

Comparison of Infant Head Shape Changes in Deformational Plagiocephaly Following Treatment With a Cranial Remolding Orthosis Using a Noninvasive Laser Shape Digitizer

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Deformational Plagiocephaly (DP) is a multi-planar deformity of the cranium occurring either pre-or postnatally in infants. In the last decade, the incidence of DP has increased substantially due to a number of factors, including supine sleeping positioning to reduce Sudden Infant Death Syndrome and the use of child carriers that increase supine positioning. Clinical questions persist about which children should be treated for DP and how to intervene, questions that are difficult to answer without accurate documentation of three-dimensional (3-D) head shape. This study explored a method for quantifying head shape and used that method to evaluate the success of orthotic treatment. Two hundred twenty-four infants who were diagnosed with DP received either a cranial remolding orthosis or a repositioning program with no orthotic intervention. Data from 25 head shape variables were collected using a noninvasive laser shape digitizer. Only variables attributable to growth showed significant differences in the control population, while the treatment population showed significant differences in pre-and post-treatment values for all variables. The study identified four variables as particularly important in assessing the head shape of infants with plagiocephaly: the cranial vault asymmetry index, radial symmetry index, posterior symmetry ratio, and overall symmetry ratio. Ninety-six percent or more of subjects in the treatment group showed improvement in each variable. These data docu-

ment the utility of a 3-D scanning device and the effectiveness of treatment with a cranial remolding orthosis.

Key Words: Deformational plagiocephaly, anthropometrics, orthotics, cranial remolding

Deformational Plagiocephaly (DP) is a multi-planar deformity of the cranium occurring either pre-or post-natally in infants. DP is nonsynostotic cranial flattening secondary to abnormal forces accentuated by postnatal posture.¹ Posterior (occipital) plagiocephaly has increased substantially in the last decade, to the point that Peitsch et al² reported that cranial flattening was present at birth in 13% of 183 single-born infants studied at Brigham and Women's Hospital in 2002. In twin births, the incidence increased to 56%. These increases in plagiocephaly follow a shift in two cultural practices that occurred in the early 1990s. The first is the change from prone to supine sleeping after pediatricians recommended this position as a way to reduce Sudden Infant Death Syndrome.^{3,4} This highly successful "Back to Sleep" program was coincidentally timed with the second change in childcare practices by parents: the use of baby swings, "bouncy" seats, and convenient and interchangeable child carriers and car seats. These seating systems have become a common method of positioning and carrying babies during daytime hours, reducing the amount of time spent in prone and other positions that offer an alternative to supine positioning.⁵ The interaction between these practices has created an environment very well-suited for head shape deformities to develop. Constant posterior contact against the back of the head during the day and night perpetuates asymmetry present at birth and in many cases exacerbates it. In addition, the increase in multiple births,⁶ a common cause of DP,^{2,7}

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and the rise in the number of children diagnosed with torticollis^{8,9} have also contributed to the increase of DP.

The growing number of infants with DP has raised clinical questions about which children should be treated for DP, and how to successfully intervene. Documentation of the effectiveness of treatment efforts requires feasible, reproducible methods to quantify head shape and asymmetry. Such a method must include the measurement of parameters useful for understanding the three-dimensional nature of head shape deformities and the change in head shape over time. Most of the published studies on head anthropometrics in DP^{1,10-16} have used differences between linear measurements to determine the need and/or success of treatment strategies including repositioning and orthotic management. These measurements have provided documentation regarding changes in cranial shape but could not reflect the asymmetry relative to circumference, volume, or overall shape of the cranium. Decision making regarding a three-dimensional (3-D) problem is challenging when quantification is bound to 2-D measures. Other studies used perceived severity and/or satisfaction scales to assess head shape changes.¹⁷⁻²² Subjective measures lend credence to clinical impressions, but do not provide objective assessment or even description of the shape. Clarren,²³ Loveday and de Chalain,²⁵ and Hutchinson et al²⁴ developed cranial vault asymmetry indices and methods that allowed inter and intrasubject comparisons, but the asymmetry was only computed at one cross-section. Bruner et al²⁶ used computed tomography (CT) and volume ratios to document the results of orthotic treatment intervention. This work did provide valuable 3-D data but the test was expensive and exposed the infant to radiation. An objective, noninvasive, reproducible assessment instrument is needed to document the 3-D head shape deformity, and the efficacy of treatment modalities such as repositioning, physical therapy and orthotic management.

