Objective Outcome Analysis of Soft Shell Helmet Therapy in the Treatment of Deformational Plagiocephaly

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Deformational plagiocephaly, cranial asymmetry secondary to positioning, continues to be a leading cause of head shape abnormalities in infants. Treatment recommendations include nonintervention, positioning therapies, and helmet therapy. Although most agree that surgical intervention is rarely indicated, the ideal therapy is not agreed on. Some even debate the necessity of treatment, especially third-party payers. The purpose of this prospective study is to use an objective outcome analysis tool, computerized tomography, to assess the efficacy of a soft shell helmet therapy. Sixty-nine children with a diagnosis of deformational plagiocephaly were enrolled in this study to assess the success of a soft shell helmet for the correction of cranial asymmetry. Computed tomography scanning was done before therapy and 6 months after the initiation of therapy. Three-dimensional reconstructions of these scans were reformatted into a standardized orientation by utilizing the nasion (radix), frontozygomatic suture lines, and posterior aspect of the foramen magnum. Intracranial volumes were calculated on a quadrant basis, and asymmetry was evaluated with regard to the hemispheres (left versus right) and the posterior quadrants. Thirty-four children (27 boys and 7 girls) completed the study protocol. The side involved was the right in 62% of cases and the left in 38%. Mean age at the initial scan was 6.3 months, and mean age at the follow-up scan was 14 months. Mean duration of helmet therapy was 7 months. Compliance with therapy was average to above average in 88% of the children and poor in 12%. There was a 36% to 54% improvement in asymmetry in the compliant patients over the 6-month study period. Soft shell helmet therapy is an effective technique to decrease cranial asymmetry based on objective outcome measurements. Additionally, it is cost-effective, with the total cost of therapy for the helmet and office visits ranging from $600 to $700. This therapy compares favorably with other more expensive and time-consuming therapies that have been reported in the literature.

Key Words: Plagiocephaly, cranial asymmetry, helmet therapy

Over the past decade, deformational plagiocephaly, cranial asymmetry secondary to positioning, has become one of the leading diagnoses of head shape abnormalities in infants. This increased incidence as documented by craniofacial centers throughout the United States[1-8] has been correlated with the implementation of the "Back to Sleep Campaign" by the American Academy of Pediatricians in 1992.[9] To date, there are still controversial aspects associated with deformational plagiocephaly, and the topic has entered the (popular/lay) press.[10] The incidence of asymmetrical occipital flattening was initially estimated to be 1 of every 300 live births before the Back to Sleep Campaign,[11,12] with more recent studies now estimating the prevalence to be between 1 of 68 and 1 of 72 live births.[13]

There are three primary options for treatment of deformational plagiocephaly: observation and repositioning, external orthotic/helmet therapy, and surgery. Although most craniofacial surgeons would agree that surgery is almost never warranted, controversy remains concerning other available treatment options. As the costs associated with nonsurgical treatment continue to escalate, the efficacy,

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validity, and necessity of such treatment have been called into question, particularly by third-party insurance payers.[4,7,10] Aspects of the immediate and long-term impact of deformational plagiocephaly have recently been documented in the literature. Of note, untreated deformational plagiocephaly does not correct on its own, and craniofacial asymmetry is retained into adulthood.[5,14–16] This retained asymmetry of the face and skull base[17] can cause those affected by deformational plagiocephaly to be perceived as abnormal by their peers.[11] In addition to the psychosocial and appearance implications, the literature is replete with examples of developmental and health problems associated with untreated deformational plagiocephaly. These aspects include an increased need for special education when compared with siblings[18]; a delay in psychological and motor development[1,18]; and an increased incidence of cerebral dysfunction,[18] strabismus,[11,18] orthodontic disorders,[11] and otitis media.

