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Decompressive craniectomy size and outcomes in adults with severe traumatic brain injury: a systematic review and meta-analysis protocol

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ADMINISTRATIVE INFORMATION**Support** - No external funding. The review is self-funded by the author.**Review Stage at time of this submission** - Formal screening of search results against eligibility criteria.**Conflicts of interest** - None declared.**INPLASY registration number:** INPLASY2026100059**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 13 October 2026 and was last updated on 13 October 2026.**INTRODUCTION**

Review question / Objective In adults aged ≥ 18 years with severe traumatic brain injury undergoing decompressive craniectomy, how does the size of the bone opening relate to mortality, functional outcomes, intracranial pressure control, and postoperative complications?

The primary objective is to compare mortality and functional outcomes between larger and smaller decompressive craniectomies and to evaluate associations between continuously measured craniectomy size and these outcomes.

Secondary objectives are to assess intracranial pressure control, rescue treatment requirements, and postoperative complications; describe how craniectomy size is defined and measured; and assess the certainty of the evidence.

Eligible studies will include randomized trials and non-randomized analytical studies evaluating size-based comparisons or within-cohort size-outcome associations. Randomized and non-randomized

evidence will be synthesized separately. Where sufficient comparable data are available, exploratory analyses will examine primary versus secondary decompression, surgical approach, and size measurement method.

Rationale Decompressive craniectomy is used to manage intracranial hypertension and brain swelling after severe traumatic brain injury. The extent of bone removal is a potentially modifiable component of the procedure that may influence decompression, functional recovery, mortality, and postoperative complications.

This review will synthesize evidence specifically addressing craniectomy size in adults with severe traumatic brain injury, including comparisons between larger and smaller decompressions and analyses of size as a continuous measure. Differences in size definitions, measurement methods, surgical approaches, and outcome assessment will be examined to determine whether studies can be meaningfully combined.

Where appropriate, meta-analysis will estimate associations between craniectomy size and outcomes. The review aims to inform surgical decision-making, assess the certainty and limitations of the available evidence, and identify priorities for future research.

Condition being studied Severe traumatic brain injury in adults aged ≥ 18 years undergoing primary or secondary decompressive craniectomy. Severe injury will be defined as a Glasgow Coma Scale score of 3–8 after initial resuscitation or explicitly classified as severe by the study authors. The review includes decompression for traumatic intracranial hypertension or brain swelling, including decompression during evacuation of traumatic mass lesions when population eligibility criteria are met.

METHODS

Search strategy Searches will cover PubMed, Embase, Scopus, Web of Science Core Collection, and Cochrane CENTRAL, with MEDLINE coverage documented according to the platform used. [ClinicalTrials.gov](https://clinicaltrials.gov) and WHO ICTRP will be searched for ongoing studies and unpublished results. No language or publication date restrictions will be applied.

Strategies combine three concepts: traumatic brain injury; decompressive craniectomy; and bone opening size or extent. Controlled vocabulary, where available, and free-text terms will be adapted to each platform.

The Scopus strategy executed on 2 October 2026 was:

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(TITLE-ABS-KEY("traumatic brain injury" OR
"traumatic brain injuries" OR TBI OR "head injury"
OR "head injuries" OR "craniocerebral trauma" OR
"craniocerebral injury" OR "craniocerebral injuries"
OR "post-traumatic brain swelling" OR
"posttraumatic brain swelling") AND TITLE-ABS-
KEY("decompressive craniectomy" OR
"decompressive craniectomies" OR
"decompressive hemicraniectomy" OR
"decompressive craniotomy" OR "trauma
craniectomy" OR "trauma craniotomy" OR
(craniectom* AND decompress*) OR
hemicraniectom*) AND TITLE-ABS-KEY(size* OR
dimension* OR diameter* OR "surface area" OR
"head size" OR "skull circumference" OR
"temporal base" OR "temporal floor" OR "standard
trauma craniectomy" OR "standard large trauma
craniectomy" OR "standard large trauma
craniotomy" OR "large decompressive
craniectomy" OR "limited craniectomy" OR
"routine temporoparietal craniectomy"))
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Historical craniotomy terminology is included to improve retrieval; eligibility will depend on operative descriptions confirming that the bone flap was left out.

Reference lists of included studies and relevant reviews will be checked, and forward citation searches will be performed for included studies. Supplementary searches of JNS/JNSPG have also been conducted. Searches will be updated before final synthesis. Exact platform-specific search histories, dates, filters, and retrieval counts will be retained for reproducibility.

