Plagiocephaly Severity Scale to Aid in Clinical Treatment Recommendations

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Abstract: Studies have attempted to categorize infant cranial asymmetry in a variety of ways using both observational and quantitative techniques, but none have created a clinical tool that can serve as a treatment guide based on clinical outcomes. In 2006, a research team from Children's Healthcare of Atlanta published the results of a prospective analysis of 224 patients with cranial asymmetries and their treatment outcomes. As a continuation of the previous work, the researchers have identified a plagiocephaly severity scale based on those outcomes to assist medical professionals who treat patients with cranial abnormalities. Our hypothesis is to validate the proposed severity scale that categorizes the clinical presentation and severity of plagiocephaly.

Of the 224 patients enrolled, 207 patients were placed in an experimental group and 17 patients who refused treatment were placed in a control group. Digital head shape data were collected. Cross-correlation matrices were computed across variables and regression models resulted in the identification of 5 meaningful variables. A 5-level clinical classification scale was created. Five 1×5 analyses of variance were computed to compare each classification level.

Four of the 5 analyses of variance identified significant overall effects for classification. A model was developed from the empirical data and the model was tested for accuracy, resulting in 12.1% overall error. The model was validated for both experimental and control groups.

The results show that the severity scale is a meaningful outcome-based scale that assists clinicians in developing a treatment plan for treating plagiocephaly. The scale has been validated across a large heterogeneous study sample.

Key Words: CHOA severity scale, congenital muscular torticollis, cranial asymmetry, cranial remolding orthosis, deformational plagiocephaly, SIDS

(*J Craniofac Surg* 2017;00: 00–00)

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Received July 5, 2016.
Accepted for publication November 28, 2016.

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The authors report no conflicts of interest.

ISSN: 1049-2275
DOI: 10.1097/SCS.0000000000003520

Cranial asymmetry defined as plagiocephaly has increased dramatically in the past 2 decades.[1,2] The focus on the supine sleeping position as a means to reduce the rates of sudden infant death syndrome in the "Back-to-Sleep campaign," and the more recent growth in the availability of reclined carriers, car seats, and infant-designed equipment, has been correlated to the rise in cranial asymmetries being seen in pediatric clinics across the world at the time of this writing.[3,4] The supine position alone is not the only concern affecting cranial asymmetry. Confounding factors such as intrauterine positioning and space, the birthing process, prematurity, congenital muscular torticollis, and other congenital conditions all contribute to a complex set of comorbidities and factors that often complicate the treatment process.[5–8]

The natural history of cranial asymmetries further complicates matters. Many times, infants with plagiocephaly will begin to correct on their own, commonly referred to as self-correction, but many do not.[8–10] Family education that focuses on the use of tummy time coupled with repositioning therapy is the most effective intervention to address cranial asymmetries for younger infants.[8,11,12] After 3 months of age, there are 2 options available to the clinician. The first option is to continue to closely monitor the head shape through clinical observation and the use of head shape measurements taken at regular intervals.[5,13,14] Head shape measurements may be taken using manual tools or with the use of more modern benign digital scanning techniques. Recent studies have reported poor inter-rater and intrarater reliability when using manual hand tools, lending support to the use of more accurate digital methods.[15,16] During instances where the infant head shape does not begin to improve after 3 months of age despite aggressive repositioning and tummy time, the second option is often chosen whereby the clinician proceeds with a custom cranial remolding orthosis (CRO).[5,12,13,17,18] There is a clinical time constraint involving use of a CRO as it is less effective after 12 to 13 months of age as the sutures begin to close. Due to the time constraint and number of confounding subjective factors and comorbidities such as congenital muscular torticollis, the clinical decision to proceed to a CRO is often a difficult one.

The age at initial treatment and the severity of plagiocephaly are critical considerations when deciding between repositioning and a CRO.[13] There are no validated clinical tools based on outcomes available to clinicians at the time of this writing to guide them in the decision-making process regarding the treatment pathways of cranial asymmetry.[19] This study will use data from a previously published prospective study by Plank et al in an effort to construct a valid and useful clinical tool. The proposed "CHOA Plagiocephaly Severity Scale" is based on clinical outcomes and offers assistance to clinicians who treat patients with cranial asymmetries.

