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Original

Is informed consent required for cranioplasty?

¿Se requiere el consentimiento informado para la craneoplastia?

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ABSTRACT

Introduction: *Cranioplasty (CP) is a standard surgical procedure in neurosurgery, and various cranial implants have been extensively employed for this purpose worldwide. Complication rates are notably high and considerably greater than those observed in other elective neurosurgical procedures.* **Method**: *A literature review was conducted using the following search terms: decompressive craniectomy, cranioplasty, and complications. The PubMed, Lilacs, and Scielo databases were consulted.* **Results**: *Articles pertinent to the subject were selected based on their citation records and respective academic impact.* **Conclusions**: *Complications arising from CP are numerous and varied. It is essential to be fully acquainted with the indications, contraindications, and potential complications of this procedure, and to routinely employ an informed consent form detailing all foreseeable risks. This practice aims to mitigate medical harm to patients and, consequently, reduce medicolegal exposure for the neurosurgeon.*

Keywords: *cranioplasty; graft; indications; complications; informed consent.*

RESUMEN

Introducción: *La craneoplastia (CP) es un procedimiento quirúrgico estándar en neurocirugía, y se han utilizado varios implantes craneales para este procedimiento en todo el mundo. Las tasas de complicaciones están aumentando en comparación con otros procedimientos neuroquirúrgicos electivos.* **Método**: *revisión de la literatura mediante los términos de búsqueda: craniectomía descompresiva, craneoplastia y complicaciones. Se utilizaron las plataformas de datos PubMed, Lilacs y Scielo.* **Resultados**: *Artículos seleccionados relevantes al tema abordado, considerando las citas y sus respectivos impactos.* **Conclusiones**: *Las complicaciones derivadas de la PC son diversas. Es necesario conocer las indicaciones, contraindicaciones y complicaciones, así como un factor de rutina o termo de consentimiento libre e informado sobre posibles complicaciones, con el objetivo de reducir los problemas médicos de los pacientes y, en consecuencia, los problemas legales para la neurocirugía.*

Palabras clave: *craneoplastia; injerto; indicaciones; complicaciones; consentimiento informado.*

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1 INTRODUCTION

The surgical repair of cranial bone defects is defined as cranioplasty (CP)[1-3]. Various techniques have been described for performing CP, and these may be broadly classified according to the type of graft material employed: autologous bone grafts versus heterologous or alloplastic materials[4].

CP is an exceedingly common procedure among patients who have sustained traumatic brain injury (TBI) or undergone decompressive craniectomy (DC)[5]. The main indications include protection of the underlying brain parenchyma, restoration of cranial contour, seizure control, preservation of neurological function, correction of aesthetic deformity, and improvement of the patient's self-esteem[4,6,7]. CP is not without complications, and the full spectrum of adverse outcomes has not been entirely characterized[8]. The reported incidence of postoperative complications ranges from 0.5% to 50%[9-16].

The present article describes the principal complications arising from CP and draws attention to the necessity of routinely obtaining informed consent, to minimize potential medicolegal and judicial conflicts arising from the physician–patient relationship.

2 METHODS

This study consists of a narrative literature review conducted to identify and synthesize evidence on the indications, contraindications, complications, and medicolegal aspects of cranioplasty (CP), with particular emphasis on the role of informed consent in neurosurgical practice.

A systematic search was performed across three electronic databases — MEDLINE/PubMed, LILACS, and SciELO — covering publications from January 1990 to December 2023. The following Medical Subject Headings (MeSH) terms and free-text keywords were used, both individually and in Boolean combination: *cranioplasty*, *decompressive craniectomy*, *cranial implant*, *postoperative complications*, *surgical site infection*, *bone resorption*, *informed consent*, and *neurosurgery*. No language restrictions were applied, although the majority of retrieved articles were published in English, Portuguese, or Spanish.

