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Cranial Growth Unrestricted during Treatment of Deformational Plagiocephaly

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Cranial orthosis · Deformational plagiocephaly · Growth · Development · Anthropometry

Abstract
Objectives: The Dynamic Orthotic Cranioplasty (DOC) Band™ is a cranial orthosis used to treat deformational plagiocephaly. The ability of this device to redirect growth and thus, improve craniofacial asymmetry has raised concerns regarding the potential restriction of cranial growth. The purpose of this study was to evaluate the growth of the head during correction of plagiocephaly. ***Methods:*** The study sample consisted of 190 children: 81 females (42.6%) and 109 males (57.4%) All patients had been diagnosed with nonsynostotic plagiocephaly, did not have other significant medical conditions, were compliant with DOC protocol, and had complete anthropometric measurements at entrance and exit from treatment. Growth of the head was evaluated using head circumference, maximum cranial width and maximum cranial length. Correction of plagiocephaly was evaluated by documenting the reduction of craniofacial asymmetry of the cranial vault, skull base and face. Paired t tests were used to assess the significance of changes in these anthropometric measurements. Differences were considered significant if $p < 0.05$. ***Results:*** Average entrance age was 6.5 months with a mean treatment time of 4.1 months. Statistical analysis demonstrated highly significant reductions in asymmetry in all three regions ($p < 0.001$). More importantly, these corrections were achieved with synchronous growth of the skull as demonstrated by highly significant increases ($p < 0.001$) in head circumference, maximum cranial width and maximum cranial length. ***Conclusions:*** These findings document statistically significant increases in cranial growth in association with concomitant reductions of the cranial asymmetries associated with deformational plagiocephaly.

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Introduction

In 1992, the American Academy of Pediatrics [1] published the results of a multi-national investigation that suggested a relationship between infant sleeping position and the frequency of sudden infant death syndrome (SIDS). In that report, the Academy recommended that infants be positioned to sleep either on their backs or sides to reduce the risk of SIDS. Subsequently, the Public Health Service initiated the 'Back To Sleep Campaign', which advocated the back or side sleeping of infants [2].

Since the publication of the Public Heath Service report, craniofacial centers around the country have observed an increase in the number of children presenting with abnormal head shapes [3–5]. The majority of these new cases fall under the classification of deformational plagiocephaly. Deformational plagiocephaly refers to an asymmetrical condition of the head arising from extrinsic molding rather than intrinsic synostotic events. The condition is primarily characterized by right or left occipital flattening, with advancement of the ipsilateral ear and prominence of the ipsilateral frontal region.

Clinical management of deformational plagiocephaly has varied greatly [6–9]. Our treatment protocol involves nonsurgical management using Dynamic Orthotic Cranioplasty™ (DOC). The orthosis is described in detail elsewhere [10, 11]. In brief, the device applies a mild, dynamic pressure to the prominent regions of the skull – constraining growth in those areas, thereby encouraging growth in the flattened regions. The magnitude of the cranial remodeling is directly proportional to the growth of the infant's skull. Periods of rapid cranial growth have the greatest potential for remodeling because during periods of growth, the skull is more disposed to the effects of external molding.

The effectiveness of this treatment is well documented [11–13]. However, the ability of the DOC Band to redirect growth and thus improve craniofacial asymmetry has raised concerns regarding the potential restriction of cranial growth [14, 15, Schroeder MA, FDA, pers. commun.]. This study was undertaken to address these concerns.

Materials and Methods

Since its inception, the DOC treatment program has included routine weekly or biweekly clinic follow-up for monitoring treatment progress and for adjusting the orthosis. By 1993, we had established an anthropometric protocol to assist us in assessing and monitoring changes in craniofacial asymmetry. The anthropometric measurements were obtained by an experienced anthropologist using spreading and sliding calipers, and a linen measuring tape. The assessment includes a series of measurements that define the symmetry or asymmetry of the cranial vault, skull base and upper face [16–18] as well as document the growth of the cranium including circumference, cranial breadth and cranial length. The anthropometric data, along with clinical notes and a detailed medical and treatment history were entered into a spreadsheet for storage and analysis.