MATERIALS AND METHODS

Two hundred twenty-four patients, aged 3 to 12 months, were observationally diagnosed with moderate to severe deformational plagiocephaly (DP) and referred to Children's Healthcare of Atlanta (CHOA) by their pediatrician, neurosurgeon, or craniofacial plastic

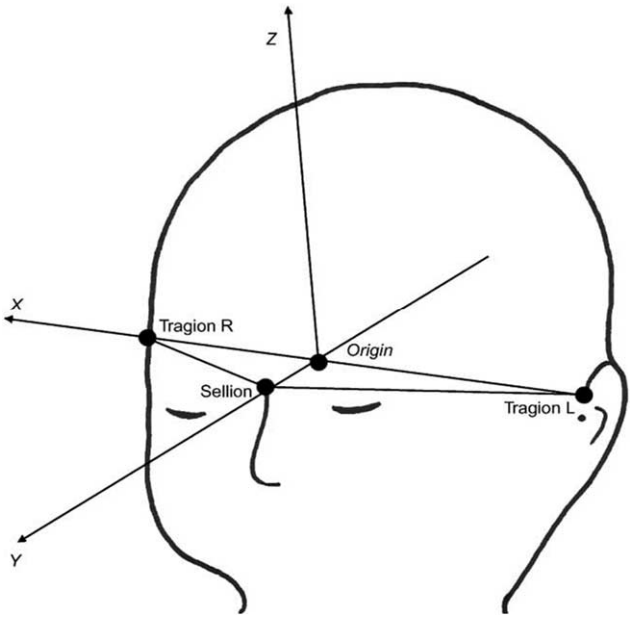

FIGURE 1. Anatomical reference system. The origin is the midpoint between the tragion landmarks. The *Y*-axis is defined through the midpoint of the sellion. The horizontal *X*-axis is perpendicular to the *Y*-axis on the reference plane. The *Z*-axis is projected superiorly and inferiorly perpendicular to the 0 reference plane.

surgeon for a CRO. Patient recruitment took place during a 1-year period and was approved by the CHOA Institutional Review Board and informed consent was obtained. Two hundred seven patients received a CRO and are referred to as the treatment group. Seventeen patients declined treatment and are defined as the control group.

Three-dimensional head shape and cranial measurements were quantified using the STARscanner (Orthomerica, Orlando, FL).[12] The STARscanner was chosen as it is specifically designed for capturing and quantifying infant head shapes in a clinical setting and is readily available to treating clinicians (Fig. 1). Bench testing has verified STARscanner accuracy to within 0.5 mm and during the study the scanner was calibrated to ambient light conditions in the treatment area. Shape acquisition data collected from the scanner were utilized to design a custom STARband CRO for each patient in the treatment group. Each orthosis was designed and built at the same fabrication facility consisting of a 4.76-mm copolymer plastic shell lined with 12.7 mm of polyethylene foam and secured with a Velcro and chafe side closure. All treating clinicians were ABC-certified orthotists trained in pediatric orthotics and followed departmental guidelines to maintain consistency regarding helmet design and fitting criteria. Each patient received an intake scan and was followed for approximately 4 months with interval scans taken at every 2 weeks for the duration of treatment. All patients were instructed to meet the following criteria:

- An entrance and exit scan is available.
- Alignment between entrance and exit scans is consistent at every level.
- All patients' scans are verified as neutral alignment in the coronal, sagittal, and vertex views.
- Orthosis usage was 23 hours/d per standard wear instructions.

Data obtained from each of the patient's scans can be grouped according to whether they are growth-related variables or symmetry indices. Descriptions of each of the variables and indices have been previously detailed in the literature.[12] Radial symmetry index (RSI) is the only measurement unique to the STARscanner comparing the length of the right and left vectors of the cranium at 15° increments. It is used to represent symmetry whereby an RSI of zero would indicate perfect symmetry.

