Long-Term Treatment Effectiveness of Molding Helmet Therapy in the Correction of Posterior Deformational Plagiocephaly: A Five-Year Follow-Up

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Objective: **To evaluate the long-term effectiveness of helmet therapy in the correction of deformational plagiocephaly and to assess the early occlusal abnormalities seen in these patients.**

Design: **A prospective study with blinded measurements.**

Patients: **Twenty-eight patients with deformational plagiocephaly who were treated with molding helmet therapy with at least 5 years of follow-up.**

Interventions: **The average length of molding helmet treatment was 6.2 months. At the time of this follow-up evaluation, the mean interval since completing the molding helmet therapy was 5.6 years.**

Main Outcome Measures: **Anthropometric measurements of cranial asymmetry included cranial vault asymmetry (CVA), orbitotragial depth asymmetry (OTDA), and cranial base asymmetry (CBA). A dental examination was also performed.**

Results: **At the completion of therapy, the most improvement was seen in the measurement of CBA, followed by CVA and OTDA. However, in evaluating the long-term stability of molding treatment, OTDA tended to continue improving after the initial treatment, while CBA and CVA appeared to regress, although none of the changes reached statistically significant levels. In dental measurements, all the dental midline and chin deviations were toward the unaffected side with respect to occipital deformation.**

Conclusion: **This study demonstrated that helmet remodeling with the dynamic orthotic cranioplasty band is effective in the correction of cranial asymmetry, with some nonstatistically significant changes in long-term cranial vault symmetry. Dental observations indicated the possibility of occlusal abnormalities that may affect dental, especially orthodontic, diagnosis and teatment planning.**

KEY WORDS: *long-term effectiveness, molding helmet therapy, posterior deformational plagiocephaly*

Plagiocephaly is a general term used for patients with cranial asymmetry. Posterior deformational plagiocephaly may occur in infants subject to intrauterine constraint or postnatal positioning. In 1992, the American Academy of Pediatrics recommended that infants be placed on their back to sleep to reduce the risk of sudden infant death syndrome (American Academy of Pediatrics Task Force, 1992). Since this recommendation, the incidence of the

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Submitted October 2006; Accepted July 2007.

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DOI: 10.1597/06-210.1

posterior deformational plagiocephaly has dramatically increased from 1 in 300 (O'Broin et al., 1999) to 8.2% of all live births (Boere-Boonekamp and van der Linden-Kuiper, 2001). The treatment modalities for deformational plagiocephaly include nonintervention, head positioning, molding helmet therapy, surgery, or any combination of these. Molding helmet therapy is currently the common treatment option for moderate to severe deformational plagiocephaly.

A number of authors have reported significant reduction in cranial asymmetry using molding helmet therapy (Clarren et al., 1979; Clarren, 1981; Ripley et al., 1994; Pollack et al., 1997; Littlefield et al., 1998; Mulliken et al., 1999; Teichgraeber et al., 2002, 2004; Littlefield, 2004; Graham et al., 2005). However, there are no reports that evaluate the long-term outcomes following molding helmet therapy. Although most head growth is completed by the age of 2 years, a significant amount of craniofacial growth continues through adolescence (Enlow and Hans, 1996). The purpose of this study was to evaluate at 5 years the long-term effectiveness of molding helmet therapy in the correction of posterior deformational plagiocephaly. In addition, the study was also designed to assess the early occlusal abnormalities seen in these patients.

Materials and Methods

All patients with posterior deformational plagiocephaly who presented at the Cleft and Craniofacial Clinic at the University of Texas–Houston Medical School between August 1, 1995, and December 31, 1998, were studied. All were previously diagnosed with moderate to severe posterior deformational plagiocephaly and underwent molding helmet therapy using the dynamic orthotic cranioplasty (DOC) band (Cranial Technologies Inc., Tempe, AZ). The inclusion criteria for the study were (1) absence of other craniofacial deformities or syndromes, (2) treatment started prior to 12 months of age, (3) completion of DOC band treatment, and (4) a complete set of pretreatment and posttreatment anthropometric measurements. The study protocol was approved by The University of Texas Houston Health Science Center Institutional Review Board. A total of 111 patients met the inclusion criteria.

