Examination of Necessary Duration of Helmet Therapy Post-Endoscopic Surgery for Infants with Sagittal Craniosynostosis

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Creation Date: September 2025; Date of Reassessment: September 2030

Clinical Question: In infants with sagittal craniosynostosis, what duration of helmet therapy post-endoscopic surgery is necessary to achieve acceptable anthropometric cranial proportions?

Background: Craniosynostosis is when one or more sutures of an infant's skull are prematurely fused. Sagittal Craniosynostosis (SC) occurs when the sagittal suture that runs across the top of the skull is prematurely fused resulting in a narrow, elongated head shape. The premature fusion of the skull can result in abnormal growth patterns as the infant develops.[1] Untreated, it can cause increased intracranial pressure, inhibit brain growth, and cause an atypical cosmetic presentation of the skull.[2] As such, surgical treatment is typically used to separate the prematurely fused sutures. Infants who undergo endoscopic surgery to treat craniosynostosis typically are younger than 6 months old.[3] Surgery is commonly followed by helmet therapy with a cranial remolding orthosis (CRO) to direct three-dimensional growth of the skull. A certified orthotist coordinates with the surgeon and pediatrician to achieve acceptable cranial presentation as bone growth and bone healing occurs. However, duration of CRO use varies and a consensus has yet to be reached as to the proper duration to ensure long-lasting anthropometric cranial proportions and minimal regression. The purpose of this CAT is to explore the duration necessary to provide infants with sagittal craniosynostosis acceptable anthropometric cranial proportions.

Search Strategy:
Databases Searched: O&PiQ and PubMed
Search Terms: (((craniosynostosis) AND (therapy) AND (sagittal) AND (duration) AND (surgical)) AND ((helmet) OR (orthotic)) AND ((endoscopic) OR (craniectomy))) NOT (plagiocephaly) NOT (nonsurgical) NOT (blood) NOT (survey)
Inclusion/Exclusion Criteria: 1-1-2018 to present; Language: English; Age: Child: birth-18 years

Synthesis of Results: The four articles reviewed look at helmet therapy (HT) duration post-surgical intervention (see Evidence Table). Three articles included infants who underwent endoscopic strip craniectomy and one article included infants who underwent endoscopic assisted craniectomy. All the articles looked at infants who had sagittal craniosynostosis (SC). A total of 73 infants with SC were included in two retrospective studies, one retrospective review, and one computational modeling study. The computational study indicated greatest duration of HT examined (8 months) resulted in highest cephalic index (CI) of 86.2 which is indicative of successful HT since untreated SC is marked by a low CI.[4] Both retrospective studies and the retrospective review indicated improvement of CI with HT; however, the study by Iyer, et al. included data from more time points with longer follow-up post-HT. The study found peak CI occurred at an average of 8.4 months of HT.[5] No significant improvement in CI with extending HT beyond the peak CI was found.[5] The study by Nguyen, et al. showed improvement of CI (71.3 → 75.6) after an average HT duration of 4.2 months.[3] However, it only examined metrics pre- and post- HT and did not follow the participants to examine CI through full growth and development. The final article examined was a retrospective review that found peak CI of 81.3 after 5.2 months of HT. [6] However, the review did not include follow-up post cessation of HT.

Clinical Message: Overall, the reviewed literature indicates a mean duration of 6.45 months of helmet therapy post-endoscopic surgical intervention results in acceptable anthropometric cranial proportions. Looking at the cephalic index of infants who underwent endoscopic surgical intervention is the primary metric of successful helmet treatment. However, studies including longer follow-up measurements indicate regression in CI post helmet therapy. Considering these findings, clinicians should incorporate expected regression in their determination of successful helmet treatment, leading to cessation of helmet therapy. Further studies with larger sample sizes and longer follow-up are needed to provide further evidence to support proper duration of helmet treatment in infants with sagittal craniosynostosis.

References

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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° 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