Furthermore, there is controversy with regard to assessing efficacy of treatments currently in use for deformational plagiocephaly. As stated by Loveday and de Chalain,[2] there is no standard tool for quantitative assessment of treatment progress or efficacy for deformational plagiocephaly described in the literature. There are many types of measurements, both subjective and objective, that have been used to assess the degree of asymmetry as well as the efficacy of treatment of deformational plagiocephaly. These include anthropometric measurements[4,11,15,17,19]; clinical experience[15]; clinical exam (Table 1); parental judgment, assessment, and rate of satisfaction[20-23]; head tracings[2]; and a combination of measurement techniques. The most popular method of evaluating treatment efficacy and progress is through external anthropomorphic measurements, and various measurement techniques have been described in the literature, some of which require more than 14 different measurements at each clinical encounter.[19] Most anthropometric measurements are performed using a caliper device that requires careful precision. In fact, the asymmetry between measurements is usually a matter of millimeters.[15,17,19] This type of measurement method is susceptible to interobserver variability and decreased compliance by infants who are averse to having their heads measured and, consequently, do not readily remain still.[2,11] The prevalence of such subjective or difficult-to-reproduce measurements emphasizes the importance of obtaining a truly objective method of measuring efficacy of treatment.

The purpose of this prospective study is to use an objective outcome analysis tool, computerized tomography (CT), to assess the efficacy of a soft shell helmet therapy. The treatment modality assessed in this study is the soft shell helmet currently used by the North Carolina Center for Cleft and Craniofacial Deformities at the Wake Forest University Medical Center.

Materials and Methods

Sixty-nine children with a diagnosis of deformational plagiocephaly who presented to the North Carolina Center for Cleft and Craniofacial Deformities at Wake Forest University Medical Center between the years 1996 and 2000 were enrolled in the study. Patients were followed until the age of 18 months and then released to the care of their pediatricians. Computed tomography scanning was obtained before therapy and just before discontinuing the helmet therapy. The three-dimensional reconstructions of cranial CT scans were reformatted into a standardized orientation using Analyze software (Mayo Clinic, Rochester, MN) (Figs 1–4). Determination of standardized orientation was accomplished by utilizing the nasion, frontozygomatic suture lines, anterior aspect of the foramen magnum, and posterior aspect of the foramen magnum. A transformation matrix was computed and applied so that the

Table 1. Positional Plagocephaly Clinical Grading Scale

Clinical Finding	*Grade 1*	*Grade 2*	*Grade 3*	*Grade 4*	*Grade 5*	*Grade 6 (A, B, C)**
Posterior asymmetry	Present	Present	Present	Present	Present	Present
Ear malposition	Absent	Present	Present	Present	Present	Present
Frontal asymmetry	Absent	Absent	Present	Present	Present	Present
Facial asymmetry	Absent	Absent	Absent	Present	Present	Present
Temporal bossing or posterior vertical cranial growth	Absent	Absent	Absent	Absent	Present	Present
Central bilateral plagioephaly	Absent	Absent	Absent	Absent	Absent	Present

*A = flatness of confluence of lambdoid sagittal suture; B = flatness extending to mastoids influencing displacement of ear; C = vertical cranial growth or lateral cranial bulging.

Fig 1 Soft shell helmet with external bump used for the treatment of deformational plagiocephaly.