The subjects for study were retrieved from a pool of 477 nonsyndromic, nonsynostotic patients treated for deformational plagiocephaly from 1993 through 1995. Only those children meeting the following four criteria were selected for additional analysis: (1) compliant with the DOC treatment protocol; (2) entered treatment prior to 1 year of age; (3) complete set of anthropometric measurements at entrance into and exit from the program, and (4) anthropometric measurements were obtained by a single anthropologist.

By including only patients who had been compliant and who had entered treatment prior to 1 year of age and by excluding patients with synostosis or other congenital/medical conditions, we ensured that all subjects in the study had some potential for correction and growth, and that presence or absence of growth occurred in conjunction with treatment.

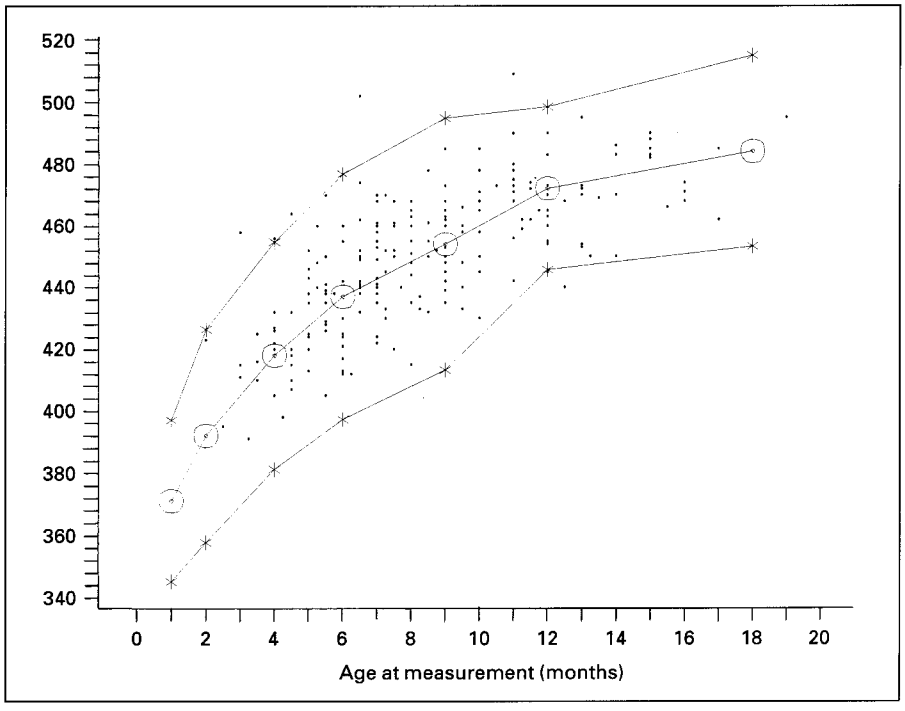
Correction of asymmetry was expressed as pretreatment measure minus post-treatment measure. Thus, a positive difference reflected a mean correction. Growth of the head was evaluated using head circumference, maximum cranial breadth and maximum cranial length. Growth was expressed as posttreatment measure minus the pretreatment measure. In this manner, a positive difference demonstrated growth of the head. Paired t tests were used to evaluate the significance of changes in anthropometric measurements. All statistical analyses were performed using SAS. [19] Differences were considered significant if $p < 0.05$.