In an effort to maintain quality control, an initial analysis was performed to determine that the 2 clinicians who were involved in digital processing were consistent in scanning technique, alignment, and measurement acquisition by assessing intrarater and inter-rater reliability. Data analysis examined differences across all 31 dependent variables (DVs) for all 224 patients. Cross-correlation matrices were computed across all 31 DVs. For variables that shared $\geq$50% common variance ($r > 0.707$), 1 of the variables was selected based on strength of the correlation, frequency of inter-relationships, as well as overall significance. Multiple regression models were formed and evaluated for the DVs to evaluate whether any of the variables were clinically and statistically meaningful. To address the effectiveness of the STARband, primary analysis of variance (ANOVA), correlated *t* tests, and multiple regression statistical techniques were utilized to compare treatment versus control groups and pretreatment versus post-treatment for the treatment group patients.

Five (1×5) ANOVAs were utilized in an attempt to apply the empirical data to the classification scale for the DVs that were clinically and statistically meaningful. The ANOVAs were conducted to determine whether statistical differences exist between or among classification levels for each variable. Post hoc tests were then conducted for these variables across all 5 levels of the classification scale. Accuracy of the classification levels was assessed by ascertaining the number of errors in classifications and analyzing endpoint overlap. A model was developed from the empirical data based on $\pm$0.5 standard deviation for each significant DV. The resulting classification model was then refined to eliminate slight endpoint overlap (using the median point of the overlapping data regions) and applied to the original data set and accuracy was again tested. The 5-level classification model was then applied to clinical observational characteristics to create an efficient clinic-friendly tool.

RESULTS

Analysis of variance showed no significant difference when comparing the measurements of 1 clinician to the other within patients and between patients (Table 1). For example, initial RSI differed by $\leq$0.252 mm from the ensemble average. Other scanning parameters also showed consistency between the 2 clinicians.

Independent *t* tests (t_{16206}) were conducted between groups for preintervention across 22 cranial measures as well as patient age and clinical classification. None of the variables evaluated showed significant differences ($\alpha = 0.01$) between the treatment and control populations at the beginning of the study, suggesting that there is similar geometry prior to intervention. Correlated (repeated measures) *t* tests were then utilized to evaluate pre/post-differences for the control and treatment groups across 25 independent variables. Significant differences ($\alpha = 0.01$) were found in all 25 variables for the treatment group, whereas 12 of 25 variables showed significant differences for the control group and are attributed to growth (Table 2).

In order to assess the predictive value of the variables, patients were divided into subgroups according to head presentation: brachycephaly (n = 44), plagiocephaly—left posterior flat (n = 57), and plagiocephaly—right posterior flat (n = 104). Two patients presented as a scaphocephalic shape and were removed from subgroup analysis due to small sample size. Cross-correlation

TABLE 1. *P* Values for Measurement Results Within and Between Patients

Measurement	Within-Patient *P*	Between-Patient *P*
L DIAG	0.176	0.425
R DIAG	0.275	0.169
CIRC	0.744	0.642

CIRC, circumference; L DIAG, left diagonal; R DIAG, right diagonal.

matrices were computed across all 31 DVs for each variable for the treatment group and each subgroup. A maximum of 22/378 variables pairs (5.8%) shared >50% common variance ($r \geq 0.707$) and as a result all variables were retained for further analyses. Through the iterative process of identification of correlation and improvement of regression models, 5 variables were identified as the best predictors of asymmetry: posterior symmetry ratio, overall symmetry ratio, cranial vault asymmetry index (CVAI), RSI, and Cephalic Index (CI). As the patients were broken down into subgroups, CI, which is used to measure brachycephaly, was determined through regression analysis to be of less value than the other predictors and was removed.

The use of a CRO as a treatment showed clinically significant improvement in each of the 4 variables when compared to the control group (Fig. 2). More than 96% of the patients in the treatment group improved in each of the 4 variables. In the control group, 30% of the patients worsened regarding head shape symmetry. For patients who improved, the amount of head symmetry improvement was much greater in the treatment group than that in the control group. The average length of time between initial and final measurements for the control group was 16.23 weeks. By contrast, the average length of time for the treatment group was only 11.88 weeks.