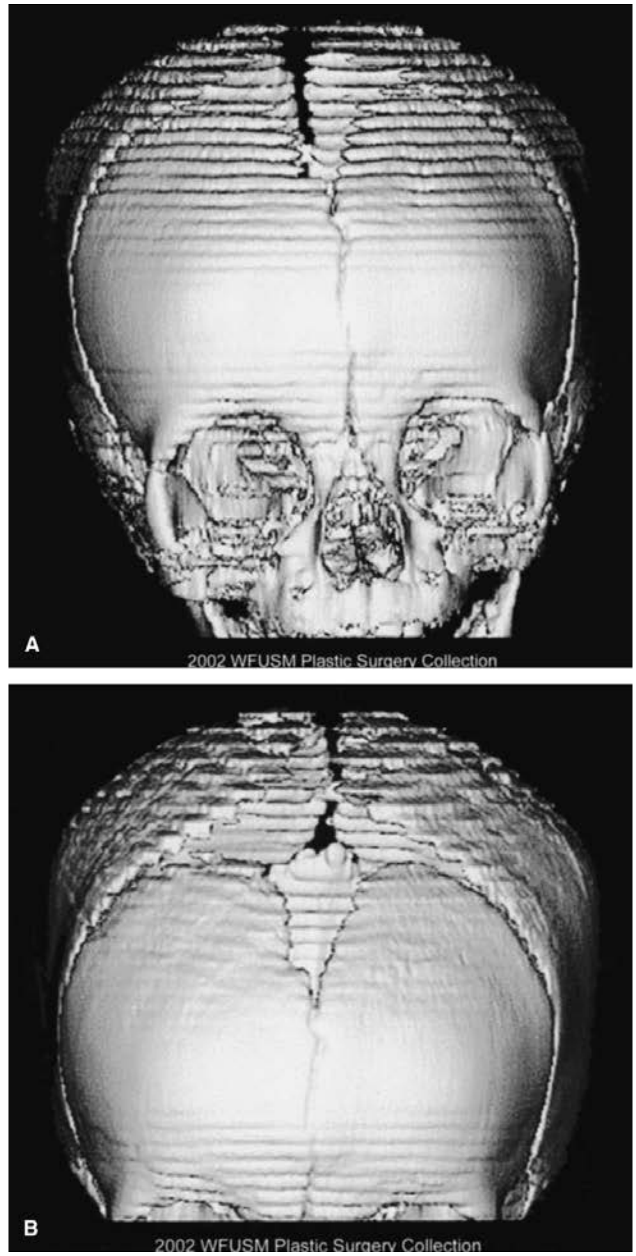

Fig 2 (A) Three-dimensional computed tomography (CT) scan before being reformatted into standardized orientation. (B) Three-dimensional CT scan after being reformatted and placed into standardized orientation.

x and *z* coordinates of the nasion and posterior aspect of the foramen magnum were aligned to correct for flexion, extension, and axial rotation. The *z* coordinates of the frontozygomatic suture lines were then aligned to correct for lateral flexion. The transaxial center of the skull, defined to be the *x* coordinate of the posterior aspect of the foramen magnum and the *y* coordinate of the anterior aspect of the foramen magnum, was then translated to the center of the image volume.

Once the three-dimensional scans were refor-

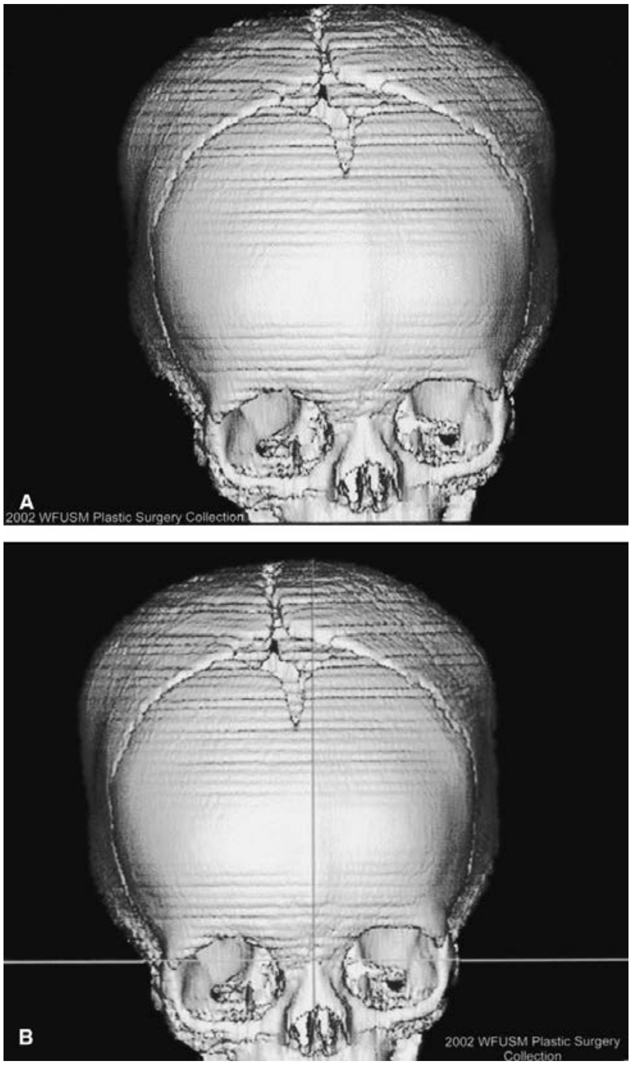

Fig 3 (A) A second three-dimensional computed tomography (CT) scan before being reformatted into standardized orientation. (B) A second three-dimensional CT scan after being reformatted and placed into standardized orientation.