Participant or population Adults aged ≥ 18 years with severe traumatic brain injury, defined as a Glasgow Coma Scale score of 3–8 after initial resuscitation or explicitly classified as severe by the study authors, undergoing primary or secondary decompressive craniectomy. Patients with traumatic mass lesions, including acute subdural hematoma or cerebral contusions, are eligible if they meet these criteria. Studies with mixed age groups, injury severities, or etiologies will be eligible only when data for adults with severe traumatic brain injury can be extracted separately.

Intervention Primary or secondary decompressive craniectomy with the bone flap left out, in which the size or extent of the bone opening is explicitly evaluated in relation to outcomes. Eligible size measures include anteroposterior diameter, other linear dimensions, surface area, and normalized measures relative to skull size. Studies may compare predefined size categories or analyze size as a continuous variable. Historical descriptions such as standard trauma craniectomy or large trauma craniotomy will be eligible only when the operative description confirms an eligible decompressive craniectomy and a size-based comparison or analysis. Reporting a uniform opening size without evaluating its relationship to outcomes is insufficient.

Comparator Decompressive craniectomies with a smaller or otherwise different bone opening size, defined by linear dimensions, surface area, normalized measures, or clearly described size categories. Study-specific thresholds will be recorded; no universal cutoff will be imposed for eligibility. Studies without separate comparator groups are eligible when they analyze the relationship between variation in craniectomy size and outcomes within a cohort. Comparisons solely against medical management or other procedures are insufficient unless a separate eligible craniectomy size analysis is available.

Study designs to be included Randomized controlled trials, non-randomized controlled studies, and prospective or retrospective analytical observational studies, including cohort and case-control studies. Single-cohort studies are eligible when they analyze variation in craniectomy size in relation to outcomes. Randomized and non-randomized evidence will be synthesized separately. Eligibility will depend on actual study methods rather than publication format.

Eligibility criteria Studies must evaluate decompressive craniectomy size in relation to at least one eligible clinical or physiological outcome. Merely reporting a uniform opening size without a size–outcome analysis is insufficient. Patients younger than 18 years, mild or moderate traumatic brain injury, and non-traumatic etiologies are excluded. Mixed populations are eligible only when data for adults with severe traumatic brain injury can be extracted separately. Craniotomy with immediate bone flap replacement, hinge or floating craniotomy, cranioplasty, and isolated skull reconstruction are excluded. Studies combining these procedures with decompressive craniectomy require a separately extractable eligible size analysis. Case reports, purely descriptive case series, reviews, protocols without results, editorials or technical descriptions without eligible original clinical data, and animal, cadaveric, laboratory or simulation studies are excluded. Letters are not excluded solely because of publication format. No language, publication date, geographic or publication status restrictions will be imposed. Unpublished reports require sufficient methods and results for eligibility assessment. Registry records without results will be documented separately. Multiple reports of the same study will be linked to avoid double counting.

Information sources Information sources will include PubMed, Embase, Scopus, Web of Science Core Collection, and Cochrane CENTRAL. MEDLINE coverage will be documented according to the search platform and database settings used. ClinicalTrials.gov and WHO ICTRP will be searched for ongoing studies and unpublished results. Reference lists of included studies and relevant reviews will be checked, and forward citation searches will be performed for included studies. Supplementary searches of JNS/JNSPG have also been conducted. Study investigators may be contacted to clarify methods or obtain missing aggregate results. Individual participant datasets will not be sought. Relevant supplementary files, registry results, and linked reports will be examined.

Searches will be updated before final synthesis. Search dates, exact strategies, filters, and retrieval counts will be retained. PROSPERO has been searched to assess overlap with registered reviews.

Main outcome(s) The co-primary outcomes are all-cause mortality and unfavorable functional outcome assessed using the Glasgow Outcome Scale (GOS) or Extended Glasgow Outcome Scale (GOSE), primarily defined as GOS 1–3 or GOSE 1–4. Alternative thresholds, ordinal analyses, and other validated functional scales will be reported separately.

Primary follow-up is six months after injury or surgery. Assessments at 5–7 months will be eligible, selecting the assessment closest to six months; ties will use the later assessment. The follow-up reference point will be recorded.

In-hospital and 30-day mortality, and outcomes at three months (2–4 months) and twelve months (10–14 months), will be analyzed separately when available. Other follow-up periods will be described without combining clinically different time points.