Results

The study sample consisted of 190 children meeting the inclusion criteria: 81 females (42.6%) and 109 males (57.4%). All patients presented with significant cranial vault asymmetry (CVA) with 180 (94.7%) also demonstrating concurrent skull base (SBA) and orbitotragial

Table 1. Reduction of asymmetries

Parameter	Entrance, mm (mean ± SD)	Exit, mm (mean ± SD)	Increase, mm (mean ± SD)	T	Prob. > |T|
CVA	8.2 (3.7)	3.2 (2.9)	5.1 (3.2)	22.0	0.001
SBA	5.8 (2.9)	3.1 (2.1)	2.7 (2.4)	14.9	0.001
OTDA	4.3 (2.2)	2.4 (1.6)	1.9 (1.8)	14.3	0.001



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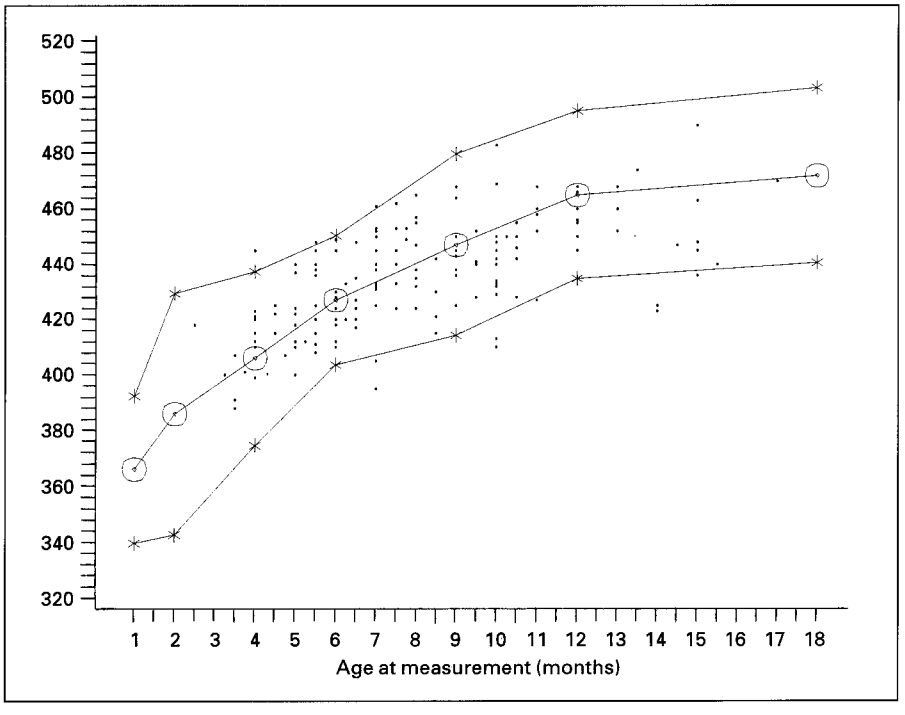

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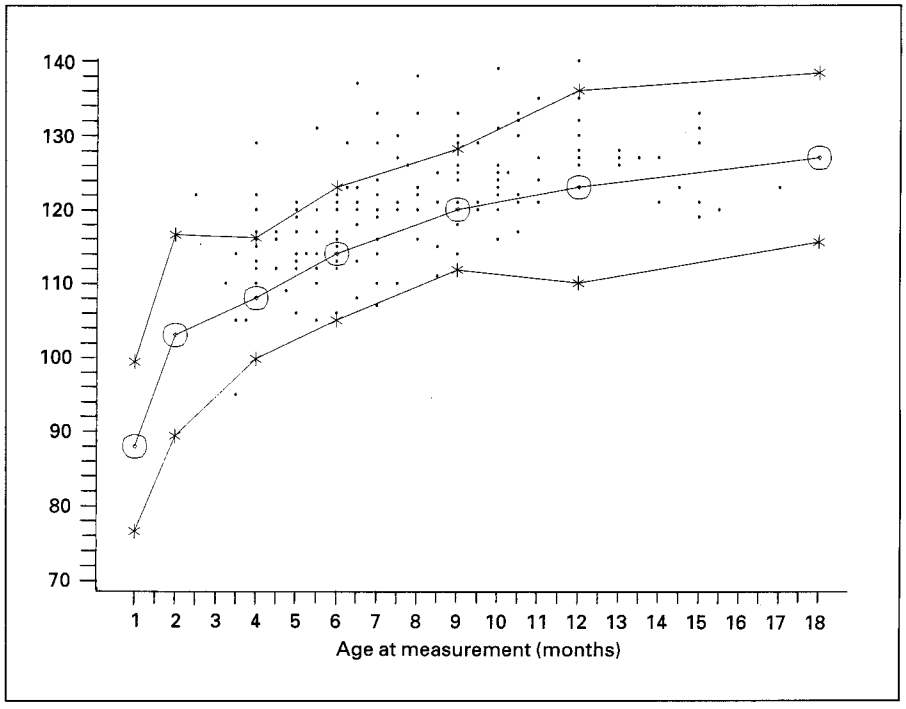
Fig. 1. Head circumference. Head circumference is plotted against age at measurement. The plots are overlaid with data from age- and gender-specific norms provided by Dekaban [20] showing means and ± 2 SD. Norms are represented by connected data points; patient data by individual data points. **a** Plot of entrance and exit head circumference measurements of 109 male patients. **b** Plot of entrance and exit head circumference measurements of 81 female patients.