This investigation sought to document the 3-D head shape in infants diagnosed with DP using a noninvasive laser shape digitizer in order to assess the value of multiple anthropometric measurements and calculated parameters. In addition, the study sought to quantify the effects of treatment using cranial remolding orthoses. According to three papers that reviewed the literature published on DP,²⁷⁻²⁹ researchers have not yet proven whether there is a statistical difference between orthotic intervention, repositioning, or non-intervention for these infants. With persisting incidence of DP, better

understanding and quantification of 3-D cranial shape will promote understanding of treatment methodologies and outcomes.

MATERIALS AND METHODS

Two hundred twenty-four infants were identified over a 1-year period who were diagnosed by a pediatrician, neurosurgeon or craniofacial plastic surgeon with moderate to severe deformational plagiocephaly and referred to Children's Healthcare of Atlanta for a cranial remolding orthosis (CRO). Subjects between 3 and 12 months of age at the time of referral were recruited for the study. The study was approved by the hospital's Institutional Review Board and informed consent was obtained. Each participating family was given written information and verbal instruction on repositioning and supervised prone play. Two hundred seven subjects received orthotic treatment. Seventeen subjects' families declined orthotic treatment and were considered controls. (Note that lack of funding does not prevent access to services at this facility, so financial considerations did not affect this choice.)

Three-dimensional head shape was quantified using the STARscanner (Orthomerica, Orlando, FL) laser data acquisition system. This device is used specifically for capturing and quantifying head shape in infants in a clinical setting. Images are captured in less than two seconds. Four eye-safe lasers create a circumferential line of light around the surface of the cranium while eight cameras reconstruct the 3-D surface. Bench testing has verified accuracy to be within 0.5 mm. During the study the scanner was calibrated to the ambient light conditions in the treatment room.

To acquire the scan, a practitioner placed a one-ply, open-faced stockinet over each infant's head to eliminate extraneous data. Black 1-cm markers (adhesive dots) were either placed on the sellion and each trignon on the child's skin or identified on the reconstructed image to define the anatomical reference plane which was used for quadrant placement and volume calculations (Fig 1). The cranium was then divided into 11 proportionally spaced cross-sections parallel to the reference plane (Fig 2).

Subjects in the treatment group were fitted with a STARband CRO based upon the scanned head shape data. Each custom orthosis was fabricated at the same central fabrication facility and consisted of a 4.76-mm (3/16 inch) copolymer shell lined with 12.7 mm (1/2 inch) of polyethylene. The side-opening bands with proximal openings were secured with a 38.1-mm (1.5 inch) Velcro strap and chafe closure.

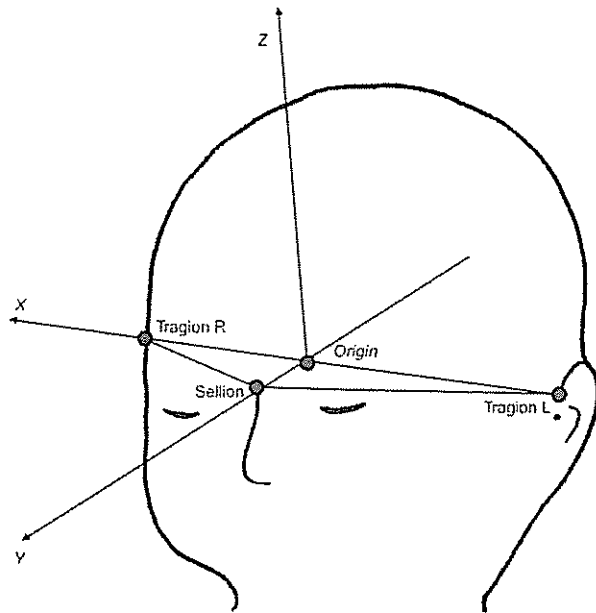


Fig 1 Anatomical Reference System. The origin is the midpoint between the trignon landmarks. The Y-axis is defined through the midpoint of the sellion. Horizontal X-axis is perpendicular to the Y-axis on the reference plane. The Z-axis is projected superiorly and inferiorly perpendicular to the 0 reference plane.