A clinically feasible model was developed using the 4 DVs (posterior symmetry ratio, overall symmetry ratio < RSI, CVAI), which the data had shown are best predictors of asymmetry. The model consists of 3 mutually exclusive, continuous levels (levels 2, 3, 4) and 2 ancillary levels (<2 and >4) for each predictive variable resulting in a 5-level model. Five 1-way ANOVA tests were performed to identify differences that might exist between classification levels (Table 3A). Follow-up post hoc Scheffé tests were conducted for variables identifying a significant omnibus F (Table 3B). Confidence intervals ranging from 95% to 50% were computed for each of the 5 variables of interest and mean value (±0.5 standard deviation) was selected as the separating criterion between adjacent levels in the model.

Errors in classifications were calculated and quantified for each level in the model and overall classification errors were shown to be 12.1%. The level associated with the most classification errors was level 2. The data in Figure 3 show classification errors for the variable CVAI. The analysis summary in Table 3B and graphic shown in Figure 3 demonstrate that CVAI can accurately discriminate among the different levels with few errors. In an effort to create a clinically useful tool that incorporates both measureable and observational data, the CHOA Severity Scale (Fig. 4) was created. The scale includes physical characteristics and traits commonly seen in each severity level. Another benefit of using CVAI in the scale is that the measurement can be achieved quickly by hand in a clinical setting without the need for expensive scanners or digitizing instruments.

TABLE 2. Correlated (Repeated Measures) *t* Tests for 25 Independent Variable Difference Scores[16]

	Treatment		Control	
Variable	Mean (SD)	Pr > t	Mean (SD)	Pr > t
Circumference	20.55 (9.34)	**<0.0001**	16.74 (8.94)	**<0.0001**
Cranial breadth	3.64 (3.00)	**<0.0001**	4.04 (3.75)	**0.0004**
Cranial length	9.53 (3.94)	**<0.0001**	6.72 (3.25)	**<0.0001**
Left oblique	8.71 (4.38)	**<0.0001**	5.57 (2.94)	**<0.0001**
Right oblique	7.05 (4.54)	**<0.0001**	6.00 (3.65)	**<0.0001**
Quadrant 1 volume (A/L)	13.86 (11.43)	**<0.0001**	13.42 (11.55)	**0.0002**
Quadrant 2 volume (A/R)	14.12 (11.58)	**<0.0001**	13.26 (13.05)	**0.0007**
Quadrant 3 volume (P/R)	27.36 (11.92)	**<0.0001**	20.13 (10.35)	**<0.0001**
Quadrant 4 volume (P/L)	24.41 (12.89)	**<0.0001**	21.22 (11.36)	**<0.0001**
Vertex height	7.24 (7.19)	**<0.0001**	6.98 (7.41)	**0.0013**
Oblique cranial maximum	5.93 (3.41)	**<0.0001**	5.66 (3.41)	**<0.0001**
Oblique cranial minimum	6.67 (3.93)	**<0.0001**	4.84 (3.65)	**<0.0001**
Oblique cranial maximum angle	7.79 (24.47)	**<0.0001**	8.71 (15.60)	0.035
Oblique cranial minimum angle	−20.72 (61.60)	**<0.0001**	−39.09 (63.16)	0.0213
Cephalic ratio	−0.03 (0.02)	**<0.0001**	−0.01 (0.02)	0.0344
Anterior symmetry ratio	0.01 (0.03)	**<0.0001**	0.00 (0.02)	0.836
Posterior symmetry ratio	0.11 (0.56)	**0.0042**	0.01 (0.04)	0.4179
Overall symmetry ratio	0.04 (0.03)	**<0.0001**	0.00 (0.02)	0.5416
Upper facial left	3.45 (7.28)	**<0.0001**	0.71 (7.61)	0.707
Upper facial right	4.56 (6.46)	**<0.0001**	4.12 (6.15)	0.0138
Anterior displacement ratio	0.01 (0.06)	**0.0006**	0.00 (0.06)	0.87
Cranial base width	2.79 (4.71)	**<0.0001**	1.01 (6.04)	0.5022
Radial symmetry index	−16.87 (12.64)	**<0.0001**	−3.30 (16.33)	0.4171
Vault asymmetry index	−3.36 (2.26)	**<0.0001**	−0.38 (1.95)	0.4324
CVAI, % change	0.39 (0.38)	**<0.0001**	−0.12 (0.75)	0.5219

Bold *P* values identify significant differences in the variables at the beginning and end of the study ($\alpha = 0.01$). Significant differences in 12 variables in the control group can be attributed to growth. CVAI, cranial vault asymmetry index; SD, standard deviation.