depth (OTDA) asymmetries. Mean age at the start of treatment was 6.5 (±1.9) months (range 2.8–11.3 months) with an average treatment time of 4.1 (±2.1) months (range 1.3–13.0 months).

Mean pre- and posttreatment measures of asymmetry as well as the mean reductions in asymmetry are presented in table 1. Mean CVA was reduced by 5.1 mm (8.2 to 3.2 mm), mean SBA decreased by 2.7 mm (5.8 to 3.1 mm) and mean OTDA was reduced by 1.9 mm (4.3 to 2.4 mm)



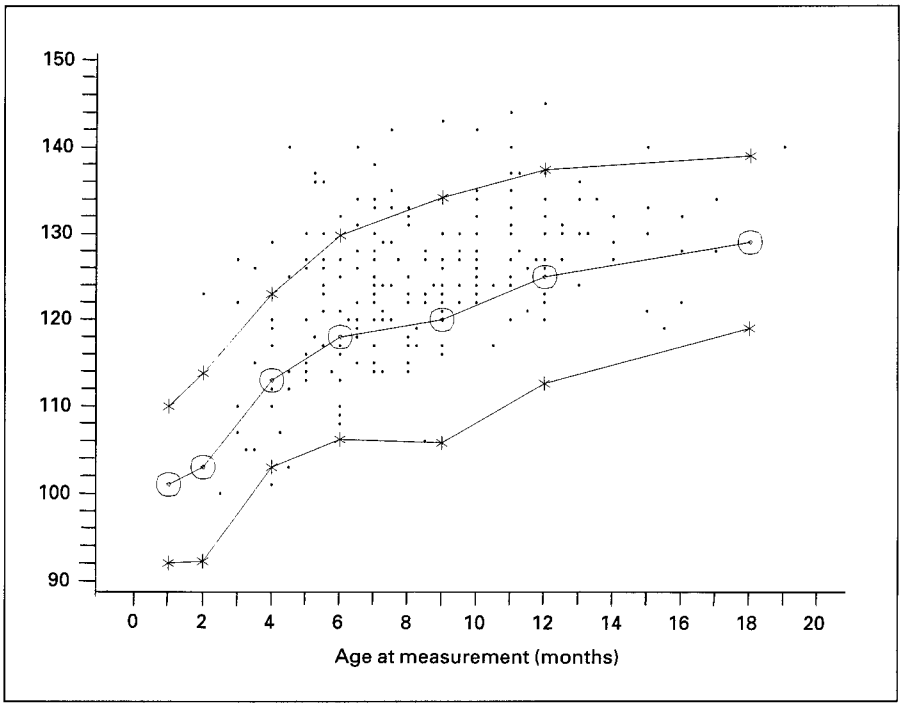


Fig. 2. Cranial breadth. Cranial breadth is plotted against age at measurement. The plots are overlaid with data from age- and gender-specific norms provided by Dekaban [20] showing means and ± 2 SD. Norms are represented by connected data points; patient data by individual data points. **a** Plot of entrance and exit cranial breadth measurements of 109 male patients. **b** Plot of entrance and exit cranial breadth measurements of 81 female patients.

following orthotic management. Statistical analyses based on paired comparison of pre- to posttreatment measurements (paired t tests) demonstrated highly significant reductions in asymmetry in all three regions ($p < 0.001$).