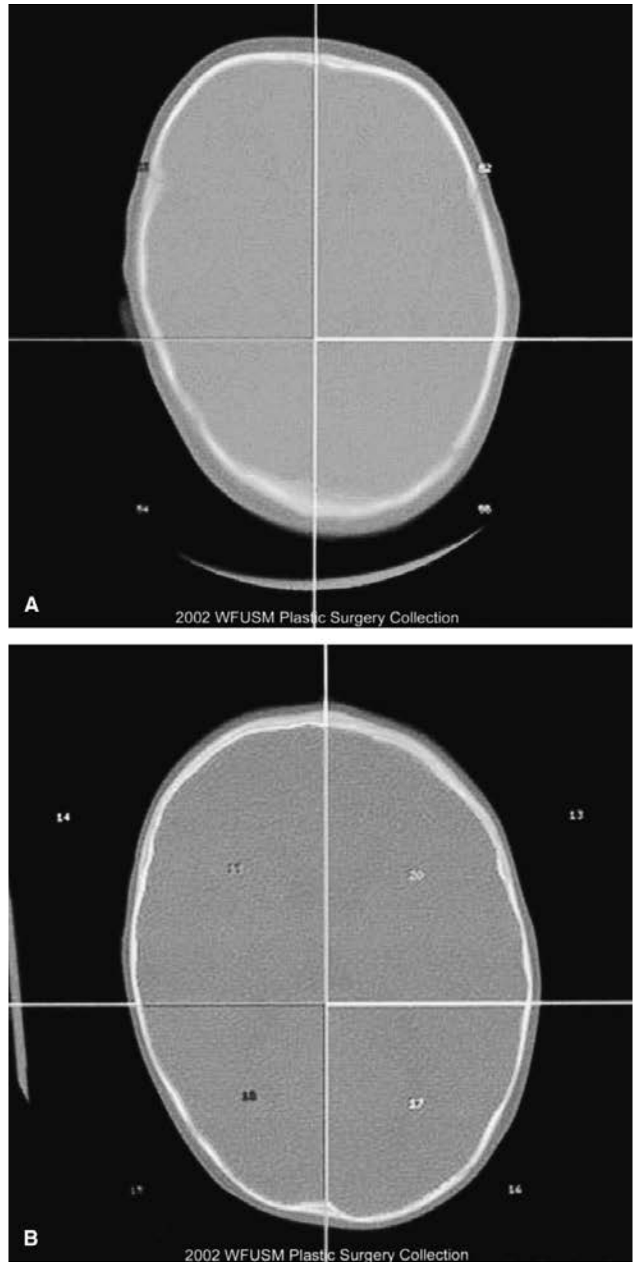

Fig 4 (A) A reformatted computed tomography (CT) scan before treatment. (B) A reformatted CT scan after helmet therapy. (C) A reformatted CT scan after treatment with determination of posterior quadrant volume.

matted into a standardized orientation, intracranial volumes were calculated. The intracranial boundary of the skull was determined automatically using thresholding. Additionally, some manual definition was used where there was incontinuity of the skull, such as the presence of an open suture or fontanelle. Intracranial volumes were calculated on a quadrant basis, and asymmetry was analyzed with regard to the hemispheres (left versus right) and the posterior quadrants. Statistical analysis of the data was performed using a paired *t* test.