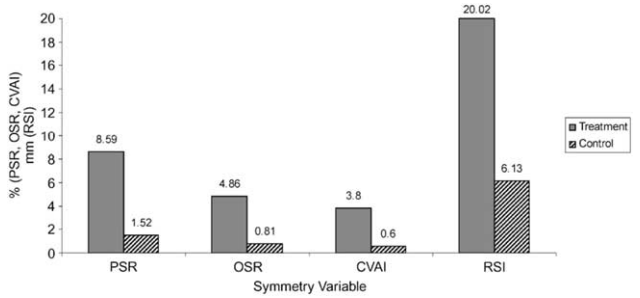

FIGURE 2. Amount of improvement in each of 4 variables pre– and post–cranial remolding orthosis treatment (gray bars) and at the beginning and end of the study for control patients (crosshatched bars). Values for posterior symmetry ratio (PSR), overall symmetry ratio (OSR), and cranial vault asymmetry index (CVAI) are percentages. Values for radial symmetry index (RSI) are in millimeter. Differences were calculated such that positive values for each variable reflect improvement toward symmetry.[16]

The classification model developed in Figure 4 also demonstrates that the severity scale is sensitive to treatment. The model identified significant ($\alpha = 0.01$) overall changes (pretreatment versus post-treatment) averaging 1.4 classification level changes in the treatment group as presented in Figure 5. Across all variable classifications, 87.7% of patients improved in their classification level due to cranial remolding (STARband) treatment, whereas in the control group only 24.4% of patients showed a classification improvement. The classification model was validated for both the experimental and control groups; therefore, the clinical classification scale presented is valid for our large group heterogeneous study sample and our hypothesis is accepted.

DISCUSSION

The successful use of a CRO as an effective treatment for head shape anomalies (plagiocephaly/brachycephaly, scaphocephaly) is well documented in the scientific literature.[17,20–22] Due to the narrow timeline, variety of shapes, and severity of clinical presentations, the decision to continue with observation or proceed with a CRO can be a difficult and anxiety-filled process for the clinical team and family. A number of scales and diagnostic criteria have been introduced and published, but none of the authors have been able to successfully integrate their scales with randomized clinical outcomes data and create a reliable tool that can be used in a clinical setting to guide clinicians and help create a treatment plan. Cost and ease of use can be challenging barriers for any scale that relies on expensive hardware/software or laser scanners, or requires biomechanists or statisticians to use in a clinical setting. The most commonly referenced scale was published by Argenta in 2004; however, the author describes it as moderately reliable and it relies solely on clinical observation.[19] In 2008, Spermon et al published an independent analysis regarding the feasibility and reliability of the Argenta scale and found that despite the ease of use, the inter-rater and intrarater reliability was not acceptable for clinical application.[23] A more recent study by Wilbrand et al in 2012 sought to define cutoff percentiles for differentiating different diagnostic groups of head shapes; however, their proposed severity scale is not related to patient outcomes and it offers no treatment guidelines; therefore, the clinical use is very limited.[24] Kluba et al published a large cohort in 2013 and stated that helmet therapy should be the treatment option of choice for moderate to severe cases, further highlighting the need for a clinical scale.[20]

Previous research published in 2006 supported the hypothesis that the use of CRO does significantly alter head shape and improve symmetry.[17] Furthermore, 4 of the variables we analyzed (all symmetry indices) showed consistency among measuring clinicians and were also found to be excellent predictors of asymmetry. The validation of this 5-level CHOA scale demonstrates not only that orthotic intervention is effective, but also that treatment decisions regarding orthotic use should be based on the level of severity.