Binary outcomes will preferentially use risk ratios with 95% confidence intervals when group risks can be calculated. Adjusted odds ratios, risk ratios, and hazard ratios will be synthesized separately, as will adjusted and unadjusted estimates. Compatible continuous functional outcomes will use mean differences, or standardized mean differences when different scales measure the same construct.

Continuous craniectomy size associations will be synthesized only when size measures, units, and statistical models are compatible. Each cohort will contribute once per outcome and follow-up synthesis.

Additional outcome(s) Secondary outcomes include postoperative intracranial pressure (ICP), ICP burden or control according to study-defined thresholds, requirement for rescue treatment for intracranial hypertension, and postoperative complications.

Complications include hemorrhagic progression, external cerebral herniation, infection, cerebrospinal fluid disturbances, hydrocephalus, and subdural hygroma. Each complication will be assessed separately. Composite outcomes will be pooled only when definitions and components are compatible.

ICP and rescue treatment will primarily be assessed during acute hospitalization, recording measurement methods, units, thresholds, treatment types, and postoperative assessment times. Complications will be assessed during hospitalization and subsequent reported follow-up

periods without combining clinically different assessment windows.

Binary outcomes will preferentially use risk ratios with 95% confidence intervals. Adjusted odds ratios, risk ratios, and hazard ratios will be synthesized separately. Continuous outcomes will use mean differences for the same measure and units, or standardized mean differences for comparable constructs measured on different scales.

Size-outcome associations will be pooled only when size measures, outcome definitions, follow-up periods, and statistical models are compatible; otherwise, they will be summarized narratively.

Data management Records will be managed in Rayyan. Deduplication will compare DOI, PMID, titles, authors, publication year, and other bibliographic metadata. Ambiguous records will be retained until resolved. Multiple reports of the same study will be linked to avoid double counting. One reviewer will screen titles and abstracts and assess potentially eligible full texts. A second person will check all selection decisions at both stages, including exclusions. Disagreements will be resolved through discussion and consensus. Full-text exclusion reasons will be recorded, and selection will be documented in a PRISMA flow diagram.

Data will be extracted into a standardized spreadsheet, piloted on at least two eligible studies if available. One reviewer will extract data, and a second person will check all entries against source reports. Extracted information will include study characteristics, population eligibility, surgical indication and approach, craniectomy size definitions and measurements, outcome definitions and follow-up, numerical results, adjustment variables, funding, and conflicts of interest.

Source reports, search histories, original exports, selection decisions, extraction files, and analysis code will be retained with version control and backups. Missing or unclear information may be requested from study investigators. Individual participant datasets will not be sought.

Quality assessment / Risk of bias analysis Risk of bias will be assessed for each result contributing to synthesis. Randomized trials will be evaluated using Cochrane RoB 2. Non-randomized studies evaluating the surgical size intervention will be assessed using the original 2016 ROBINS-I framework.

Prespecified confounding domains include age, initial injury severity, pupil reactivity, imaging severity or traumatic mass lesions, preoperative intracranial pressure where applicable, surgical indication and timing, primary versus secondary

decompression, surgical approach, and concurrent care. Size measurement methods and timing will be examined, including whether postoperative swelling or complications could influence the measured size.

One reviewer will perform assessments, and a second person will check all judgments and supporting evidence. Disagreements will be resolved through discussion and consensus. Domain-level judgments will be reported without conversion into numerical quality scores. Critical-risk non-randomized results will be described but excluded from pooled causal effect estimates. Findings without a defensible causal interpretation will be reported as associations.

Reporting bias will be examined by comparing publications with available protocols and registry records. Funnel plots and appropriate tests for small-study effects will be considered only when at least ten compatible studies contribute to an analysis; asymmetry will not automatically be interpreted as publication bias.

GRADE will assess certainty for the main outcomes separately by comparison, follow-up, and study design. Risk of bias, inconsistency, indirectness, imprecision, publication bias, and applicable upgrading factors will be considered. The starting certainty level and relationship to ROBINS-I will be documented to avoid double counting confounding limitations.

Strategy of data synthesis Findings will be summarized in tables and narratively. Meta-analysis will require at least two independent studies with compatible populations, craniectomy size contrasts, outcome definitions, and follow-up periods. Randomized and non-randomized evidence, categorical comparisons and continuous size associations, and adjusted and unadjusted estimates will be synthesized separately.

Random-effects models will use restricted maximum likelihood estimation of between-study variance and modified Hartung-Knapp confidence intervals that are no narrower than conventional random-effects intervals. Effect estimates will be reported with 95% confidence intervals.