Growth of the head (circumference, breadth, length) during treatment is visually presented in figures 1–3. Data from the patients treated with orthotic management are represented by periods (i.e. '.'). Data for age-matched norms are represented by connected asterisks ('*'). Age-

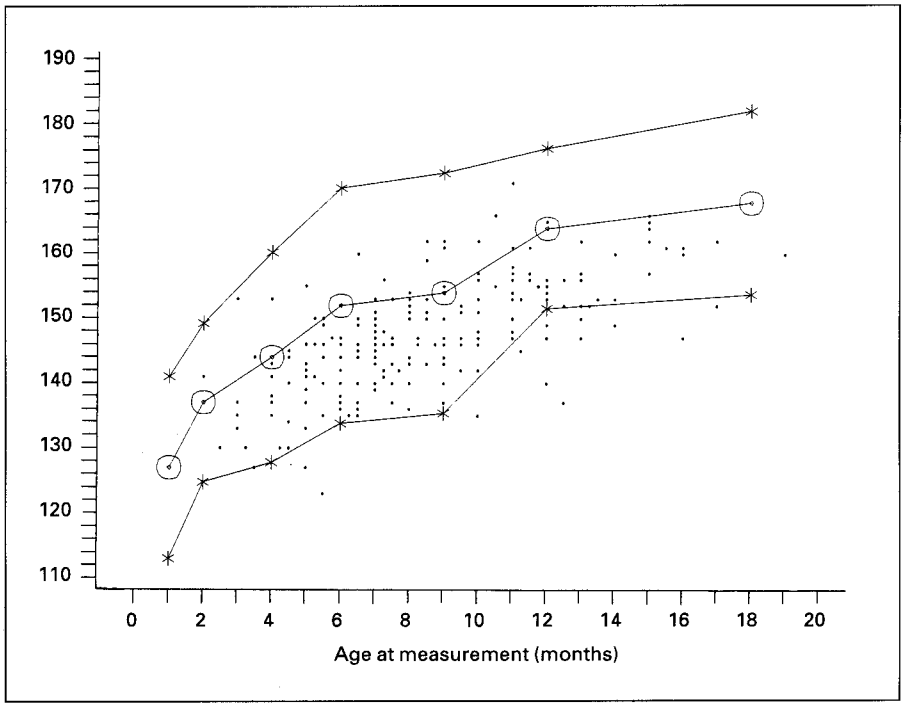


Fig. 3. Cranial length. Cranial breadth is plotted against age at measurement. The plots are overlaid with data from age- and gender-specific norms provided by Dekaban [20] showing means and ± 2 SD. Norms are represented by connected data points; patient data by individual data points. **a** Plot of entrance and exit cranial length measurements of 109 male patients. **b** Plot of entrance and exit cranial length measurements of 81 female patients.

matched means for males and females at 1, 2, 3, 6, 9, 12 and 18 months of age are taken from Dekaban [20]. As can be seen from the figures 1–3, the growth trajectories of infants being managed orthotically follow a course similar to the trajectories of normals.