The sample size for this study was calculated using the method of Chen et al. (2004). Since there was insufficient data in the current literature to make a meaningful sample size estimate for the statistical model in this study, the sample size was estimated based on available but incomplete information. After conducting the study, the initial sample size parameter estimates were validated on the data collected. If these estimates had been inaccurate and the study was not sufficiently powered to be meaningfully interpreted, the sample size would have been recalculated based on the data collected and the study would continue. Significance levels would also have been adjusted accordingly. However, if these estimates were accurate and the study as conducted was sufficiently powered, there would be no need to increase the sample size. Based on this strategy, the initial sample size was estimated using PASS statistical software package (PASS 2005, Kaysville, UT). In accordance with our previous study (Teichgraeber et al., 2004), the current study was designed to detect a mean difference (δ) of 1.2 and a standard deviation (SD) of 2.1, to achieve .05 alpha and .2 beta. Since we did not have data for the 5-year follow-up, we estimated the sample size using a one-sample t-test power analysis. The calculation yielded a sample size of 28. The sample was then randomly selected from among the 111 patients using the NCSS software package (NCSS 2004, Kaysville, UT).

All 28 patients were followed in our clinic (follow-up rate = 100%). Of this cohort, 14 (50%) were male and 14 (50%) were female. Treatment was initiated at a mean age of 6.7 months (SD, 2.5). The patients included 2 patients (7.1%) with a history of prematurity and 1 (3.6%) with a multiple birth history. In addition, the breech position was involved in 1 (3.6%) infant and congenital torticollis in 2 (7.1%) infants. Right posterior deformational plagiocephaly was diagnosed in 22 infants (78.6%), and left posterior deformational plagiocephaly was present in 6 infants (21.4%). The average length of treatment was 6.2 months (SD, 3.8). At the time of this follow-up evaluation, the mean patient age was 6.7 years (SD, 0.82) and the mean interval since completing the molding helmet therapy was 5.6 years (SD, 0.91). Finally, all of the parents in the study were pleased with the corrected head shape achieved by molding therapy (100%).

Protocol for Anthropometric Measurements and Dental Evaluation

The anthropometric measurements for cranial asymmetry were performed following the same protocol that was used previously (Farkas, 1994; Kolar and Salter, 1997). Measurements were performed by one investigator using a spreading caliper (GPM Measurements, Zurich Switzerland). Cranial vault asymmetry (CVA) was determined by measuring the distance between the left frontozygomatic point and right euryon point minus the distance between the right frontozygomatic point and the left euryon point (Fig. 1). Orbitotragial depth asymmetry (OTDA) was calculated using the right exocanthion point to the right tragus point minus the left exocanthion point to the left tragus point (Fig. 2). Cranial base asymmetry (CBS) was determined using the inion point to the right tragus minus the inion point to left tragus (Fig. 3) (Kolar and Salter, 1997). All measurements were blinded from the previous recorded measurements.

A dental examination was also performed, with certain measurements and observations noted. Specifically, overbite, overjet, permanent first molar relationship, and dental

