COAST Study

The COAST (Core Outcome set for Cranioplasty After Stroke or TBI) study established a standardized set of outcomes to be collected and reported after cranioplasty. This consensus-based COS is structured into four core domains:

- **Life Impact**
- **Pathophysiological Manifestations**
- **Resource Use / Economic Impact**
- **Mortality**

Purpose

To reduce heterogeneity in outcome reporting and improve comparability across clinical studies, registries, and clinical practice.

Final Core Outcome Set (n = 20 outcomes)

♂ Life Impact

- **Cosmesis**
  - Overall cosmetic outcome following cranioplasty
  - Patient satisfaction with cosmetic result
- **Function**
  - Overall functional outcome following cranioplasty †
  - Level of functional independence †
- **Cognition**
  - Impact of cranioplasty on overall cognition
  - Impact on communication and language †
- **Mental Health**
  - Impact on mental well-being
- **Quality of Life**
  - Patient-reported quality of life †

Pathophysiological Manifestations

- **Complications**
  - Overall complications †
  - Surgical site infection †
  - Wound/soft tissue-related issues
  - Intra-cranial hematoma
  - Seizures †
  - Hydrocephalus
  - Graft-specific complications
- **Radiology**

    - Bone flap resorption
- **Neurology**
    - Change in level of consciousness

Resource Use / Economic Impact

- Timing of cranioplasty procedure
- Need for repeat interventions

☠ **Mortality**

- Mortality †

(†) Indicates outcome reached consensus in Delphi phase directly.

Methodology

- Developed through systematic review + qualitative study
- 2-round Delphi survey (153→109 participants)
- Final online consensus meeting
- Stakeholders: patients/relatives, surgeons, physicians, nurses/AHPs/researchers

Implementation

This COS defines **“what to measure”**, not **“how to measure”**. Further work is needed to select standard instruments for each outcome (e.g., mRS, EQ-5D, cognitive tests).

COAST Study Core Outcome Set (2025)

A standardized Core Outcome Set for cranioplasty after stroke or TBI was proposed by the COAST study (Mee et al., Brain & Spine, 2025), including:

- Neurological function
- Cognitive performance
- Seizure incidence
- Surgical complications
- HRQoL

Recommended timepoints: baseline, 3 months, 12 months.

Summary Table

Domain	Assessment Tools / Indicators	Timepoints
Neurological recovery	GCS, NIHSS, cognitive testing	Pre-op, 3–12 months
Functional status	GOS, mRS, FIM	3, 6, 12 months

Domain	Assessment Tools / Indicators	Timepoints
Complications	Infection, bone resorption, seizures, hydrocephalus	Immediate–12 months
Cosmetic satisfaction	PROMs, interviews, satisfaction scales	1, 3, 6 months
Quality of life	EQ-5D, SF-36, disease-specific PROMs	3–12 months

Consensus methodology research

In a multi-phase consensus methodology including systematic review, qualitative study, two-round Delphi process, and final consensus meeting. Mee et al. from Cambridge, Oulu, Madrid, Ibadan, Bristol, Cali, Winnipeg, Perth, Modena, London, Lund, Worcester (MA), Adelaide, Milan, Norwich published in the **Journal:** *Brain & Spine* to develop an internationally agreed-upon core outcome set (COS) for cranioplasty following a decompressive craniectomy for stroke or traumatic brain injury. The COAST study successfully defined a 20-item core outcome set across four domains (life impact, pathophysiological manifestations, resource use/economic impact, mortality) based on structured consensus among a wide range of global stakeholders. This COS aims to enhance the consistency and comparability of future cranioplasty studies [1)].

Critical Review

The COAST study represents an ambitious and commendable effort to bring standardization to an under-structured field—cranioplasty outcomes. By following the COMET methodology and involving a multidisciplinary and international panel, it enhances the legitimacy and breadth of the final COS.

Strengths: - Wide stakeholder inclusion ensures diverse perspectives (patients, surgeons, allied health professionals). - Rigid adherence to established consensus-building methodology. - The scale of participation (153 individuals across 16 countries) and structured Delphi rounds followed by a consensus meeting reflect robust procedural rigor. - A focused categorization of outcomes into clinically meaningful domains is pragmatic.

Weaknesses: - No formal validation of the selected outcomes in prospective cohorts—feasibility and sensitivity remain theoretical. - Regional representation appears skewed toward academic centers in high-income countries; the extent to which the COS reflects the realities of resource-limited settings is unclear. - The study refrains from discussing any potential conflicts between patient-centered outcomes and those favored by clinicians, nor does it address the weighting or prioritization of these 20 outcomes. - Lack of granularity in reporting stakeholder-specific scoring trends reduces interpretability of consensus dynamics.

Final Verdict: Solid methodology but lacks immediate translational validation. It is an important foundational step for future research standardization, though not yet a clinical tool. A validation phase in real-world clinical trials is critical.

Takeaway for Practicing Neurosurgeons: Begin familiarizing yourself with the COAST COS as a reporting standard, especially when engaging in clinical research on cranioplasty. It does not yet influence clinical decision-making directly.

Bottom Line: Methodologically sound initiative establishing a consensus-based framework for cranioplasty outcomes, but clinical adoption will hinge on future validation studies.

Rating: 7/10

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1)

Mee H, Korhonen TK, Castaño-Leon AM, Adeleye A, Allanson J, Anwar F, Bhagavatula ID, Bond K, Clement C, Rubiano AM, Grieve K, Hawryluk G, Helmy A, Honeybul S, Iaccarino C, Lagares A, Marcus H, Marklund N, Muehlschlegel S, Owen N, Paul M, Pomeroy V, Shukla D, Servadei F, Viaroli E, Warburton E, Wells A, Timofeev I, Turner C, Whiting G, Hutchinson P, Kolias A. A core outcome set for cranioplasty following stroke or traumatic brain injury - The COAST study. Brain Spine. 2025 Jun 1;5:104288. doi: 10.1016/j.bas.2025.104288. PMID: 40585434; PMCID: PMC12205645.