocephalus and epilepsy were less frequently encountered in the ultra-early and early groups ($p<0,05$). The overall complication rate was 24.6% (985 patients) including internal hydrocephalus (20%), infection (18%), external hydrocephalus (15%), epilepsy (15%), acute extradural (14%) or subdural hematomas (10%), and subdural hygroma (8%). CP stabilized CSF derangement in 80% of cases, which did not progress into overt hydrocephalus, whereas 17% with definite diagnosis of post-traumatic hydrocephalus required a Ventriculo-Peritoneal shunt (VPS). Simultaneous CP and VPS led to infections in all cases, regardless of implant material. Conclusion Surgery timing has a greater impact on CP complications than implant material. CSF derangement represents the single most relevant factor influencing the clinical course of patients undergoing CP.

Keywords Decompressive craniectomy · Cranioplasty complications · Post-traumatic hydrocephalus · Implant material in neurosurgery · Surgical timing

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Published online: 20 September 2025

Introduction

Cranioplasty (CP) is a well-established neurosurgical procedure offered for reconstructing calvarial defects and provide brain protection, improved cosmesis and functional recovery in the aftermath of decompressive craniectomy (DC), not only for traumatic brain injury (TBI), but also in selected vascular and oncological cases [16]. Beyond protecting the brain, CP facilitates the normalization of cerebrospinal fluid (CSF) dynamics and blood flow, promoting neurological recovery [14, 19]. In the current neurosurgical practice, CP is regarded as the gold standard treatment following DC in TBI survivors, however there is a lack of agreement on the indication in patients with poor functional status [3].

While technically straightforward, CP carries notable risks, including subdural fluid collections, infections, hydrocephalus, seizures, sinking skin flap syndrome (SSFS) and subdural hygromas, which are often underestimated in clinical practice [1, 16]. Timing of reconstruction and choice of implant material are critical determinants of CP outcomes. A large cohort study involving 754 patients demonstrated that early cranial reconstruction (15–30 days post-DC) reduces infection rates but increased hydrocephalus risk, whereas delayed procedures (>90 days) lower hydrocephalus rates but elevated seizure risk [17]. Hydrocephalus remains one of the more challenging complications to manage [10]. Various shunt techniques have been proposed, with ventriculoperitoneal shunting (VPS) being a widely accepted method [22]; however, optimal timing and the role of VPS remain debated [10]. Recent evidence offers conflicting views on combined versus staged CP and VPS procedures [8, 15, 18, 22, 24, 25]. Given the scarcity of scientific evidence on this topic, we aimed to gather insights from nine tertiary European neurosurgical centers regarding the management of this complex patient population. Our specific focus was to investigate the interplay between CP timing, and implant materials on various postoperative complications, emphasizing post-traumatic hydrocephalus.

Materials and methods

This study falls under the umbrella of CREPES (Calvarial REconstruction Pathway: an Exploratory Study): an over-arching European study group exploring the impact of structured cranioplasty pathways (standard operating procedures for referral processes, decision making and follow up strategies for patients undergoing CP following primary and secondary DC) on patients outcomes. As per protocol (originally submitted to the European Association of Neurosurgical Societies research committee in 2023) the present study represents a retrospective, multicenter, observational analysis leveraging on a prospectively compiled and systematically maintained database. The research was conducted across nine European tertiary neurosurgical centers: Strasbourg University Hospital, Strasbourg (France); Oxford University Hospitals, Oxford (United Kingdom); Neurocenter of South Switzerland, Lugano (Switzerland); Kantonspital in Winterthur, Winterthur (Switzerland); Ulm University Hospital, Ulm (Germany); Fondazione Poliambulanza Hospital, Brescia (Italy); Lorenzo Bonomo Hospital, Andria (Italy); Aristotle University Hospital, Thessaloniki (Greece), and Siena University Hospital, Siena (Italy). The participating centers were selected based on their established expertise in neurosurgical care and their capability to maintain high-quality data repositories, ensuring the robustness and reliability of the collected information. The involvement of multiple centers ensures a representative sample of practices across different healthcare systems and geographic regions, thus increasing the generalizability of the findings.