ABC-certified orthotists trained in pediatric orthotics provided treatment. Orthotists in the study had specific training in DP and cranial remolding orthoses. Treating orthotists utilized established departmental cranial remolding guidelines to maintain consistency in trimlines and fit criteria. The orthosis facilitates normal cranial symmetry by providing contact over prominent areas of the skull and leaving a void over flattened areas.

Following an intake scan, each subject was followed for approximately four months, with interval scans obtained every two weeks for the duration of treatment. Subjects in the study met the following additional criteria:

- Entrance and exit scans were available for the infant. Coronal, sagittal, and vertex views had neutral alignment in the scanner.
- The alignment between entrance and exit scan was consistent at every cross-section.
- Families reported compliance with the 23 hour/day wear regimen.

The following were recorded for each subject: birth date, start date, and time in treatment.

Analyzed data obtained from the scans included the following:

- circumference
- maximum anterior-posterior (AP) dimension
- maximum medial-lateral (ML) dimension
- maximum and minimum oblique diameters (transcranial distances at 15° increments), and the angles at which these extrema are found
- left and right oblique diameters at 30°
- quadrant volumes (anterior-left, anterior-right, posterior-left, and posterior-right, determined by anatomical coordinate system)
- cranial base width (distance from left to right trignon)
- vertex height (parallel distance from the base (level 0) to the apex (level 10)).

These variables were classified as Growth-Related Variables. In addition, the following Symmetry Indices were calculated from scan data: anterior, posterior and overall symmetry ratios,

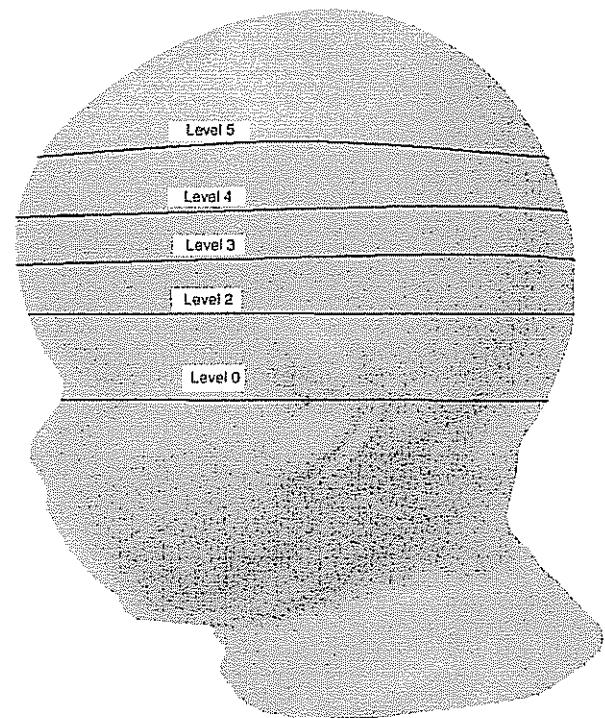


Fig 2 Placement of cross-sections relative to the origin. Nine cross-sections are superior and two cross-sections are inferior to the reference plane. Establishing proportionally spaced cross-sections allows critical evaluation and comparison over time for both growth and shape changes.

