

Evidence Table

	Cross et al., 2022	Iyer et al., 2018	Nguyen et al., 2023	Rudolph et al., 2022
Population	-Single-subject -Sagittal CS -4 mo old at time of surgery -EAC procedure	-31 patients -Non-syndromic sagittal CS -Median age of 2.7 months at time of surgery -Underwent ESC surgery	-28 Sagittal CS -14 Metopic CS -Sagittal or metopic CS -SCS: 3.29 mo average age for ESC -MCS: 3.43 mo average age for ESC -Underwent ESC surgery -Less than or equal to 6 mo old at surgery -Pre- and post-helmet therapy 3D imaging available	-13 patients -Isolated sagittal craniosynostosis - Mean age of 3.3 months at time of surgery -Underwent ESC surgery
Study Design	Computational modeling study	Retrospective cohort study	Retrospective cohort study	Retrospective Review
Intervention	Finite Element (FE) Modeling of Helmet therapy post-EAC procedure	Post-operative helmet therapy at various durations	ESC followed by post-op helmet therapy	ESC followed by post-op helmet therapy (2015-2019)
Comparison	No Helmet therapy post-EAC	Different durations of helmet therapy: helmet removal at or before peak CI vs beyond reaching peak CI	Comparison between SCS and MCS for duration, age at completion, and number of helmets required	Maximal rate of change of width, length, and CI were compared against the postoperative week these occurred
Methodology	3D CT-based finite element model analysis for duration of 2 mo, 5 mo, 8 mo	Obtained CI with physical measurement of head width and head length with calipers every 3 months during helmet therapy and 1-year post-helmet therapy, and 3D laser scans at intervals of pre-op, 1 wk, 4 wks, 6-8 wks, 3 mo, 4.5 mo, and 6.5 mo post-op. Peak CI determined as highest CI measured throughout duration of study.	Obtained data from electronic health records. Measured pre- and post-helmet therapy cranial metrics using 3D imaging. Analyzed differences in therapy duration and outcomes statistically. Criteria for success was CVAI ≤ 3.5 for both SCS and MCS, CI ≥ 75 for SCS, and IFA $> 125^\circ$ for MCS and qualitative evaluation by surgeon and orthotist to confirm satisfactory head shape.	Obtained CI with measurement of head width and head length by one orthotist using topographical laser scanning technology. Took measurements preoperatively and postoperatively every 2-3 weeks. Mean changes in CI, width, and length over time were analyzed to determine the postoperative day in which the CI, width, and length growth rates reached their respective peaks
Outcome	-Skull length	Cephalic index measured at pre-op, peak CI, helmet removal, and at last	-CI	-Skull length

Measures	-Skull width -Cephalic index -Healing patterns -Intracranial contact pressure patterns	follow-up	-Interfrontal angle -Cranial vault asymmetry index -Age at surgery -Age at start of helmet therapy -Age at completion of helmet therapy -Duration of helmet therapy -Number of helmets required	-Skull width -Cephalic index -Number of helmets required -Postoperative day starting helmet therapy -Duration of helmet therapy -Length of follow-up -Rate of change of CI
Key Findings	All scenarios showed healing of the skull bone by 20 mo	-Peak CI reached at 8.4 mo postsurgery -Mean peak CI was 0.83	-Metopic patients (MC): Interfrontal Angle (IFA) improved from 117.3° → 127.9° (p = 0.02).	-Preoperative average CI was 73.4 -Largest CI mean growth rate/day by 4.9 weeks postoperatively (average patient age = 4.4 months)
	-Lack of helmet did not impact the level or pattern of bone formation or bone healing -Lack of helmet resulted in dorsal bulge by 36 mo -Dorsal bulge eliminated with introduction of helmet regardless of duration -8 mo helmet duration encouraged greater bitemporal widening compared to 2mo and 5mo -Greatest length recorded with no helmet therapy -Shortest length with 8 mo helmet therapy -Highest width with 8 mo helmet therapy -Lowest width with no helmet therapy -Highest CI of 86.2 achieved in 8 mo therapy -Lowest CI of 75 in no helmet therapy - Distribution of intracranial contact pressures similar for all scenarios at 36 mo of age	-CI at last follow-up showed retraction post-helmet therapy to an average of 0.78 -Longer helmeting after peak CI reached did not improve CI at last follow-up -Patients with helmets removed after peak CI achieved had a lower CI at final follow-up than those who ended helmet therapy at/before peak CI -Peak CI was strongest predictor of CI at final follow-up -Age at surgery and pre-op CI did not significantly affect final outcomes	-CVAI decreased from 4.67 → 2.60 (p = 0.02) -Sagittal patients (SC): Cephalic Index (CI) improved from 71.3 → 75.6 (p < 0.001). Cranial Vault Asymmetry Index (CVAI) decreased from 2.53 → 1.16 (p < 0.001) -Age at completion of HT: SC: 7.9 months MC: 10.0 months (significantly later, p = 0.007) - Number of helmets required: SC: 1.54 helmets. MC: 2.21 helmets (more helmets needed, p = 0.002) -Duration of HT: SC: 4.2 months. MC: 6.0 months (longer, p = 0.009) - Suture type was only significant predictor of helmet therapy duration -MSC required significantly longer helmet therapy and more helmets than SCS	-Significant average increase in CI from baseline (5.1%) to 77.3 when CI max mean growth rate occurred -Strong positive correlation (R = 0.957, P < .001) between the day of maximal CI rate increase and day cranial width was found to exhibit the mean fastest growth rate (5.2 weeks postoperatively; average patient age = 4.46 months) – -CI growth rate significantly decreased by the day the average rate of cranial growth in the AP dimension peaked (15.5 weeks postoperatively; average patient age = 6.84 months) -Mean maximal CI of 81.3 was achieved in an average of 22.7 weeks when patients were on average 8.5 months of age -Age, number of postoperative CROs, incision complications, postoperative day that CRO treatment was initiated and CRO compliance were not significantly

	-Helmet therapy shifted higher pressures to temporal, occipital, and dorsal regions			associated with mean peak CI, the mean maximal rate of change of CI, or the day either of these milestones was achieved
Study Limitations	-Lack of morphological and contact pressure validity -Single case model -Simplified model of bone healing -Helmet simulation not modeled as physical 3D object, considering material properties	-Retrospective design limits ability to establish causation and increases risk of bias -Small sample size -Single-institution study -Multiple surgical techniques used -No standardized helmet protocol -Limited follow-up duration	-Study design limits generalizability -Small sample size -Cohort was predominately female -Single manufacturer of helmet -Multiple different orthotists guiding helmet therapy introduces variability -Lacked long-term follow-up	-Retrospective design limits ability to establish causation and increases risk of bias -Small sample size -Single-institution study -Cohort was predominately male - Only utilized CI which cannot quantify all characteristics of the phenotype -Limited follow-up duration