Results

Thirty-four of the initial 69 patients completed the study protocol. There were 27 male infants (79%) and 7 female infants (21%). This increased prevalence among male infants is consistent with other case series and patient populations, which report a

Table 2. Compliance Rating

Wears all the time as instructed	Excellent
Wears 75% of time as instructed	Good
Wears 50% of time as instructed	Fair
Wears 25% of time as instructed	Poor
Wears 0% of time as instructed	Poor

male predominance of 60% to 70%.[13,17-19,21] The deformational plagiocephaly was more commonly on the right than on the left (62% versus 38%) and is consistent with that reported in the literature.[5,6,8,13,16–19,21,22] The mean age at the initial CT scan was 6.3 months, and the mean age at the follow-up scan after treatment was 14 months. The mean duration of soft shell helmet therapy was 7 months. The helmet was worn continuously during the first 12 weeks of treatment and thereafter was worn during sleeping only. Of the 34 children who completed the study protocol, 30 (88%) were considered to have average to above average compliance with therapy. Compliance with therapy was determined by a combination of clinical evaluation, physical examination, helmet assessment, and conversations with parents during regular clinic visits (Table 2). There were no complications associated with the helmet therapy throughout the entire study.

Efficacy of treatment was measured according to percent decrease asymmetry. This was calculated on a volumetric basis, comparing three-dimensional reconstructions of cranial CT scans before and after treatment, and analyzed with regard to the hemispheres and posterior quadrants. For children who were compliant with treatment, intracranial volume asymmetry was decreased by 39.1% and 36.2% for the hemispheres and posterior quadrants, respec-