The study covered a substantial timeframe of a 12-year period (from 1 st January 2010 to 31 st December 2021), capturing over a decade of clinical practice and outcomes. During this interval, data from a total of 4007 patients who had undergone CP following DC for severe head injury were collected and analyzed. The inclusion criterion focused on patients who had received DC as a life-saving procedure for the management of elevated intracranial pressure (ICP) secondary to closed severe head injuries, followed by CP as a reconstructive intervention. Exclusion criteria included incomplete clinical records or procedures performed outside the designated time frame.

Data collection was meticulously planned and executed to ensure completeness and accuracy. For each patient included in the study, the authors collected comprehensive data, including the following parameters:

- *Demographic details*: age, gender.
- *Clinical data related to previous decompressive surgery*: confirming severe trauma as the primary indication for DC along with the corresponding anatomical region of calvarial decompression.
- *Details of calvarial reconstruction*: the time elapsed between the initial DC and the reconstructive procedure, the implant material used for CP (autologous bone, titanium, polyetheretherketone (PEEK), polymethyl methacrylate (PMMA), porous hydroxyapatite (PHA) were also recorded.
- *Post-operative outcomes*: the occurrence of any post-operative complications, which were identified using the Clavien-Dindo classification, focusing on events necessitating revision surgery or unplanned hospital readmission.

All participating centers adhered to standardized protocols for data reporting, which were established prior to data collection to ensure uniformity.

Given the potential influence of timing on surgical outcomes, the interval between DC and CP was stratified into three groups as per the most commonly accepted classification of timing of surgery [17]:

1. *Ultra-early CP*: performed within 30 days of the initial surgery. This group represented the earliest window for reconstruction, hypothesized to potentially reduce intracranial pressure dysregulation but carrying a theoretical increased risk of infection.
2. *Early CP*: performed between 31 and 90 days post-decompression. This intermediate timing aimed to balance the risks of infection with the benefits of earlier cranial reconstruction.
3. *Late CP*: performed after 90 days. Late interventions are often preferred in the context of prolonged clinical instability or the need for further neurological recovery.

Postoperative complications were defined as any deviation from the expected standard post-operative course occurring after CP. The Clavien-Dindo classification system [2] was employed to categorize complications in a standard manner, with a specific focus on Grade III (requiring surgical, endoscopic, or radiological intervention) and Grade IV (life-threatening complications requiring intensive care management). Only complications necessitating revision surgery or resulting in unplanned hospital readmission were considered for analysis, ensuring a focus on clinically significant adverse outcomes.

Statistical analysis

Statistical analysis was conducted to assess the relationship between categorical variables, particularly the association between surgical timing, implant material, and postoperative complication rates. Descriptive statistics were used to summarize baseline demographic and clinical data as number and proportions. Categorical variables were compared using the chi-squared (χ^2) test; Fisher's exact test was applied to ensure the validity of statistical inference. The level of statistical significance was set at $p<0.05$. Stratified analyses were performed to examine complication rates across the three predefined timing groups for CP (ultra-early, early, and late), as well as to assess differences in outcomes based on the type of implant material used. Postoperative complications, particularly those classified as Clavien-Dindo grade III or IV, were analyzed for their association with prior VPS placement and simultaneous surgical interventions. The use of multicenter, prospectively built database enhanced the robustness of statistical evaluation by minimizing reporting bias and improving generalizability. All analyses were performed using standard statistical software SPSS (SPSS, version 22.0, IBM Corporation, NY, US) and Excel (Microsoft Corp., version 2003, Redmond, US).

Results

A total of 9 tertiary neurosurgical centers across 6 European countries participated in this study, encompassing 4007 patients with a median follow-up duration of 42 months (range: 18 to 162 months). Among the cohort, 2284 patients (57%) were men, while 1723 patients (43%) were women, with a mean age of 49 years (range: 18 to 62 years). DC was predominantly performed on the left side in 2484 patients (62%), whereas 1523 patients (38%) underwent right-sided procedures. As per study protocol, no bifrontal craniectomies were included in this data collection to ensure internal validity across multiple centers.

Regarding timing of surgery, 352 patients (8.8%) underwent ultra-early CP (<30 days), 1627 patients (40.5%) underwent early CP (31–90 days), and 2028 patients (51.7%) underwent late CP (>90 days). CP materials included various types of patient specific implants such as titanium (962 patients, 24%), PEEK (922 patients, 23%), PMMA (801 patients, 20%), and PHA (761 patients, 19%), as well as autologous bone flaps (561 patients, 14%).

