The Standard of Deformational Severity and Treatment Duration for Inclusion and Discharge of Cranial Remolding Orthoses

Courtney Tani, MSPO; Hanger Clinic; ctani@hanger.com Creation Date: May 2021

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Clinical Question: For children diagnosed with plagiocephaly, what should the standard be for inclusion and discharge for deformational severity (mild, moderate, or severe) and treatment duration for cranial remolding? **Background:** The term positional plagiocephaly refers to a flattening of the skull due to continuous application of an external force¹⁻². A physical exam and measurements can determine the severity of plagiocephaly. The typical measurements taken are the cranial width, the cranial length, and two transcranial diameters³; which are taken about 30 degrees off midline. With these measurements we can determine the cephalic index (CI); which is the ratio of the cranial width and length, the diagonal difference (DD); which is the difference between the two transcranial diameters and the cranial vault asymmetry index (CVAI); which is percent difference between the diagonal differences Using the values from the CI and DD the severity of plagiocephaly can be determined. DD is used to measure deformational plagiocephaly (an asymmetric head shape) and CI is used to measure a symmetric posterior deformation, also known as brachycephaly. Mild plagiocephaly is defined as a DD of 3-10 mm and a CI of 82-90%⁴. Moderate plagiocephaly is defined as a DD of 10-12mm and a CI of 90-100%⁴. Severe plagiocephaly is defined as a DD greater than 12mm and a CI greater than 100%⁴ Children can have a combination of deformational plagiocephaly and brachycephaly, putting them in different mild, moderate or severe categories for each depending on their measurements. The severity of the patient's deformational flattening(s) will determine if treatment is recommended.

A child's skull is rapidly changing, 85% of the postnatal cranial growth occurs within the first year, this where the bones stiffen and the suture lines fill³. Due to the amount of cranial growth that occurs within the first year, it is important to provide timely interventions to obtain optimal results. There are multiple conservative treatments that improve deformational head shapes. Helmet therapy or cranial remolding are known to be very effective in correcting cranial asymmetry. The cranial remolding orthosis (CRO) works to fit tightly around the protruding aspects of the skull and have empty space where there is flattening, as the skull continues to grow, the protruding parts of the skull are limited which promotes growth towards the flattened portions of the skull¹. There is an abundance of knowledge on CRO's and plagiocephaly, however, there is limited information on when patients should be included in treatment and when they should be discharged. Therefore, this literature review was conducted to determine the standard for inclusion and discharge for cranial remolding treatment. **Search Strategy:**

Databases Searched: Google Scholar, PubMed, oandp.org

Search Terms: (Cranial Remolding OR Cranial Remolding Orthoses OR Cranial Helmets) AND Plagiocephaly Inclusion Criteria: Present – 15 years, English

Exclusion Criteria: Brachycephaly, Craniosynostoses

Synthesis of Results: Five studies were identified (see Evidence Table). Generally, the subjects included were diagnosed with non-synostotic plagiocephaly ranging from ages 3 to 18 months. In addition, they had a starting CVAI> 3.0. There is evidence comparing CVAI, DD, CI, and treatment duration. The measurements were typically taken pre and post cranial remolding treatment. Key findings from these studies show that starting treatment early improves overall results and decreased treatment duration²⁻⁴. In addition, patients with more severe deformation tend to have a longer duration of treatment² Length of treatment was determined by amount of skull growth still available and overall severity improvement. The main limitation of these studies were that they are all retrospective study designs, which means there were no control groups for comparison.

Clinical Message: Overall, the results indicate that the standard for inclusion of CRO intervention in children with plagiocephaly should be CVAI > 3.0. The standard for start of treatment should be before 6 months for optimal correction and shorter duration of treatment. A final CVAI of < 5mm indicates a successful treatment and proper discharge criteria. These standards are recommended, but studies have shown that patients with plagiocephaly can have improvement with CRO after 6 month of $ages^{2-3, 5, 7}$ with a variety of deformational severity.