anterior ear displacement ratio, cranial vault asymmetry index, radial symmetry index, and cephalic index. The anterior (ASR) and posterior symmetry ratios (PSR) are the ratio of the volume of their respective two quadrants. The overall symmetry ratio (OSR) is the mean value of the posterior symmetry ratio and the anterior symmetry ratio. A value of 1 represents perfect symmetry. The anterior ear displacement ratio (AED) is the ratio of the left and right linear distances from each trignon point forward within the horizontal plane of the trignon to the sellion. The cranial vault asymmetry index (CVAI) uses length in mm at 30-degree diagonals (left and right oblique) as measured from the origin axis at cross-section level three, closest to the equator of the skull.²⁵ The index is calculated as the percent difference of a length in one quadrant versus the corresponding length in the other quadrant. Zero percent represents equal proportions. The radial symmetry index (RSI) is a measurement unique to the STARscanner. It compares the length of the vectors on the right and left sides of the cranium at 15-degree increments (Fig 3). Vectors originate from the origin of the anatomical coordinate system and measure to the outside of the cranium at a single cross-section. The RSI is the sum total of the absolute value of the differences at each increment, excluding 0 and 180°, at level 3. Perfect symmetry is repre-

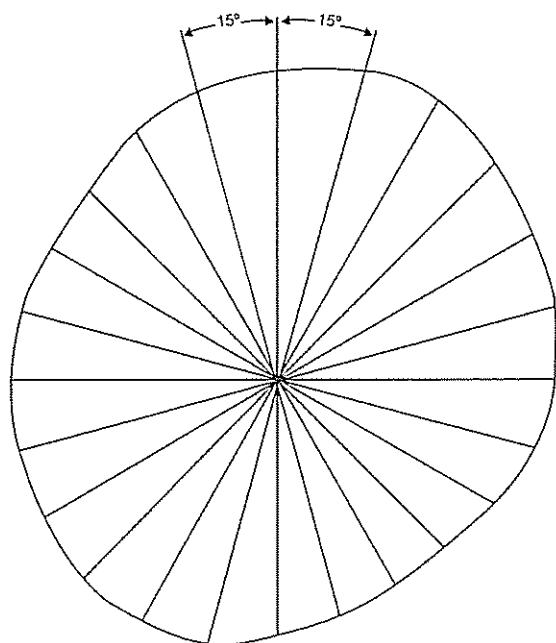


Fig 3 Radial Symmetry Index (RSI) calculation based on radii at 15-degree intervals.

sented by a total of 0 mm. Finally, the cephalic index (CI; ratio of ML maximum to AP maximum) is simply cranial width divided by cranial length, a more common index for evaluation of disproportional head shapes such as brachycephaly and scaphocephaly.

Data analysis sought to understand differences in all variables. The general hypothesis was that treatment with a cranial remolding orthosis will produce a significant improvement in head symmetry. An initial analysis was conducted to insure consistent use of the scanning device among different practitioners. The next step was to examine whether differences existed between experimental and control group patients prior to intervention. Thirty-one dependent variables were measured and recorded using the STARscanner for 224 subjects and analyzed using primarily analysis of variance (ANOVA), correlated *t*-tests, and multiple regression statistical techniques for treatment vs. control contrasts and pre- vs. post-treatment contrasts. Independent *t*-tests were conducted between groups for preintervention across 22 cranial measures as well as patient age. The next step in the analysis process was to examine pre/post difference scores (intervention effects for both the Control and Treatment groups). Correlated (repeated measures) *t*-tests were computed for each group across the independent variables. A more stringent α -level (0.01 vs. 0.05) was selected for significance due to the large number of variable differences ($n = 25$) examined.

Anticipating that certain non-growth-related variables would be more descriptive of the effects of treatment, the analysis focused on the most informative and clinically useful. To evaluate the utility of the variables, cross-correlation matrices were computed across the 31 dependent variables. For variables pairs that shared 50% or greater common variance ($r > 0.707$) one of the variables was selected, based upon strength of the correlation, frequency of inter-relationships (among variables), and overall clinical significance. To compare the predictive value of the variables versus clinical observation, the patients were divided into subgroups of brachycephaly, plagiocephaly-right, plagiocephaly-left, and scaphocephaly based on clinical observation. Multiple regression models were formed and evaluated for the DVs identified from the correlation procedures. Evaluation of the regression models (across various groups and subgroups of subjects) resulted in the identification of statistically and clinically meaningful variables. Using these key variables, numbers of subjects who became either more or less symmetric through the study were

quantified and the amount of improvement or worsening was analyzed.