Cerebrospinal fluid (CSF) derangement was more frequently associated with large defects and the incidence of Sinking Skin Flap Syndrome (SSFS). SSFS was more frequently diagnosed in patients undergoing late surgery: in fact, VPS placement prior to cranial reconstruction was significantly associated with SSFS ($P=0.0243$). On the contrary, hydrocephalus and epilepsy were less frequently encountered in the ultra-early and early groups ($p<0.05$).

The overall postoperative complication rate was 24.6% (985/4007 patients). No patient mortality related to immediate or delayed surgical complications was observed. The most common complications were internal hydrocephalus (184 cases, 18.7%), infections (195 cases, 18%), external hydrocephalus (162 cases, 15%), epilepsy (162 cases, 15%), acute extradural hematomas (151 cases, 14%), acute subdural hematomas (108 cases, 10%), and subdural hygromas (86 cases, 8%). Subgroup analysis revealed a significant correlation between subdural hematoma and hygroma rates and the presence of VPS implanted prior to CP ($P<0.0357$).

CP stabilized CSF derangement in 80% of cases, which did not progress into overt hydrocephalus, whereas 18.7% with definite diagnosis of post-traumatic hydrocephalus

required a VPS. Notably, simultaneous implant of CP and VPS resulted in deep surgical site infections in 41 cases (11 meningitis, 9 ventriculitis, 2 empyema) and called for removal of both foreign bodies, irrespective of the implant material used ($P<0.001$).

The overall infection rate did not significantly differ among the materials used, except for PHA implants, which demonstrated a lower infection rate (1.2%, $P=0.05$) [12, 28].

These findings emphasize the importance of CP timing and the presence of sunken brain or ventriculomegaly in preoperative planning. A summary of the patient population, timing, and complications is provided in Tables 1, 2 and 3, and Table 4.

Table 1 Patient population characteristics

Characteristics	N of patients	Percentage
Total Number of Patients	4007	100%
Gender		
- Male	2284	57%
- Female	1723	43%
Mean Age (yrs)	49 (18–62)	-
DC and CP Side		
- Left	2484	62%
- Right	1523	38%
Timing		
- Ultra-early	352	8.8%
- Early	1627	40.5%
- Late	2028	51.7%
Implant material		
- Autologous bone	561	14%
- Titanium	962	24%
- PEEK	922	23%
- PMMA	801	20%
- PHA	761	19%
Mean Follow up (months)	42 (18–162)	-

Table 2 Surgical complications by type: CSF derangements, infections, hematomas, seizures

Complications	*N* of patients	Percentage
Total Number of Patients*	985/4007	24.6%
CSF derangements	378/985	38.4%
Post-traumatic hydrocephalus	184/985	18.7%
External hydrocephalus	162/985	16.4%
Subdural hygroma	86/985	8.7%
Non-CSF related complications		
Surgical Site Infection (Superficial)	68/985	6.7%
Surgical Site Infection (Deep)	127/985	12.9%
Seizures	162/985	16.4%
Epidural hematoma	151/985	14%
Subdural hematoma	108/985	10%

*Some patients presented with an association of the complications listed in the present table

Table 3 Surgical complications by timing of cranioplasty, and correlation with sinking skin flap syndrome complicating the initial decompressive craniectomy

Complications 985 (24.6%)	Ultra-early CP (<30 days) Group 1	Early CP (31–90 days) Group 2	Late CP (>90days) Group 3
External hydrocephalus 162 (15%)	*31 (8,8%)*	33 (2%)	98 (4,8%)
Infections 195 (18%)	*98 (27%)*	62 (3,8%)	35 (1,7%)
Seizures 162 (15%)	12 (3,4%)	44(2,7%)	106 (5,2%)
Epidural hematoma 151 (14%)	96 (27,3%)	34 (2,1%)	21 (1%)
Subdural hematoma 108 (10%)	50(14,2%)	37 (2,3%)	21 (1%)
Subdural hygroma 86 (8%)	*24 (7,4%)*	28 (2,4%)	34 (1%)
*CD related complication Sinking skin flap syndrome** *97*	*0*	11	86

*Delayed complication of the decompressive craniectomy procedure, rather than acomplication of cranioplasty itself

Table 4 Surgical site infections per implant material

	N of patients	Percentage
Number of Patients	195/4007	4.9%
PHA	9/195	4.7%
Autologous	60/195	31%
PMMA	50/195	25.5%
PEEK	44/195	22.3%
Titanium	32/195	16.5%

Discussion

In this large series of CP for the management of post-traumatic patients with calvarial defects, we identified a significant correlation between surgical delays and the prevalence of complications, with approximately one-third of our patient experiencing complications related to the CP procedure. Notably, the majority were minor, requiring only hospitalization for imaging studies and lumbar punctures. This observation is encouraging, as it highlights the potential for successful management of postoperative issues, providing they are promptly addressed.