The CHOA scale provides a low-cost solution for measuring severity of plagiocephaly that can easily be employed in a clinical setting with a simple tape measure. While quantifying head shape is certainly important for assessing severity, it is also important on a clinical level to acknowledge the observational characteristics and qualitative differences that are present to varying degrees and are associated with the different levels of the severity scale. For example, an infant who measures a level 2 would likely present with minimal asymmetry in only 1 posterior quadrant. By contrast,

TABLE 3. Analysis of Variance Summary

A. Omnibus—F summary table

Variable	df	F-Value	Pr > F	Result
Cephalic ratio	4172	0.61	0.6556	Not significant
PSR 1	4172	10.07	<0.0001	Significant
OSR 2	4172	20.15	<0.0001	Significant
RSI 1	4172	20.99	<0.0001	Significant
CVAI 1	4172	22.51	<0.0001	Significant

B. Scheffé post hoc analysis summary

Variable	1 Versus 2	1 Versus 3	1 Versus 4	1 Versus 5	2 Versus 3	2 Versus 4	2 Versus 5	3 Versus 4	3 Versus 5	4 Versus 5
Cephalic ratio*										
PSR 1						***		***		
OSR 1		***	***	***		***	***	***	***	
RSI 1			***	***		***	***	***	***	
CVAI 1			***	***		***	***	***	***	

CVAI, cranial vault asymmetry index; df, degree of freedom; OSR, overall symmetry ratio; PSR, posterior symmetry ratio; RSI, radial symmetry index. (*) Post hoc tests not conducted due to nonsignificant omnibus (overall) F; (***) significant difference ($\alpha = 0.01$) between conditions.

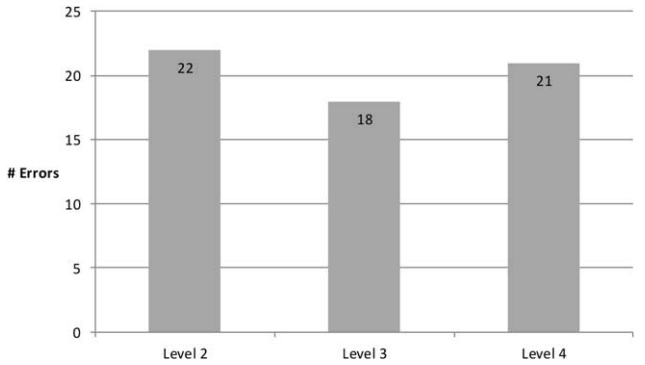

FIGURE 3. Cranial vault asymmetry index classification errors. Represents the number of errors corresponding to each of the severity scale levels.

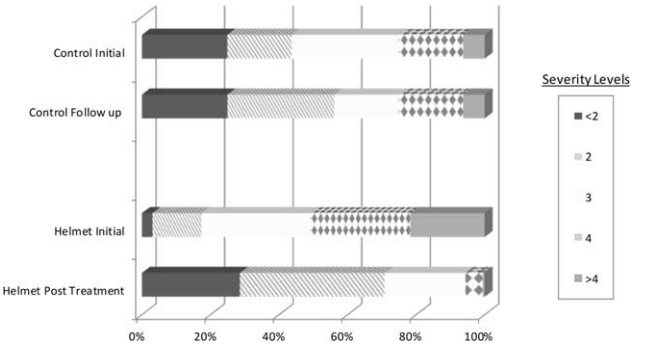

FIGURE 5. Pretreatment versus post-treatment classifications reveal that the severity scale is sensitive to treatment changes. The proportions of patients in the control group did not change.

an infant measuring a level 4 is likely to have 2- or 3-quadrant involvement, severe posterior flattening, moderate anterior ear shift, and anterior involvement including orbit and cheek asymmetry. While passive cervical range of motion data were not collected, it is also safe to assume that the presence or likelihood of torticollis increases as one moves from level 1 to level 5 and severity increases. Patients were not excluded due to the presence of torticollis that could be viewed as a limitation when determining the effectiveness of the helmet intervention; however, both the control and experimental groups consist of patients with torticollis. Congenital muscular torticollis as a comorbidity is not seen as a limitation regarding the validity of the severity scale.