RESULTS

Two practitioners were responsible for the processing of digital images used in the study. The practitioners were consistent in their scanning technique, alignment of the scans, and measurement of data from the scans. Individual practitioners' average measurements of initial RSI, for example, differed by no more than 0.252 mm from the ensemble average. Other parameters showed similar consistency between different practitioners.

No significant differences ($\alpha = 0.01$) were noted between treatment and control populations at the beginning of the study for any of the variables evaluated. Independent *t*-tests ($t_{16,206}$) were conducted between groups for preintervention across 22 cranial measures as well as patient age and clinical classification. Four variables were excluded as follows: Right and left oblique angles were excluded since they are categorical measures. Time of treatment and CVAI were excluded since they are difference measures and remained undefined in the pre-intervention data set.

The next step in the analysis process was to examine pre/post difference scores for both the Control and Treatment groups. Correlated (repeated measures) *t*-tests were computed for each group across the 25 independent variables. For the treatment group, significant differences ($\alpha = 0.01$) were found in all 25 variables. For the control group, significant differences were found in 12 of the 25 variables; these 12 variables can be directly attributable to growth (Table 1).

Analysis to identify useful variables included the division of subjects into subgroups of brachycephaly ($n = 44$), plagiocephaly-left ($n = 57$) and plagiocephaly-right ($n = 104$). Two patients were classified as scaphocephaly and due to the small sample size were excluded from subgroup analyses. Correlation matrices across all variables for the Treatment group as well as each subgroup were computed and examined. Surprisingly, only a maximum 22/378 variable pairs (5.8%) were found to share greater than 50% common variance ($r \geq 0.707$). Since 5% of the variable pairs ($n = 19$) would be expected to share greater than 50% common variance due to chance at $\alpha = 0.05$, all variables were retained for subsequent analyses. Through the iterative process of identification of correlation and improvement of regression models, five variables were identified as the best predictors of asymmetry:

Table 1. Correlated (Repeated Measures) *t*-tests for 25 Independent Variable Difference Scores

Variable	Treatment		Control	
	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 percent 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.

Posterior Symmetry Ratio (PSR), Overall Symmetry Ratio (OSR), Cranial Vault Asymmetry Index (CVAI), Radial Symmetry Index (RSI), and the Cephalic Index (CI). When the regression models focused on the plagiocephaly subgroups and excluded the brachycephaly subgroup, the CI was

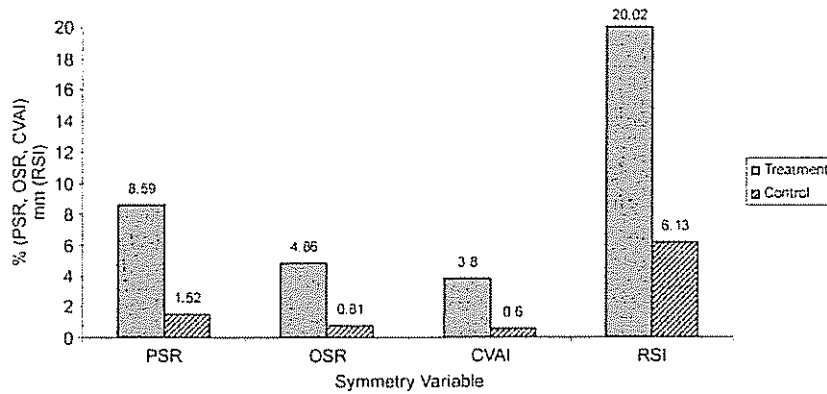


Fig 4 Amount of improvement in each of four variables pre- and post-CRO treatment (gray bars) and at the beginning and end of the study for control subjects (crosshatched bars). Values for Posterior Symmetry Ratio (PSR), Overall Symmetry Ratio (OSR), and Cranial Vault Asymmetry Index (CVAI) are percentages. Values for Radial Symmetry Index (RSI) are mm. Differences were calculated such that positive values for each variable reflect improvement toward symmetry.

no longer among the most useful variables. Due to the focus on plagiocephaly, the remainder of the analysis will focus on the four remaining key variables.