Eligibility criteria for inclusion were: original research articles, systematic reviews, meta-analyses, case series, and case reports addressing CP techniques, materials, outcomes, or complications; studies involving adult or pediatric patients undergoing CP for any indication; and publications with full text available. Studies were excluded if they were editorial letters without original data, conference abstracts, or articles unrelated to the scope of this review.

Titles and abstracts were independently screened by both authors, followed by full-text assessment of potentially relevant studies. Discrepancies were resolved by consensus. Reference lists of selected articles were also manually examined to identify additional relevant publications not captured by the electronic search.

Data were extracted and organized thematically into the following domains: (1) materials and surgical techniques; (2) timing of reconstruction; (3) postoperative complications; (4) risk factors for adverse outcomes; (5) contraindications; and (6) medicolegal considerations and informed consent. Given the heterogeneity of study designs and outcome reporting, a formal meta-analytic approach was not undertaken, the findings are presented descriptively and synthesized narratively.

3 DISCUSSION

For the performance of CP, two main categories of material are available: autogenous bone grafts and alloplastic materials, the latter comprising titanium, ceramics, porous polyethylene, polymethylmethacrylate, and hydroxyapatite[17-20]. Among the implant materials most frequently used are titanium plates and titanium mesh[8,21]. Autologous materials include grafts harvested from the outer table of the parietal bone, the ribs, or the iliac crest[4]. Material selection depends on the patient's underlying pathology, age, size and location of the bony defect[15,22].

Autologous bone grafts derived from the calvaria are consistently preferred over other donor sites, such as the iliac crest or ribs. The advantages include proximity to the recipient area—allowing access through a single incision—satisfactory aesthetic scarring within the scalp, the same embryological origin and structural properties as the bone at the defect site, and favorable volume and contour [4].

At the donor site, it is imperative to preserve the inner cortical layer with sufficient thickness and rigidity to ensure cerebral protection, while also maintaining an acceptable aesthetic contour[23].

With respect to custom alloplastic materials, options include bioceramic compounds, titanium mesh, and methylmethacrylate[4,24]. Compared with autologous grafts, these materials offer the advantage of not being subject to resorption. However, they carry a significantly greater risk of infection and implant loss[25].

Custom prostheses are indicated when limiting factors preclude the use of autografts — such as inadequate dimensions, compromise of the donor bone, insufficient donor bone thickness, or the presence of comorbidities that contraindicate their harvest[4]. The optimal timing of CP following the initial injury remains a subject of ongoing debate[26,27]. Schuss et al.[28] concluded that patients undergoing early CP (less than 2 months after craniectomy) experienced a higher rate of complications compared with those who underwent delayed reconstruction (greater than 2 months).

Complications of CP are influenced by multiple factors, including local characteristics of the defect, timing of reconstruction, size of the bony gap, and its proximity to the paranasal sinuses[29]. The main complications include: local infection, seroma, reoperation, intracranial hemorrhage, extra-axial fluid collections, hydrocephalus, seizures, bone resorption, asymmetry of the cranial contour, skin necrosis, and extrusion of the graft or prosthesis[30-32]. Complications specifically related to cranial implant materials include infection, skin necrosis, and, in some cases, the need for multiple surgical revisions or reconstruction using vascularized tissue transfer[33-35]. According to Sundseth et al.[36], the most common complications following CP are postoperative surgical site infection and bone resorption. Sobani et al.[37] identified a 33% complication rate in their cohort of patients undergoing CP, including wound dehiscence, intracranial hemorrhage, bone resorption, subsidence of the CP, and intraoperative events such as arterial hypotension and bradycardia.

The growing prevalence of DC has led to a concomitant increase in the number of CP procedures performed[38]. Autologous cranial bone flaps have been the most widely used material worldwide[39]. The complication rate of CP following DC ranges from 10% to 40%[12]. DC — or removal of the cranial bone flap — is an established and effective treatment modality for reducing elevated intracranial pressure (ICP) in cases of malignant cerebral edema secondary to severe TBI, intracranial hemorrhage, cerebral infarction, or tumor-related mass effect[40,41]. Following DC, CP is generally performed not only to protect the brain from further injury but also for cosmetic purposes and to improve the patient's neurological function. Nevertheless, CP continues to be associated with a high complication rate, particularly infection, exceeding that of other neurosurgical procedures[40,42].