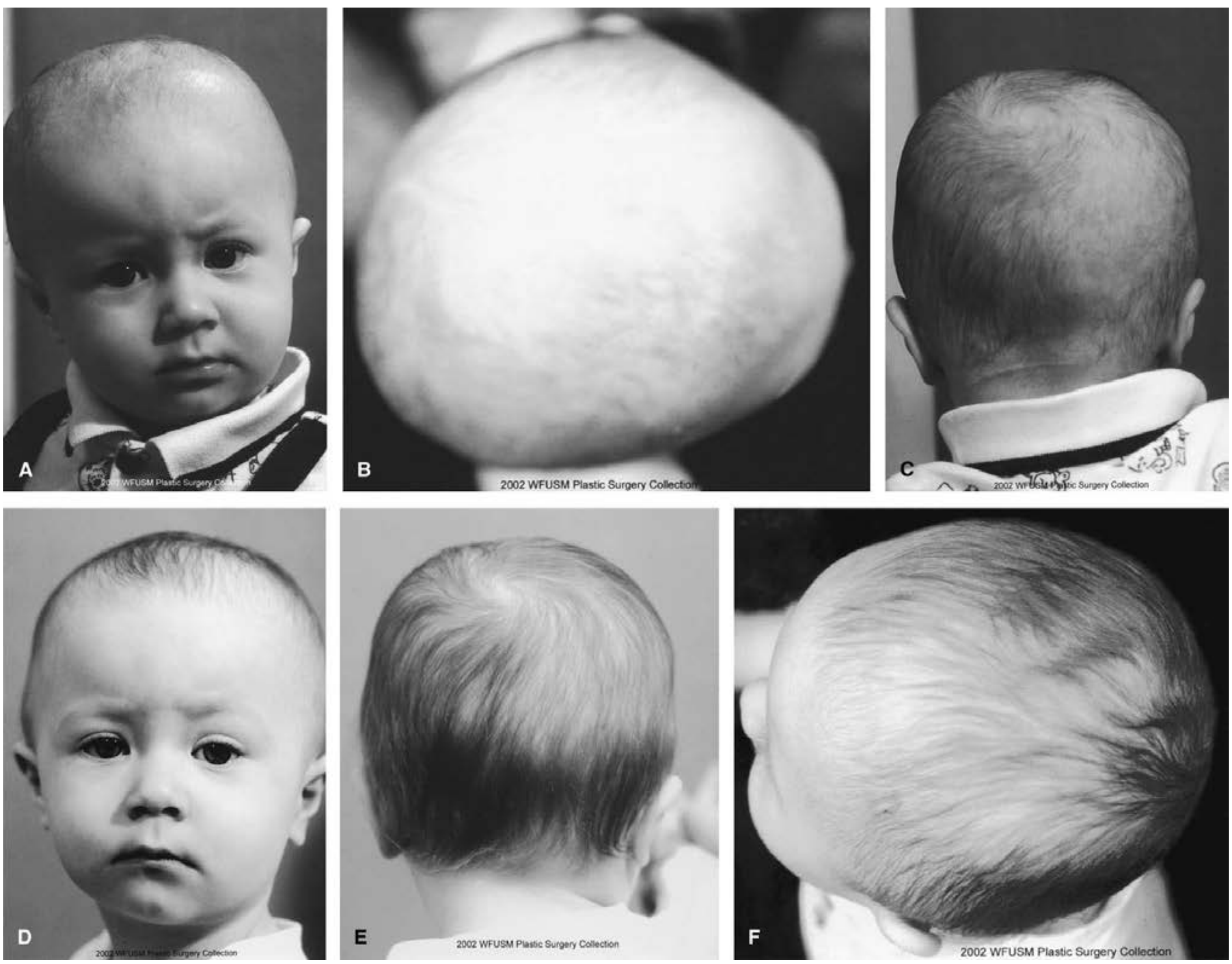

Fig 5 (A-C) Patient before helmet therapy. (D-F) Patient 6 months after helmet therapy.

tively. Statistical analysis was performed using a paired *t* test. For the hemispheres (left versus right), $P < 0.001$. For the posterior quadrants (back left versus back right), $P < 0.001$. The *P* value for the front quadrants was not significant at 0.357.

As the amount of correction required to achieve a "normal" level of skull symmetry is adjusted, the results achieved using soft shell helmet therapy vary correspondingly. When the normal symmetry level is adjusted from 100% to 97%, the percent decrease of asymmetry ranges from 39.1% to 54.2% for the hemispheres and from 36.2% to 42.3% for the posterior quadrants, respectively.

Discussion

The results of the study corroborate the efficacy of soft shell helmet therapy as an effective technique to decrease cranial asymmetry associated with deformational plagiocephaly (Figs 5–7). Our results are based on an objective outcome measurement, intracranial volumes derived from three-dimensional CT scans reformatted into a standardized orientation. Furthermore, this is the first measurement technique that uses intracranial volumes to assess efficacy of treatment of deformational plagiocephaly. Although the results obtained from this study are comparable to those of other studies reported in the literature, it is possible that a three-dimensional volumetric correction equates to a significantly greater clinical improvement, and thus may not fully represent the overall clinical improvement.

The technique used in this study is completely independent of observer bias or patient compliance with obtaining measurements. Other measurement techniques described in the literature, such as anthropometric measurements, head tracings, clinical experience, and parental assessment, are observer dependent and potentially introduce a subjective component to the measurement process. By eliminat-

Fig 6 (A-C) Patient before helmet therapy. (D–F) Patient 6 months after helmet therapy.

Fig 7 (A-C) Patient before helmet therapy. (D-F) Patient 6 months after helmet therapy.

ing any subjectivity from the measurement process, CT scanning could be considered a more accurate technique for the assessment of efficacy of treatment. Although serial application of this measurement technique would expose infants to significant radiation exposure, and thus would not be recommended as a standard part of patient follow-up, the technique of using intracranial volumetric measurements is ideal to validate efficacy of soft shell helmet therapy.

There are numerous orthotic devices available for the treatment of deformational plagiocephaly. Several require infants to be followed in clinic on a frequent basis throughout the course of treatment. Soft shell helmet therapy does not necessitate frequent clinical visits and is a noninvasive technique that is well tolerated by infants. Additionally, it is cost-effective and economical, with the total cost of therapy ranging from $600 to $700. This therapy compares favorably with other more expensive and time-consuming therapies that have been reported in the literature.

Conclusions

The soft shell helmet therapy used by the North Carolina Center for Cleft and Craniofacial Deformities at the Wake Forest University Medical Center is an effective treatment of deformational plagiocephaly.

The objective method of quantifying efficacy of treatment used in this study validates this therapeutic modality for the treatment of deformational plagiocephaly.