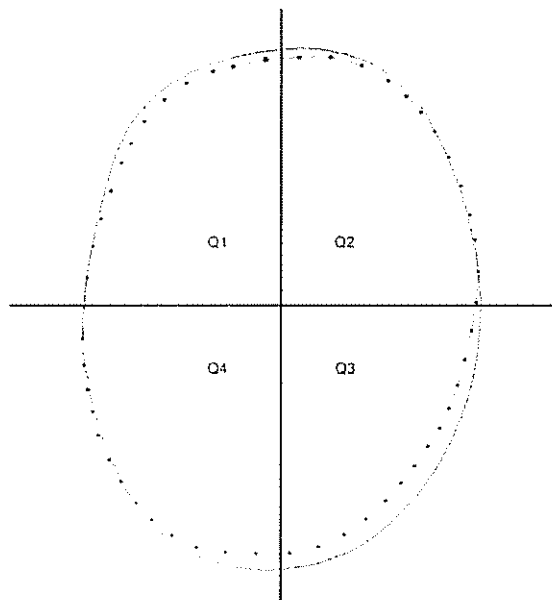


Fig 5 Pre-(dotted line) and post (solid line)-treatment circumferences for a subject representing typical improvement in the treatment group. This subject's improvement in the four key symmetry variables was: Posterior Symmetry Ratio 12.9%, Overall Symmetry Ratio 8.7%, Cranial Vault Asymmetry Index 6.61%, and Radial Symmetry Index 28.1 mm. Positive Y (anterior) is at the top of the figure.

Ensemble average analysis of the plagiocephaly treatment and control populations focusing on the four key variables showed clinically significant improvement in each variable with CRO treatment (Fig 4). To provide a visual reference, Figure 5 displays pre-and post-treatment circumferences for a subject in the treatment group with typical improvement. These ensemble average data combine cases in which improvement occurred for a given variable as well as cases in which a given variable became clinically worse (less symmetric). In the treatment

Table 2. Amount of Improvement (Top) or Worsening (Bottom) for Each of Four Key Variables

		PSR	OSR	CVAI	RSI
Subjects who improved					
Treatment	N	157	159	157	161
	Mean	0.09	0.05	4.02	20.3
	Max	0.2	0.12	9.97	53.4
Control	N	10	11	10	10
	Mean	0.0001	0.013	0.016	10.7
	Max	0.09	0.06	4.96	32
Subjects who became worse					
Treatment	N	6	4	6	2
	Mean	-0.038	-0.02	-0.52	-2.1
	Max	-0.065	-0.03	-1.27	-4
Control	N	6	5	6	6
	Mean	-0.019	-0.08	-0.989	-4.55
	Max	-0.027	-0.014	-2.604	-11.4

The top half of the table shows the number of subjects who improved, and the average and maximum improvement for subjects in each population who improved. The bottom half of the table shows the number of subjects who became worse and the average and maximum worsening for subjects in each population who became worse. 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 mm.

group, at least 96.3% of subjects improved in each of the key variables. No individual subject in this group failed to improve in at least one of the key variables. In the much smaller control group, over 30% of subjects became worse. For those subjects who improved, the amount of improvement was much greater in the treatment group. For subjects who worsened, the differences were not as great (Table 2). The extrema reveal individual cases with remarkable improvement. An example is the maximum improvement in CVAI of 9.97%, reflecting a change from CVAI of 14.65 to 4.68% with CRO treatment. The pretreatment CVAI in this case is among the worst clinical presentations seen in this practice, and the improvement reflects a 68.1% difference. By contrast, the percent difference for the control group averaged -11.84%, a worsening.