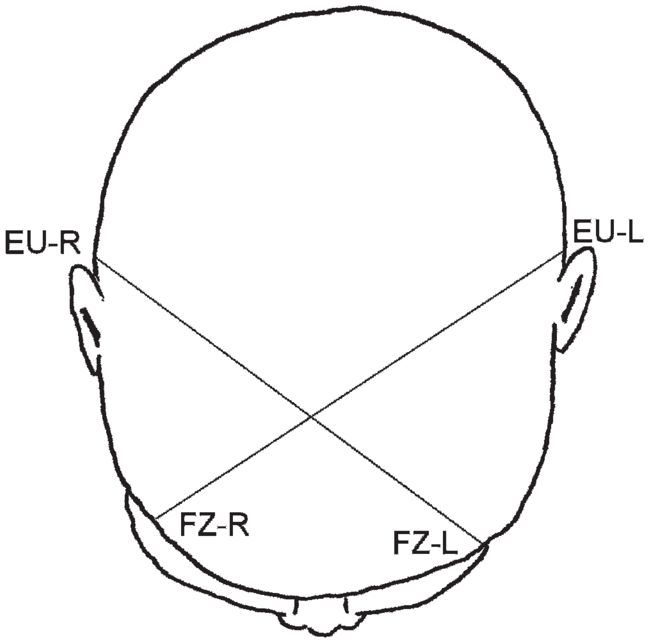

FIGURE 1 Anthropometric measurement for cranial vault asymmetry (CVA).

midline coincidence were documented as well as the presence of any crossbites, open bites, or oral habits.

Statistical Analysis

Anthropometric data of three measurements (CVA, OTDA, and cranial base asymmetry [CBA]) and from

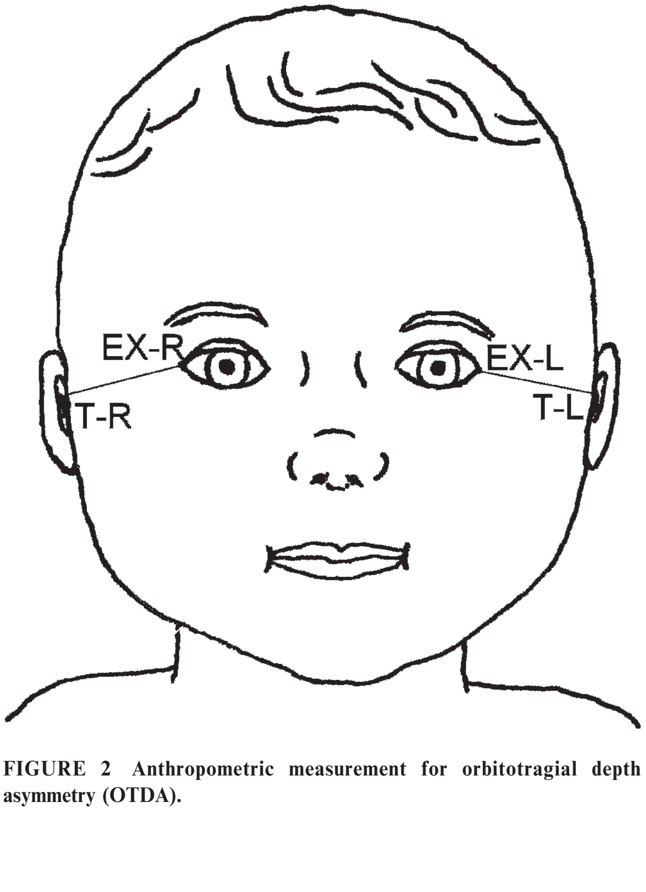

FIGURE 2 Anthropometric measurement for orbitotragial depth asymmetry (OTDA).