The significance of growth of the head during orthotic management was evaluated by comparing posttreatment and pretreatment measurements of head circumference, cranial breadth and cranial length (table 2). Statistical analysis of these paired measurements revealed statisti-

Table 2. Increase of cranial breadth, length and circumference

Parameter	Entrance, mm (mean ± SD)	Exit, mm (mean ± SD)	Increase, mm (mean ± SD)	T	Prob. > |T|
Cranial breadth	119.9 (8.2)	125.9 (7.2)	6.0 (5.0)	16.5	0.001
Cranial length	141.8 (9.2)	148.7 (9.0)	6.8 (5.0)	18.9	0.001
Circumference	434.3 (20.1)	453.5 (19.7)	19.2 (11.9)	22.3	0.001

cally significant increases in all three parameters ($p < 0.001$). Mean head circumference, a measure of the overall size of the head, increased from 434.3 ± 20.1 mm at entrance to 453.5 ± 19.7 mm at exit. Not surprisingly, cranial breadth and length also increased significantly during treatment. Cranial breadth increased from an entrance mean of 119.9 ± 8.2 to 125.9 ± 7.2 mm at exit; while mean cranial length increased from 141.8 ± 9.2 mm at entrance to 148.7 ± 9.0 mm at exit. Thus, significant correction of the asymmetries was achieved with synchronous and significant growth of the skull.

Discussion

Three observations are evident from the anthropometric data: (1) patients exhibit statistically significant reductions in craniofacial asymmetry during orthotic management (table 1); (2) patients demonstrate statistically significant increases in circumference, cranial breadth and cranial length during treatment (table 2), and (3) infants treated with DOC banding exhibit growth trajectories similar to normals (figs. 1–3).

In short, these findings demonstrate that DOC treatment results in significant reduction of craniofacial asymmetry, while more importantly documenting that this correction is achieved with concomitant, statistically significant growth of the skull.

At the same time, we note that infants with plagiocephaly exhibit a wider and shorter head shape then their age-matched normals – a condition that is consistent with the recognized positional etiologies of plagiocephaly. A review of figures 1–3 reveals that although male and female head circumferences plot symmetrically about the normal means, cranial breadth plots consistently above, while cranial length consistently falls below. Thus, although exhibiting normal growth trajectories, infants with plagiocephaly tend to present with, and retain, a more brachycephalic configuration.

The primary purpose of this investigation has been to examine the effect of DOC on head growth, and not to establish the efficacy of the program. However, as both simple repositioning and orthotic management have been reported to be successful in the treatment of deformational plagiocephaly [3, 6, 8, 9, 11, 21–23], there is some confusion regarding the 'best' method for treating this condition. Fortunately, guidelines established at the 1997 Craniosynostosis and Skull Molding Symposium help bring some clarity to this issue [24]. These guidelines recognize that when diagnosed and treated at an early age, deformational plagiocephaly may be managed successfully by simple repositioning of the child off the flattened occiput – additionally noting that physical therapy should be instituted if there is evidence of congenital muscular torticollis. On the other hand, if repositioning is unsuccessful, or if the initial deformity is too severe or the child is too old for repositioning to be effective (5–6 months of age), orthotic management should be considered as the next logical alternative. Surgical intervention is recommended only for the most severe cases, and only after all conservative measures have been exhausted. The recommendations recognize that repositioning, orthotic management and surgical intervention are not necessarily mutually exclusive alternatives. Not surprisingly, a careful review of the three studies documenting the success of repositioning reveals that all three recommend some form of orthosis to treat those infants who were too severe or failed repositioning [9, 21, 22].

In this investigation, we have documented the ability of our orthosis, the DOC Band, to reshape the head without restricting the overall growth of the skull. However, we recognize that any cranial orthosis has the *potential* to restrict cranial growth. For that reason, our treatment incorporates special controls to minimize this risk while assuring effectiveness. Not the least of these controls is the requirement that patients return for weekly or biweekly visits during which time adjustments are made to ensure proper growth. Thus, patient compliance is imperative. The results of this investigation document the success of the DOC program to treat deformational plagiocephaly both safely and effectively.

References

1 American Academy of Pediatrics: AAP Task Force on Infant Positioning and SIDS: Positioning and SIDS. Pediatrics 1992;89:1120–1126.

2 Havens DH, Zink RL: The 'Back to Sleep' campaign. J Pediatr Health Care 1994;8:240–242.

3 Argenta LC, David LR, Wilson JA, Bell WO: An increase in infant cranial deformity with supine sleeping position. J Craniofac Surg 1996;7:5–11.