DISCUSSION

This investigation sought to quantify the effect of treatment with a cranial remolding orthosis to alter 3-D head shape in infants with deformational plagiocephaly. Documentation of 3-D headshape is a clinical challenge, but new non-contact scanners and digitizers are making the process more efficient and, potentially, more effective. Scanners such as the one used in this project produce substantial amounts of data, so this investigation also focused on the most useful indicators of symmetry, recognizing this as a goal of the management of DP.

The vast majority of studies published regarding DP report linear measures and therefore cannot produce symmetry indices similar to those in the present study. Consequently, it is difficult to compare these data to previous results in the literature. Bruner et al²⁶ reported 3-D shapes from CT scans, but used only a measure of intracranial volume asymmetry, and reported only changes and not absolute pre- or post-treatment values.

The primary limitation of this investigation relates to the control group. This group was much smaller than the treatment group, and was not randomly selected. Instead, the control group was self-selected, composed of subjects whose families declined CRO treatment. Furthermore, several families of subjects in the control group decided to begin CRO treatment during the study and therefore left the sample. Consequently, the control group was probably composed of DP cases that stayed the same or showed self-improvement. It was reassuring to note that no significant differences were noted in pretreatment variables between the treatment and control groups. Also, the nature of the control group

imposed a conservative effect on the analysis, further demonstrating the clinical significance of the effect of the CRO on head shape. If the control population was biased toward cases that either did not worsen or resolved through growth or repositioning, the pre/post difference results (Table 1) become more compelling. In any case, a carefully constructed control group for a study like this one would be difficult to justify ethically. Another limitation is that at the point of publication, the subjects were not followed past 18 months of age. While it is suspected that the slowing of cranial growth reduces the opportunity for head shape change after 12 months of age, the long-term effects of deformational plagiocephaly should be documented, and will be the subject of further research.

An additional limitation relates to the potential generalization of the results given the fact that, at present, very few centers worldwide have access to the type of scanner utilized in this study. Despite this limitation, this project was able to document the utility of some measurements, and the CVAI in particular, that can be recorded without a digitizing scanner.

Results showed consistency among practitioners. Similar categories of variables (e.g. quadrant volumes, symmetry ratios) exhibited similar ranges of variability as reflected by standard deviation (Table 1). Oblique maximum and minimum angles exhibited the greatest overall variability based on standard deviation and an additional analysis of coefficient of variation. These measures are not true "difference" scores relative to the other variables as there is no pre- and post value for them; therefore, they may not be of specific interest.

Not surprisingly, the variables found to be the best predictors of asymmetry were the symmetry indices. While this seems obvious, it is informative to note that identifying information such as age at onset or basic head anthropometrics did not predict asymmetry, a result similar to the findings of Peitsch et al.² The ratios or indices found to be the best predictors in plagiocephaly (CVAI, RSI, PSR, and OSR) are useful to clinicians because they provide an accurate, reproducible comparison of one subject to another regardless of age or head circumference. As mentioned, an additional value of the CVAI lies in its ability to be duplicated by hand in the absence of a scanner. Although subject to clinical error, calipers or contoured strips can be used to create the cross-sectional shapes from which diagonals can then be measured and compared.

The study's fundamental hypothesis was supported. CRO treatment did significantly alter head shape and improve symmetry. Despite the

aforementioned limitations associated with the control population, the results further support that symmetry improved significantly more with CRO treatment than without. It is important to note that at our center, CRO intervention is not recommended for children with mild DP. A sound repositioning education and home program is recommended in these cases and typically produces positive results. Previous authors have reported good skull correction with early repositioning (0–3 months) for children diagnosed with deformational plagiocephaly and this is the treatment of choice for infants diagnosed with DP without secondary changes to the forehead or facial structures.

At the authors' center, the STARscanner has provided physicians and other staff with consistent and clinically relevant data that can be used to follow progression, improvement, and study treatment and nontreatment interventions for the population of young infants with head shape asymmetries.

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