Binary outcomes will preferentially use risk ratios when group risks can be calculated. Adjusted odds ratios, risk ratios, and hazard ratios will be pooled separately on logarithmic scales. Continuous outcomes will use mean differences for the same scale or standardized mean differences for comparable constructs measured on different scales. Change scores and final values will be analyzed separately unless a justified compatible analysis is available.

Continuous size associations will be pooled only when measures, units, and statistical models are

compatible. Linear dimensions and surface area will not be treated as interchangeable. Correlations and regression coefficients will not be combined indiscriminately. Dose-response meta-analysis is not planned.

Each cohort will contribute once per outcome and follow-up synthesis. Overlapping populations will be resolved using recruitment periods, setting, and report completeness.

Heterogeneity will be assessed using tau-squared, I-squared, and clinical and methodological differences. Prediction intervals will be considered with at least five compatible studies. Uncertainty from very small study sets will be emphasized.

For log risk-ratio analyses, single-zero-event studies will use a 0.5 continuity correction to all cells, with an alternative sparse-data analysis as a sensitivity analysis where feasible. Double-zero studies will be displayed but will not contribute to relative risk estimates. Missing standard deviations may be derived from compatible confidence intervals or standard errors using documented formulas.

When pooling is inappropriate, structured narrative synthesis will report effect estimates, uncertainty, and reasons for incompatibility. Analyses will use R, with package versions and code reported.

Subgroup analysis Where sufficient comparable data are available, exploratory subgroup analyses will examine primary versus secondary decompressive craniectomy, unilateral versus bifrontal or bilateral approaches, and craniectomy size measurement method.

Subgroup differences will be assessed using interaction tests rather than comparing statistical significance within subgroups. Randomized and non-randomized evidence will remain separate.

Exploratory meta-regression will be considered only with at least ten studies per covariate and adequate variation. Study-level associations will be interpreted cautiously because of potential confounding and ecological bias. When data are insufficient, subgroup characteristics will be described narratively.

Sensitivity analysis Where sufficient studies are available, sensitivity analyses will assess the robustness of pooled findings to risk of bias, population eligibility, operative classification, craniectomy size measurement, and data handling. Analyses will examine the exclusion of high-risk randomized results and serious-risk non-randomized results. Critical-risk non-randomized results will already be excluded from pooled causal estimates.

Additional analyses will examine studies with mixed populations contributing separately

extractable eligible subgroups; historical operative labels requiring interpretation; postoperative size measurements potentially influenced by swelling or complications; and derived or imputed numerical data.

Where overlapping cohorts cannot be fully resolved, alternative eligible reports will be examined without including overlapping participants in the same analysis. Alternative sparse-data methods will be considered to assess the influence of continuity corrections in binary outcome analyses.

Sensitivity analyses will retain the separation of randomized and non-randomized evidence, adjusted and unadjusted estimates, and clinically different follow-up periods. If too few studies are available, these limitations will be discussed narratively.

Language restriction No language restrictions will be applied. Translation will be arranged when necessary, with clinically important details checked.

Country(ies) involved Brazil.

Other relevant information Database searches were conducted on 2 October 2026, and preliminary title and abstract screening began before registration. At submission, data extraction, risk of bias assessment, and data synthesis have not started.

This consolidated protocol was prepared after searches and preliminary screening had begun. It will not be described as having preceded all review activities. Preliminary selection decisions will be reassessed against the finalized eligibility criteria where necessary.

The protocol has one named author. A second person will check all selection decisions, extracted data, and risk of bias judgments as described in the methods; this checking process is not independent duplicate screening or extraction.

Subsequent methodological amendments will be dated, justified, and documented in the registration and final report. The completed review will be reported according to PRISMA 2020, with reproducible search documentation.

Keywords Traumatic brain injury; Decompressive craniectomy; Craniectomy size; Hemispheric craniectomy; Mortality; Functional outcomes; Systematic review; Meta-analysis.

Dissemination plans The completed review will be submitted to a peer-reviewed journal and reported according to PRISMA 2020. Search strategies, study-level extracted data, and analysis code will

be made available as supplementary materials or through a public repository where sharing is permitted. Findings will be disseminated regardless of the direction or statistical significance of the results.

Contributions of each author

Author 1 - Glendha Bastos Pontes - Conceived the review, developed the methods and searches, and prepared the protocol. She will conduct selection, extraction, risk of bias assessment, synthesis, and manuscript preparation, with checking by a second person as specified. She is the corresponding author and guarantor.

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