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Evidence Table									
	Graham, Adams- Huet, Gilbert, et. Al., 2019 ²	Grigsby, 2009 ³	Matarazzo, Pinto, Peccin, and Schreen, 2016 ⁵	Lam, Pan, Strickland, et. Al., 2017 ⁶	Yoo, Rah, and Kim, 2012 ⁷				
Population	499 infants with non-synostotic plagiocephaly, initial treatment age between 3 and 18 months, completed CRO treatment	58 infants that met the inclusion criteria underwent and completed helmet treatment.	56 infants with positional asymmetries including brachycephaly, plagiocephaly, and a combination of both. Completed CRO treatment	Total of 552 infants that completed their recommended treatment and had a full set of records. Average age was 6.2 months and diagnosed with plagiocephaly, brachycephaly, or both.	108 infants that underwent helmet treatment after being diagnosed with nonsynostotic plagiocephaly.				
Study Design	Retrospective chart review with 3 Texas offices of Level 4 Prosthetics & Orthotics	Retrospective chart review of patients seen at Atlantic Prosthetics and Orthotics at the University of North Carolinas Hospitals.	Retrospective analysis of data obtained by one single clinician	Retrospective chart review was conducted with risk factors and treatment methods for positional head shape deformity.	Retrospective chart review of data collected between 2008 and 2011.				
Intervention	CRO were prescribed with wear time of 23 hours per day, CROs used were STARbands manufactured by Orthomerica,	Starband CROs with side opening based on a cast of the patient.	CRO were prescribed with 23 hours a day wear time, CROs used was the STARband produced by Orthomerica.	CRO, repositioning (RP), physical therapy (PT), or both	CRO which was customized based on a 3D CT scan and measurements of the patient's head.				
Methodology	Divided the infants into 20 subcategories according to age and severity at initial treatment. These groups were analyzed to track the change in head shape and the rate of change.	Patients were divided into two groups based on age during treatment (at least half of treatment before Age 1, and at least half of treatment after Age 1). Average treatment length and average percentage of correction was compared between the two groups.	Divided infants into two groups (group 1: younger than 6 months, group 2: older than 6 months). DD, CI, PSR, and CVAI were compared between the two age groups.	ODD and CR were measured on all the patients' pre and post treatment and the overall improvement. These measurements were compared between each treatment	Divided patients into multiple groups based on age, severity, and compliance. Age of initiation: Group 1 (5 months or less), Group 2 (6 to 8 months), Group 3 (9 to 11 months), and Group 4 (12 months). Severity: Mild (6 to 10mm), Moderate (11 to 15 mm), Severe (>16mm). Compliance: Poor (<15 hours), Good (15 to 19 hours), Excellent (>20 hours)				

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Outcomes	Change in CVAI, treatment time	Treatment duration, Diagonal Difference	Diagonal Difference (DD), Posterior Symmetry Ratio (PSR), Cranial Vault Asymmetry Index (CVAI), Cephalic Index (CI)	Difference (ODD), the Cranial Ratio (CR), and overall improvement between pre and post treatment of ODD and CR	CVA, CVAI, treatment duration
Key Findings	Treatment time tended to significantly increase with increase in severity. Post treatment asymmetry measurements were significantly larger with infants who started with greater cranial deformation and who started treatment at an older age.	Cranial remolding treatment can be effective for patients who complete at least half of their treatment after 1 year of age with similar asymmetry correction, but the treatment time to achieve this is longer than patients much younger.	CVAI and DD results were significantly decreased when comparing before and after treatment for both groups, but the reduction in group 1 was significantly higher. The sooner the treatment is established, the sooner and better the response will be.	The largest changes in results were achieved in cases where CRO therapy was used at some point during clinical management.	Helmet therapy should be started before 9 months, lasting for 7.83 months or more and having a wear time of 20 hours or more per day. In addition, treatment effect was greater in the younger patients. The change in CVA was greatest in the severe group. The greater the initial CVA was the longer the treatment period was.
Study Limitations	Measurements of infants were performed by multiple clinicians.	The older patients presented with more severe asymmetry than the younger patients, meaning they did not start at the same baseline. There were more patients in the younger group. Measurements were not taken by the same practitioner.	The analysis of the groups were made with plagiocephaly, brachycephaly, and a combination of both instead of dividing into each cranial deformation category. There was a small sample size.	Patients were not randomized for treatment, which means there were patient-specific factors and parental preferences that impacted course of treatment.	The patients were measured by 3 different physicians. There was no control group.

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