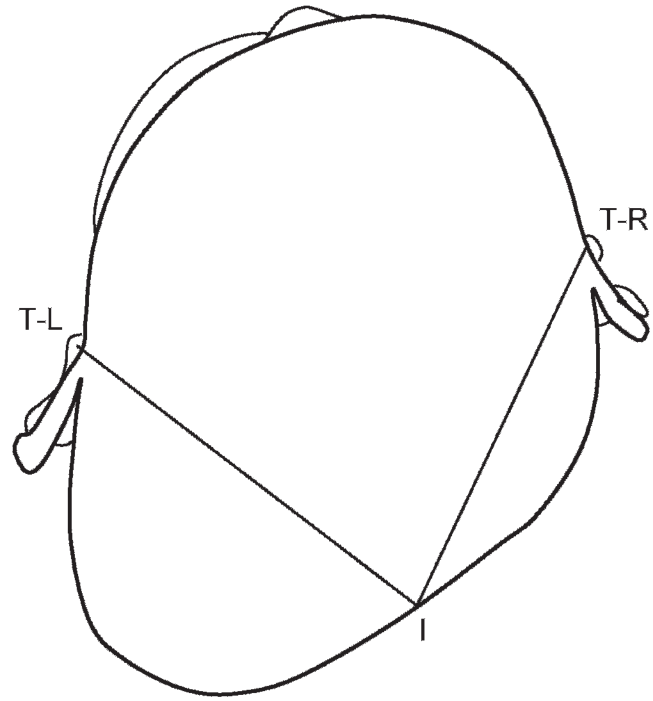

FIGURE 3 Anthropometric measurement for cranial vault asymmetry (CBA).

three time points (before molding therapy [initial], after molding therapy [exit], and the 5-year follow-up [FU]), were analyzed using the NCSS statistical software package. To control head growth from being a potential confounding variable, the direct head measurements were standardized using the following equation:

$$Growth-Adjusted\ Difference\ (\Delta) = \frac{(R - L)}{(R + L)/2} \times 100,$$

where R and L represent the right and left direct head anthropometric measurements, respectively.

The hypothesis being tested was that molding therapy could correct the head shape and that the correction was likely to persist for at least 5 years. To this end, analysis of variance (ANOVA) for repeated measures was computed to determine the statistically significant difference for each growth-adjusted measurement: CVA, OTDA, and CBA, respectively. The response variable was the values from the anthropometric measurements. The within-subject factor was the three time points (initial, exit, and FU). Within-subjects contrasts were computed. During the computation of ANOVA for repeated measures, the growth-adjusted measurements were normalized to have the plagiocephaly on the right side for the purpose of treatment outcome evaluation. The assumptions for ANOVA repeated measures were evaluated and were not violated. In addition, a Pearson correlation matrix was computed to determine the correlation among the three anthropometric measurements at different time points. Finally, since the data for chin deviation and dental measurements were not normally

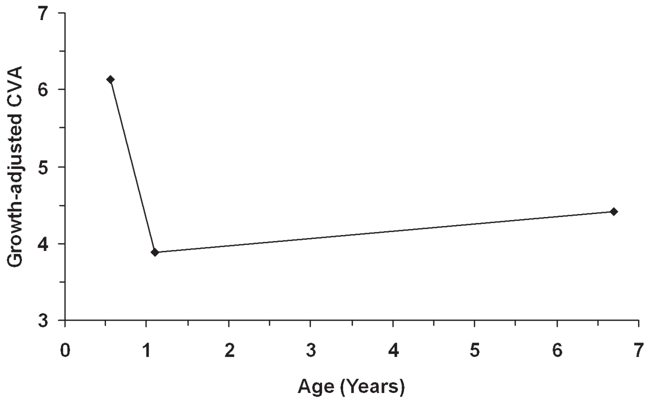

FIGURE 4 Comparison of cranial vault asymmetry (CVA) pretreatment, posttreatment, and at 5-year follow-up.

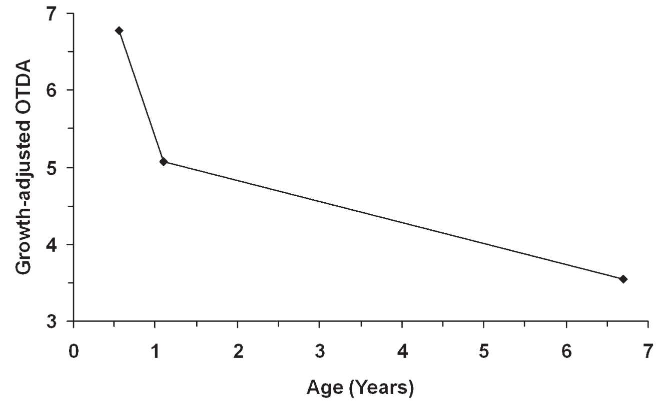

FIGURE 5 Comparison of orbitotragial depth asymmetry (OTDA) pretreatment, posttreatment, and at 5-year follow-up.

distributed, descriptive analyses and the Spearman correlation for chin deviation and dental occlusion were performed to determine the patterns of malocclusion and mandibular asymmetry.