4 Turk AE, McCarthy JG, Thorne CCHM, Wisoff JH: The 'Back to sleep campaign' and deformational plagiocephaly: Is there cause for concern? J Craniofac Surg 1996;7:12–18.

5 Kane A, Mitchell L, Craven K, Marsh J: Observations on a recent increase in plagiocephaly without synostosis. Pediatrics 1996;97:877–885.

6 Clarren SK, Smith DW, Hanson JW: Helmet treatment for plagiocephaly and congenital muscular torticollis. J Pediatr 1979;94:43–46.

7 Nichter LS, Persing JA, Horowitz JH, Morgan RF, Nichter MA, Edgerton MT: External Cranioplasty: Historical perspectives. Plastic Reconstr Surg 1986;77:325–332.

8 Pattisapu JV, Walker NL, Myers GG, Cheever J: Use of helmets for positional molding. Concepts Pediatr Neurosurg 1989;9:178–184.

9 Pollack IF, Losken HW, Fasick P: Diagnosis and management of posterior plagiocephaly. Pediatrics 1997;99:180–185.

10 Pomatto JK: Cranial Technologies Inc, US Patent No 5,094,229, March 10, 1992; developed in conjunction with Stephen P. Beals, Southwest Craniofacial Center, and Kim H. Manwaring, Division of Neurosurgery, Phoenix Children's Hospital.

11 Ripley CE, Pomatto JK, Beals SP, Joganic EF, Manwaring KH, Moss SD: Treatment of positional plagiocephaly with Dynamic Orthotic Cranioplasty. J Craniofac Surg 1994;5:150–159.

12 Littlefield TR, Beals SP, Manwaring KH, Pomatto JK, Joganic EF, Golden KA, Ripley CE: Treatment of craniofacial asymmetry with Dynamic Orthotic Cranioplasty. J Craniofac Surg 1998;9:11–17.

13 Kelly KM, Littlefield TR, Pomatto JK, Ripley CE, Beals SP, Joganic EF: Importance of early recognition and treatment of deformational plagiocephaly with orthotic cranioplasty. Cleft Palate Craniofac J 1999;36:127–130.

14 Craniosynostosis and Skull Molding Symposium. Scottsdale, February 1997.

15 International Society of Craniofacial Surgery, VII International Congress. Santa Fe, September 1997.

16 Farkas LG: Anthropometry of the Head and Face in Medicine. New York, Elsevier, 1981.

17 Hajnis K: Kopf-, Ohrmuschel- und Handwachstum (Verwendung bei den Operationen der angeborenen Missbildungen und Unfallsfolgen). Acta Univ Carol [Biol] Praha 1972; 1974;2–4: 77.

18 Kolar JC, Salter EM: Craniofacial Anthropometry. Practical Measurement of the Head and Face for Clinical, Surgical and Research Use. Springfield, Thomas, 1997.

19 SAS Institute Inc: SAS/STAT User's Guide, Version 6. Cary, SAS Institute Inc, 1989 vol 2, pp 846.

20 Dekaban AS: Tables of cranial and orbital measurements, cranial volume, and derived indexes in males and females from 7 days to 20 years of age. Ann Neurol 1977;2:485–491.

21 Hellbusch JL, Hellbusch LC, Bruneteau RJ: Active counterpositioning treatment of deformational plagiocephaly. Neb Med J 1995;80: 344–349.

22 Moss SD: Nonsurgical, nonorthotic treatment of occipital plagiocephaly: What is the natural history of the misshapen neonatal head? J Neurosurg 1997;87:667–670.

23 Mulliken JB, Vander Woude DL, Hansen M, LaBrie RA, Scott RM: Analysis of posterior plagiocephaly: Deformational versus synostotic. Plastic Reconstr Surg 1999;103:371–380.

24 Consensus Statement Issued at the Craniosynostosis and Skull Molding Symposium. Scottsdale, February 1997.