A crucial finding from our study is the temporal trend in complication rates. We noted a higher incidence of complications occurred early in the study period, suggesting a remarkable impact of standard operating procedures for referral, decision making and follow up on clinical outcome of CP patients. In fact, such progressive transition from unstructured to structured cranioplasty pathways led to a significant reduction in complications rate. Two critical factors emerged as risk factors for complications: (i) the

presence of a VPS at the time of CP, and (ii) the identification of a sunken brain on preoperative CT scans. These findings align with the existing literature, which recognizes the complexities introduced by shunt-dependent hydrocephalus in patients undergoing CP.

DC is widely recognized as a "third-tier" or last tier intervention for managing medically refractory ICP in trauma patients admitted to neuro-intensive care unit [20]. In patients who survive severe TBI, CP is a vital component of cranial defect reconstruction. Despite the historical application of CP techniques, recent advancements in materials and methods have led to a notable evolution in the discipline. The complications associated with autologous bone grafts, particularly concerning postoperative infections and bone resorption, can reach up to 50% and more in pediatric populations [7, 13, 23, 26]. This has promoted the exploration of heterologous materials such as PMMA, titanium, PEEK, and PHA. Our findings corroborate recent studies reporting overall complication rates averaging one third of patients, with no statistically significant differences among these materials except for a tendency for a better outcome with PHA [4, 6, 27], particularly regarding infection rates [4, 6, 27].

The ongoing debate regarding the ideal timing and materials for CP remains pertinent. The conclusion drawn from an editorial published in 2015, stating that "cranioplasty still needs an ideal material and surgical timing" remains relevant today [23]. Managing shunt-dependent hydrocephalus in patients requiring CP poses a significant challenge, with complication rates reported as high as 56% [8]. In our experience, several techniques have proven effective in mitigating complications, including (i) minimizing the artificial epidural space beneath the bone flap, (ii) ensuring the cranial defect aligns with the presumed skull line prior to CP, (iii) closely monitoring individual patient fluid and pressure dynamics before the procedure, and (iv) tailoring pre/postoperative management based on these dynamics, utilizing methods such as adjustable programmable valves, patient positioning adjustments, gravitational valve implantation, and, when necessary, temporary ligation of the shunt [9]. Our experience contribute valuable insights to the ongoing debate regarding the management and timing of CP in patients with hydrocephalus requiring shunt treatment [21, 29].

While there is a consensus that VPS placement is a significant risk factor for complications in CP procedures (including subdural or epidural fluid collections, intracerebral hemorrhage, infections, bone flap resorption, and seizures), the optimal timing for these interventions, whether as one-stage or two-stage procedures, remains less clear [10]. In the early stage of the present study, 41 patients, undergoing to simultaneous CP and VPS experienced a deep surgical site infections, as a result we decided to stop such practice, favoring whenever possible, prior CP followed by VPS. Some studies advocate for staged surgeries due to lower postoperative complications rates [8, 21]. For instance, Schuss et al. analyzed 41 CP procedures, noting that simultaneous VPS placement led to a significantly higher complication rate compared to staged procedures (47% vs. 12%; $P=0.03$, OR 6.2, 95% CI 1.33–29.0) [21]. Similarly Heo J et al. found complication rates of 56% for simultaneous procedures and 21% for staged ones [8]. In contrast, Meyer et al. reported no statistically significant difference in complication rates between simultaneous and staged procedures in their series of 58 patients [15].

Our findings indicate a significant difference in complication rates between one-stage and two-stage surgeries, suggesting that the timing of these procedures may indeed influence outcomes. However, it is essential to recognize that factors beyond timing—such as the surgical technique and the presence of a sufficient dural scar—play a critical role in postoperative success.