Results

Cranial Asymmetry Measurements

For cranial vault asymmetry, there was a statistically significant change among the three growth-adjusted measurements, $F(2, 54) = 4.31$, $p = .02$. After the completion of molding helmet therapy, the mean pretreatment growth-adjusted CVA of 6.14 had decreased to 3.89, a statistically significant decrease of 2.25 (95% confidence interval [CI]: 0.31, 4.18). However, the growth-adjusted CVA was increased to 4.41 at 5 years after the molding helmet therapy, a non–statistically significant increase of 0.52 (95% CI: −1.42, 2.45). Finally, compared with the pretreatment CVA, there was a non–statistically significant decrease of 1.73 (95% CI: −0.21, 3.67) at the 5-year follow-up (Fig. 4).

For orbitotragial depth asymmetry, there was a statistically significant change among the three growth-adjusted measurements, $F(2, 54) = 3.20$, $p = .049$. After the completion of molding helmet therapy, the mean pretreatment growth-adjusted OTDA of 6.77 had decreased to 5.08, a non–statistically significant decrease of 1.69 (95% CI: −1.38, 4.75). The growth-adjusted OTDA was further decreased to 3.55 at 5 years after the molding helmet therapy, a non–statistically significant decrease of 1.53 (95% CI: −1.53, 4.59). Finally, compared with the pretreatment OTDA, there was a statistically significant decrease of 3.22 (95% CI: 0.15, 6.28) at the 5-year follow-up (Fig. 5).

For cranial base asymmetry, there was a statistically significant change among the three growth-adjusted measurements, $F(2, 54) = 10.38$, $p < .001$. After the completion of molding helmet therapy, the mean pretreatment growth-adjusted CBA of 11.59 had decreased to 4.83, a statistically significant decrease of 6.77 (95% CI: 3.15, 10.38). The growth-adjusted CBA was increased to 7.41 at 5 years after the molding helmet therapy, a non–statistically significant increase of 2.58 (95% CI: −1.02, 6.20). Finally, compared with the pretreatment CBA, there was a statistically significant decrease of 4.18 (95% CI: 0.57, 7.79) at the 5-year follow-up (Fig. 6).

The results of the Pearson correlation showed that there was a statistically significant positive relationship among CVA, OTDA, and CBA. The full Pearson coefficient matrix is presented in Table 1. Finally, since the sample size estimate was accurate and the study as conducted was sufficiently powered, there was no need to recalculate and increase the sample size.

Chin Deviation Measurements

Chin point deviation was observed in 19 of the 28 (67.9%) patients. The mean deviation was 1.34 ± 0.98 mm. All deviations were toward the unaffected side with respect to occipital deformation. For example, if a child demonstrated right posterior deformational plagiocephaly, the chin point was consistently deviated toward the left.

For all 28 patients, the result of the Spearman rank correlation matrix showed that there is a statistically

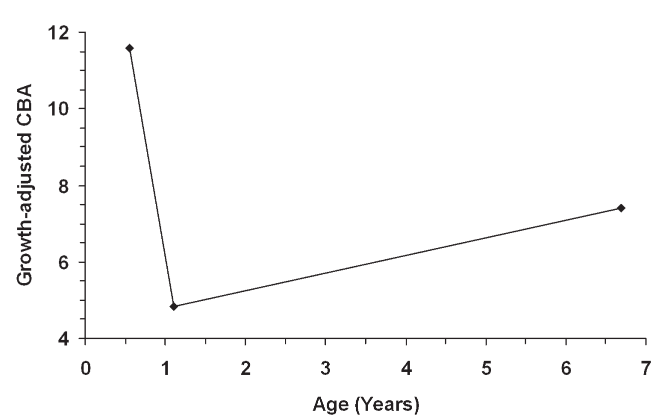

FIGURE 6 Comparison of cranial vault asymmetry (CBA) pretreatment, posttreatment, and at 5-year follow-up.