The primary limitation of this research design is the control group. The control group, being small relative to our treatment group, and the group being self-selected (refusing cranial remolding treatment) are limiting factors in the design. A larger randomized control group would be difficult to design in terms of ethics since the majority of patients were originally sent to our treatment team for cranial remolding evaluation and desired an orthosis. The fact that 30% of our control group worsened is not surprising as most of our patients seek cranial treatment due to a perceived prior worsening. Another study limitation relates to the study time line. Patients were not followed past 18 months of age, so long-term conclusions may be difficult to draw, although anatomically, it is well established that head asymmetry should not change appreciably after 18 months since the head will grow proportionally. Compliance is another parameter that may affect the results. Families were initially instructed to wear the helmet 23 hours/d; however, actual compliance was not measured or tracked over time. It is reasonable to assume that some patients were less compliant than others. It is also

Level	Clinical Presentation	Recommendation	CVAI
1	• All symmetry within normal limits	No treatment required	< 3.50
2	• Minimal asymmetry in one posterior quadrant • No secondary changes	Repositioning program	3.5 to 6.25
3	• Two quadrant involvement • Moderate to severe posterior quadrant flattening • Minimal ear shift and/or anterior involvement	Conservative treatment: Repositioning program cranial remolding othosis (based on age and history)	6.25 to 8.75
4	• Two or three quadrant involvement • Severe posterior quadrant involvement • Moderate ear shift • Anterior involvement including noticeable orbit asymmetry	Conservative treatment: cranial remolding othosis	8.75 to 11.0
5	• Three or four quadrant involvement • Severe posterior quadrant flattening • Severe ear shift • Anterior involvement including orbit and cheek asymmetry	Conservative treatment: cranial remolding othosis	> 11.0

FIGURE 4. Children's Healthcare of Atlanta plagiocephaly severity scale.

reassuring that the severity scale shows sensitivity to treatment regardless of compliance. Studies involving the compliance of cranial remolding helmets would be extremely helpful in the future to help define optimal wear time and overall treatment length.

It is interesting to note that of the severity scale levels, level 2 was the most prone to error across the 4 predictive variables. While the magnitude of errors relative to the other levels did not appear to be significant, it may highlight the difficulty and lack of reliability at the onset of the diagnosis for mild patients (level 2 and below) and may imply that there is a need to base a clinical diagnosis on more than simply 1 measurement. A logical progression of that theory would suggest the use of age as a clinical factor when assessing severity; however, our data strongly support the hypothesis that age cannot be used as an indicator of severity. It is important to stress that the CHOA scale is applicable only to patients with plagiocephaly. Unfortunately, due to the small brachycephalic cohort (44 patients), the data involving CI do not support a severity scale for brachycephaly at this time but the authors acknowledge a need for a clinical scale to evaluate severity of brachycephaly.

Regarding how severity is related to the use and success of a CRO, the data show that when using the severity scale, the higher the severity, the more likely the head shape will improve with the use of a CRO. For example, when looking at CVAI, 47.1% of the level 3 severity patients improved at least 2 classification (severity) levels and 57.5% of the level 4 patients improved at least 2 classification levels. Patients originally diagnosed as level >4, which is the highest degree of severity, showed the largest improvement as 77.1% of those patients improved 2 levels or more.

Recent work published in 2014 by van Wijk et al has questioned the efficacy of CROs,[25] despite a number of authors and publications supporting the use of a CRO for the treatment of DP.[17,20,22,23,26] Not only this study aligns with previous authors who support the use of CROs for the treatment of DP, but the analysis also highlights the importance and role that severity plays in the clinical decision-making process. The CHOA severity scale provides an efficient and reproducible method for the clinical team to evaluate plagiocephaly in an infant both observationally and quantitatively and provide a treatment plan in a less biased manner that is based on outcomes. Further investigation of this topic should focus on patient compliance with cranial remolding therapy and may involve a larger multicenter randomized approach evaluating the effectiveness of the CHOA scale at guiding treatment decisions.

ACKNOWLEDGMENTS

The authors acknowledge Janet S. Dufek, PhD, for statistical guidance. A portion of this work involving the effectiveness of a

cranial remolding orthosis was previously published,[16] and the authors acknowledge the efforts of Laura Plank, CO, for her work in that publication.

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