The infection rate following CP ranges from 7% to 22%[12,43-47]. Risk factors include prolonged operative time, craniectomy with temporal muscle resection, preoperative subgaleal fluid collection, fever, scalp swelling, and local inflammation[12,48]. Patients with postimplant infection may present with fever, edema, or purulent discharge from the surgical wound [48].

Yasuhara et al.[8] identified patient-related factors associated with postoperative infection, including male sex, brain tumor diagnosis, short interval between surgery and the onset of complications, use of ceramic materials, hydroxyapatite, resin, or artificial dura mater, malnutrition, multiple prior surgeries, wound contamination, and sinusitis. Surgical factors associated with infection included the presence of a cerebrospinal fluid (CSF) fistula, wound dehiscence, and inadequate management of the paranasal sinuses. Morton et al.[45] reported that infection following CP occurred at a mean of 31 postoperative days, with an overall infection rate of 6.6%, and suggested that CP may be performed as early as 14 days after craniectomy to minimize this risk. Rosseto et al.[42] identified the following infection risk factors: motor deficit, Glasgow Outcome Scale score below 4, low hemoglobin levels, recent systemic infection, an interval of 29–84 days between DC and CP, and performance of both DC and CP during the same hospital admission. CP utilizing cryopreserved autologous bone flaps has been associated with infection rates of up to 33%[49].

Sudden death following CP has been reported in the literature[50-52]. Several authors[51,53-56] have speculated that active suction through epidural and subgaleal drains may be a contributing factor to these sudden fatalities, as may impaired cerebral autoregulation.

Additional complications associated with CP include ischemic and hemorrhagic stroke[31,37,57-60]. According to Mangubat and Sani[59], cerebral infarction following CP is uncommon and appears to result from vascular injury, venous stasis, and reperfusion within previously injured brain tissue. This risk must be thoroughly evaluated before proceeding with CP. Malignant cerebral edema has also been described as a postoperative complication[53,61-64].

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Bone resorption occurs predominantly in association with autologous grafts — particularly autoclaved bone — with an incidence ranging from 1.4% to 44.4%[65-73]. Other reported complications include subarachnoid hemorrhage, dural laceration, CSF fistula, and donor site morbidity such as infection, wound eschar, and pain[74].

Contraindications to CP include: cerebral prolapse due to elevated ICP, skin necrosis overlying the bony defect, hydrocephalus, neurological instability, and local or systemic infection[42,74,75].

Resolution 1931/09 of the Brazilian Federal Council of Medicine (CFM)[76], which approved the revised Code of Medical Ethics, affirms in several provisions the requirement for free and informed consent. Notably, Articles 22 and 101 prohibit the physician from:

> *Art. 22. Failing to obtain the consent of the patient or their legal representative after providing clear explanations about the procedure to be performed, except in cases of imminent risk of death. (...)*

> *Art. 101. Failing to obtain from the patient or their legal representative the free and informed consent form for the performance of research involving human subjects, after duly explaining the nature and consequences of such research.*

Informed consent has become increasingly prevalent in medical practice, including neurosurgery, yet it remains insufficiently disseminated in the literature. A more objective, concise, and clear form of communication must be established with the patient or their legal representative — one that provides a precise explanation of the procedure to be undertaken. Such a practice is likely to enhance satisfaction for both parties in the physician–patient relationship.

In the Appendix 1 below is a proposed informed consent form for patients scheduled to undergo CP.

4 CONCLUSION

A thorough assessment of the potential risk factors associated with CP is essential to prevent complications for both the patient and the surgeon. The elevated complication rate following CP warrants careful preoperative evaluation, with particular attention to the appropriateness of the surgical indication and the selection of the most suitable reconstructive material for each individual patient. The routine use of a free and informed consent form is not merely a legal obligation but a fundamental component of responsible neurosurgical practice — one that may avert serious medicolegal consequences for the neurosurgeon.