The quantifiable decrease in intracranial volume asymmetry achieved with the use of soft shell helmet therapy compares favorably with other more expensive and time-consuming therapies that have been reported in the literature.

As a validated treatment modality for deformational plagiocephaly, insurance companies and third-party payers should appropriately increase their reimbursement rates for the treatment of deformational plagiocephaly by health care professionals.

REFERENCES

1. Argenta LC, David LR. Observations and thoughts on the changing constellation of cranial deformities. J Craniofac Surg 1998;9:491–492
2. Loveday BP, de Chalain TB. Active counterpositioning or orthotic device to treat positional plagiocephaly? J Craniofac Surg 2001;12:308–313
3. McAlister WH. Invited commentary: posterior deformational plagiocephaly. Pediatr Radiol 1998;28:727–728
4. Moss SD. Nonsurgical, nonorthotic treatment of occipital plagiocephaly: what is the natural history of the misshapen neonatal head? J Neurosurg 1997;87:667–670
5. Kane AA, Mitchell LE, Craven KP, et al. Observations on a recent increase in plagiocephaly without synostosis. Pediatrics 1996;97:877–885
6. Argenta LC, David LR, Wilson JA, et al. An increase in infant cranial deformity with supine sleeping position. J Craniofac Surg 1996;7:5–11
7. Sandove AM. Positional plagiocephaly. J Craniofac Surg 1996; 7:3
8. Turk AE, McCarthy JG, Thorne CH, et al. The "Back to Sleep Campaign" and deformational plagiocephaly: is there cause for concern? J Craniofac Surg 1996;7:12–18
9. American Academy of Pediatrics Task Force on Infant Positioning and SIDS. Positioning and SIDS. Pediatrics 1992;89: 1120–1126
10. Fowler GA. Baby may have a flat head, but parents shouldn't get too bent out of shape. US News and World Report, August 28, 2000:57
11. Rekate HL. Occipital plagiocephaly: a critical review of the literature. J Neurosurg 1998;89:24–30
12. Bruneteau RJ, Mulliken JB. Frontal plagiocephaly: synostotic, compensational, or deformational. Plast Reconstr Surg 1992; 98:21–31
13. Boere-Boonekamp MM, van der Linden-Kuipe LT. Positional preference: prevalence in infants and follow-up after two years. Pediatrics 2001;107:339–343
14. Papay FA. Special commentary on treatment of craniofacial asymmetry with dynamic orthotic cranioplasty. J Craniofac Surg 1998;9:18–19
15. Ripley CE, Pomatto J, Beals SP, et al. Treatment of positional plagiocephaly with dynamic orthotic cranioplasty. J Craniofac Surg 1994;5:150–159
16. Huang MH, Gruss JS, Clarren SK, et al. The differential diagnosis of posterior plagiocephaly: true lambdoid synostosis versus positional molding. Plast Reconstr Surg 1996;98:765–774
17. Kelly KM, Littlefield TR, Pomatto JK, et al. Importance of early recognition and treatment of deformational plagiocephaly with orthotic cranioplasty. Cleft Palate Craniofac J 1999;36: 127-130
18. Miller RI, Clarren SK. Long-term developmental outcomes in patients with deformational plagiocephaly. Pediatrics 2000; 105:E26
19. Littlefield TR, Beals SP, Manwaring KH, et al. Treatment of craniofacial asymmetry with dynamic orthotic cranioplasty. J Craniofac Surg 1998;9:11–17
20. Vles JS, Colla C, Weber JW, et al. Helmet versus nonhelmet treatment in nonsynostotic positional posterior plagiocephaly. J Craniofac Surg 2000;11:572–574
21. David DJ, Menard RM. Occipital plagiocephaly. Br J Plast Surg 2000;53:367-377
22. O'Broin ES, Allcutt D, Earley MJ. Posterior plagiocephaly: proactive conservative management. Br J Plast Surg 1999;52:18–23
23. Pollack IF, Losken HW, Fasick P. Diagnosis and management of posterior plagiocephaly. Pediatrics 1997;99:180–185