It is possible that factors beyond the timing of the procedures play a more critical role in influencing complication rates. A key step in cranioplasty involves meticulous dissection of the subcutaneous tissue and dura. In patients requiring VPS implantation, two factors may complicate the procedure and heighten the risk of postoperative complications. First, if CP is performed too soon after DC, prior to the formation of a sufficient dural scar, dissection within the correct plane may be difficult, often resulting in an unavoidable breach of the dura into CSF-filled spaces. This artificial communication with the epidural space can lead to postoperative fluid collections in patients with CSF circulation disturbances. Furthermore, the inability to adequately secure the bone graft with tack-up sutures—due to a lack of an intact dural scar—can create a substantial artificial epidural space beneath the bone flap. This hypothesis is substantiated by previous studies that reported a significantly higher incidence of postoperative subdural and epidural hygromas in patients undergoing early CP [9].

Limitation of the study

Despite the very large size of our cohort and the added value of our multicenter study there are four key limitations that we must point out:

1) The retrospective non-randomized nature of our analysis presents inherent biases, and the absence of a control group limits the robustness of our findings.
2) The decision to consider only patients undergoing reconstruction for unilateral calvarial defects increased the internal validity of the study. In fact the surgical

technique for unilateral DC in trauma patients is much more standardized than those used for bifrontal DC (including the following variations: preserving or not a bone strip over the superior sagittal sinus, suturing the anterior third of the superior sagittal sinus and cutting the falx to decompress the anterior commissure, reconstructing the frontal sinus in case of craniofacial trauma or iatrogenic violation of sinus integrity). This said, the result of this decision is that we cannot provide inferences regarding the management of patients with diffuse raised ICP without surgical masses who underwent bifrontal DC as their index procedure.

3) The adhesion to previously established classification on timing of surgery mentioned in our material section has a critical shortcoming which is the assumption that operating after 90 days or at any other time point afterwards would be the same. This is obviously debatable as previously pointed out in scientific literature. In fact, we can expect that the clinical needs of TBI patients might be remarkably different at 4 months versus 1 or 2 years after initial TBI. Furthermore, while reconstructing calvarial defects at 6 months or 1 year after DC allows clinicians to better understand the clinical trajectory of TBI, such a choice prevents us from understanding how those patients would have behaved in the context of a prompt reconstruction [5].
4) While SSFS has been extensively discussed in our results, we should point out that this does not represent a complication of CP, but is rather a clinical manifestation which has more to do with the extent of the DC, the proximity to the superior sagittal sinus and granulation of Pacchioni, and the deranged CSF dynamics caused by altered transmural venous pressure which is the hydrodynamic force behind CSF resorption [11].

Conclusion

Our study is one of the largest series of unilateral calvarial reconstruction for DC in TBI patients. However the limitations herein described underscore the importance of prospective registries to further validate our conclusions regarding timing of surgery, post-traumatic epilepsy and hydrocephalus. In summary, we managed to provide valuable insights into the complications associated with CP, particularly in the context of shunt-dependent hydrocephalus. As we continue to refine our techniques and strategies, it will be essential to engage in further research to elucidate the optimal timing and materials for CP, ultimately enhancing patient outcomes in this complex and evolving field

Author contributions All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by S.C., I.Z. and M.G. The first draft of the manuscript was written by S.C. and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Funding Furthermore, no financial support, grants, or funding from any organization, institution, or commercial entity was received for the research, authorship, or publication of this article.

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

Declarations By employing a robust multicenter design, standardized data collection protocols, and rigorous statistical methodologies, this study aimed to provide a nuanced understanding of the impact of cranioplasty timing and material choice on postoperative outcomes in patients undergoing reconstructive surgery after decompressive craniectomy.

Human ethics This study adhered to the Ethical Principles for Medical Research Involving Human Subjects as outlined in the Declaration of Helsinki, with the original issuance in 2004 and subsequent revisions in 2008 and 2013. The reporting of our findings complied with the STROCSS (Strengthening the Reporting of Observational Cohort Studies in Surgery) guidelines. The study received ethical approval n° IRB00011687 from the Institutional Review Board (IRB) of the French National Neurosurgery Society (SFNC).

Clinical trial number Not applicable

Consent to participate This is an observational study and utilized only aggregated patient data, ensuring that no individual patient could be identified. As such, obtaining informed consent was not required.

Competing interests The authors declare no competing interests.

Conflict of interest The authors declare that they have no conflicts of interest related to the content of this manuscript

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