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Appendix 1. Proposed Informed Consent Form for Cranioplasty

Proposed Informed Consent Form for Cranioplasty

Name of Institution:

_____

FREE AND INFORMED CONSENT FOR CRANIOPLASTY

Patient:

_____

As a patient, I have the right to be informed about the need for a cranial implant, as well as the benefits and risks arising from the surgical intervention required for the management of my health condition.

In full agreement with the criteria established by my physician — whom I have freely chosen — I acknowledge the following: the purpose of this document is not to cause alarm, but it must not conceal the fact that, regardless of the professional expertise of the surgical team or the resources available at the institution, complications or even death may occur.

I have received information regarding my medical condition and the planned surgical procedure.

Diagnosis: _____

Type of surgical procedure: _____

Neurosurgeon: _____

Cranioplasty is a highly prevalent surgical procedure in the daily practice of the neurosurgeon. In certain cases, this procedure is considered high risk. The surgery involves the placement of an autologous or heterologous cranial implant. The purpose of this intervention is to provide cerebral protection, achieve an aesthetic outcome, improve neurological status in selected cases, and enhance the patient's self-esteem.

The procedure is performed under general anesthesia.

Risks and Potential Complications:

1. Infection: involving the skin or the brain, potentially resulting in meningitis, subdural empyema, cerebral abscess, or ventriculitis.
2. Wound dehiscence.
3. Exposure of the implanted material.
4. Requirement for an additional surgical intervention.
5. Risk of sudden death.
6. Risk of epileptic seizures.
7. Cranial asymmetry.
8. Allergic reaction to the implanted material.
9. Hemorrhagic or ischemic stroke.
10. Risks inherent to general anesthesia.

I, the undersigned, _____, aged _____ years, or, in the event of legal incapacity, represented by _____, CPF: _____, ID: _____, hereby acknowledge that I have been clearly and objectively informed of the full details of the procedure to which I will voluntarily submit, including its prognosis, potential sequelae, and other consequences, as well as possible alternative cranial implant materials, their associated risks and effects. I confirm that all questions raised by me have been answered in a satisfactory and comprehensible manner.

Therefore, freely and in full awareness, I hereby grant consent to the neurosurgeon and the institution at which I will undergo cranioplasty treatment, accepting the possibility that the complications described herein — or other exceptional occurrences — may arise, without this implying any error, negligence, or omission on the part of the surgical team.

I authorize my physician, _____, and the surgical team to take whatever measures they deem appropriate in the interest of my health — measures that, by reason of urgency, may not permit the request of a new informed consent form — including, but not limited to: admission to the intensive care unit (ICU), modifications to anesthetic technique, changes in implant material, and alternative diagnostic or therapeutic interventions.

I further authorize the medical team and the institution to remove material from the operative site for anatomopathological and bacteriological study. I also authorize the medical team to capture photographs and video recordings for scientific, academic, and educational purposes, always subject to the obligation of medical confidentiality regarding the identification of the patient.

Note: CPF = Brazilian social security number; CRM = Brazilian State Medical License Number

Appendix 1. Continued...

Risks and Potential Complications:
It is fully understood that, in certain circumstances, this procedure may be curative; however, in other situations it may not achieve complete resolution. Following surgery, preexisting aesthetic defects may persist, and an additional intervention may be required due to cosmetic concerns.
Furthermore, I affirm that I retain the right, at any point, to withdraw this authorization.
Thus, in an express and informed manner, I grant my consent.
_____
Signature of the patient or legal representative
_____
Signature of the attending physician / CRM / CPF
The legal representative of the patient acts on behalf of the patient in the following circumstances:
— The patient is a minor;
— The patient has an intellectual disability;
— The patient voluntarily requests representation;
— The patient's clinical condition does not allow for personal consent.

Note: CPF = Brazilian social security number; CRM = Brazilian State Medical License Number