TABLE 1 Pearson Correlation Matrix for Growth-Adjusted Head Measurements*

		CVA	*OTDA*	*CBA*
Before treatment				
CVA	γ	1.000	.393	.561
	p	.000	.039	.002
OTDA	γ	.393	1.000	.558
	p	.039	.000	.002
CBA	γ	.561	.558	1.000
	p	.002	.002	.000
After molding therapy				
CVA	γ	1.000	.449	.547
	p	.000	.016	.003
OTDA	γ	.449	1.000	.554
	p	.016	.000	.002
CBA	γ	.547	.554	1.000
	p	.003	.002	.000
5-year follow-up				
CVA	γ	1.000	.466	.386
	p	.000	.012	.043
OTDA	γ	.466	1.000	.439
	p	.012	.000	.019
CBA	γ	.386	.439	1.000
	p	.043	.019	.000

* 0 to .25 (or 0 to −.25): no or a little degree of correlation; .25 to .50 (or −.25 to −.50): fair degree of correlation; .50 to .75 (or −.50 to −.75): moderate to good correlation; .75 to 1.0 (or −.75 to −1.0): very good to excellent correlation.

significant negative correlation between chin deviation and cranial vault asymmetry ($\gamma = -.516$, $p = .005$) (Table 2). In addition, there was a statistically significant negative correlation between chin deviation and orbitotragial depth asymmetry ($\gamma = -.440$, $p = .019$). Finally, there was a non–statistically significant negative correlation between cranial base asymmetry ($\gamma = -.209$, $p = .285$).

Dental Midline Measurements

Dental midline deviations from the facial midline were present in 19 of 27 (70.4%) patients, but they were not necessarily the same 19 patients who possessed chin point deviations. The upper and lower central incisors in one patient were not erupted; therefore, his dental midline was not assessed.

Lower dental midline deviations from the facial midline were present in 17 of 19 (89.5%) patients. The mean lower dental midline deviation was 1.00 ± 0.97 mm. The lower dental midline in 14 patients (73.7%) was shifted toward the unaffected side with the opposing arch, while the lower dental midline in 3 patients (15.8%) was shifted toward the affected side. However, there was no statistically significant correlation between the lower dental midline and head CVA, OTDA, and CBA (Table 2).

TABLE 2 Spearman Correlation Matrix for Chin and Lower Dental Midline Deviation

		CVA	*OTDA*	*CBA*
Chin deviation	γ	−.516	−.440	−.209
	p	.005	.019	.285
Lower dental midline	γ	−.175	−.092	−.120
	p	.381	.646	.552

Upper dental midline deviations from the facial midline were presented in 5 of 19 (26.3%) patients. The mean upper dental midline deviation was 1.4 ± 0.55 mm. The upper dental midline in two patients (10.5%) shifted toward the unaffected side with the opposing arch, while the lower dental midline in three patients (15.8%) shifted toward the affected side.

In three patients, both upper and lower dental midlines were shifted. In two patients, both midlines shifted toward either the unaffected side (one patient) or the affected side (one patient). In the third patient, the lower midline shifted toward the unaffected side, while the upper midline shifted toward the affected side.

Occlusion Examination

Posterior crossbites were observed in 5 (17.9%) of 28 patients. Seventeen patients (60.7%) possessed permanent molars in occlusion. Among these patients, 13 (76.4%) were classified as Angle Class I or end-on relationship, 2 (11.8%) were classified as Class II, and another 2 (11.8%) were Class III.

Finally, 22 patients had fully erupted upper and lower central incisors. The mean overbite was 1.36 ± 2.42 mm, and the mean overjet was 2.14 ± 1.52 mm. An anterior open bite was observed in four patients (18.2%), and an anterior crossbite was observed in one patient (4.5%).

Discussion

Currently, there are no long-term studies on the effect of helmet therapy for posterior deformational plagiocephaly. The only study to date that attempted to address this question was the report of Littlefield et al. (1997) on the efficacy of DOC band treatment. The follow-up in that study was 10.31 months, in comparison to 5.6 years in the current study.

Over roughly a 6-month period of helmet therapy, the overall growth-adjusted changes for CVA, OTDA, and CBA were 2.25, 1.69, and 6.77, respectively. The overall growth-adjusted changes for the growth stage after the molding therapy were 0.52, 1.53, and 2.58, respectively. These are relatively small changes when compared with those achieved with molding therapy. Moreover, these changes occurred over a much longer period, that is, 5.6 years instead of the usual 6-month helmet-molding period. The data demonstrate that very little change occurred over the posttreatment period, but a significant change occurred during the helmet therapy. This is further supported by the observation that during helmet therapy, two of the three growth-adjusted measurements showed a statistically significant change. However, during the posttreatment period (5.6 years), no statistically significant changes were observed.

As reported in a number of studies (Clarren et al., 1979; Littlefield et al., 1997; Mulliken et al., 1999; Teichgraeber et al., 2004; Graham et al., 2005), the DOC band is effective in the correction of cranial asymmetry in patients with posterior deformational plagiocephaly. All of the parents in the study were pleased with the corrected head shape achieved by molding therapy. At the completion of the molding therapy, the most improved growth-adjusted change was seen in the measurement of cranial base asymmetry, followed by the cranial vault changes. The least improvement was seen in the orbitotragal asymmetry. However, in evaluating the long-term stability of the DOC band treatment, the study showed that orbitotragal asymmetry tends to continue to improve after the initial treatment, while cranial vault and base asymmetries appear to recidivate.

The reasons for the small amount of regression in cranial vault and base asymmetries are unclear. It may be due to head growth. The resultant asymmetry at the end of the DOC treatment may continue to grow proportionally with normal head growth. Although we have attempted to normalize the head growth by using the average value of the asymmetries, this may not be the best method to account for growth changes. Cranial base resistance may be another reason for the relapse. It has been shown that the cranial base can be both deformed and corrected (Ripley et al., 1994; Littlefield et al., 1998). Stabilizing the corrected cranial base with a helmet can be difficult. The CBA change is probably primarily made on the bones surrounding the cranial base, not the cranial base itself. This uncorrected cranial skull base may destabilize the changes the DOC made on the cranial vault and the bony structures surrounding the cranial base. Finally, there is a question of torticollis. If torticollis is present after the helmet is removed, it may continue to deform the skull base. Treatment of torticollis may eliminate the deforming force on the skull base from the sternocleidomastoid muscle.

Finally, the authors presented the chin deviation, dental midline changes, and dental occlusal findings associated with posterior deformational plagiocephaly. As expected, all the dental midline and chin deviations were toward the unaffected side with respect to occipital deformation. Dentofacial sequelae may affect dental and orthodontic diagnosis and treatment planning. Further investigation into these long-term effects is warranted.

There are some inherent limitations to this study. The first limitation is that the study included only 28 of the original 111 patients. With limited resources, the authors selected the smallest population base that would allow them to reach adequate statistical power. While a larger sample would further ensure that the results are robust, the sample collected was sufficient to detect significant results, that is, an improvement in head shape after 5 years that is highly unlikely to be due to chance. An additional limitation is the inherent problem associated with anthropometric measurements. Anthropometric measurements do not always accurately describe the nature and extent of the deformities. The measurements are operator dependent, relying heavily on the judgment of the examiner to determine the exact point of the landmarks at each visit. In addition, when the motion of a typical, active infant is added, the differences in measurements of mere millimeters become questionable. These limitations may result in some noticeable discrepancies in the patient measurements over time. In the future, use of computed tomography, especially cone-beam computed tomography, which significantly reduces radiation to the patients, or 3D photogrammetry techniques to directly record the entire 3D shape, may help eliminate these limitations.

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