Diagnosis and management of deformational plagiocephaly

A review

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Object. The increase in the prevalence of nonsynostotic occipital deformational plagiocephaly in infants, which resulted from the American Academy of Pediatrics’ 1992 recommendation to have healthy infants sleep supine, has been accompanied by significant controversy in diagnosis and management. The controversy was exacerbated by the 1998 FDA classification of cranial orthotic devices as Class II devices requiring premarket notification, and the subsequent increase in treatment-associated costs.

Methods. Two independent reviews of the literature were conducted to clarify the objective evidence available within the context of pediatric craniofacial knowledge.

Results. Although deformational plagiocephaly is not a life-threatening problem, it is a source of disfigurement for children that may be detrimental to their well-being. Current methods for quantifying the degree of disfigurement have limited interrater reliability, and no prospective randomized controlled trials comparing the efficacy of cranial orthoses to repositioning and physical therapy protocols have been published. Despite this lack of Class I evidence, cranial orthoses are routinely and effectively used to treat persistent severe deformational plagiocephaly. The need for the current FDA regulations has not been supported by clinical experience and reported complications.

Conclusions. This review resulted in the following recommendations: 1) more parental education is needed to minimize the development and progression of deformational plagiocephaly; 2) mild deformity can be treated with repositioning and physical therapy protocols; and 3) severe deformity is likely to be corrected more quickly and effectively with cranial orthosis (when used during the appropriate period of infancy) than with repositioning and physical therapy. The available data do not support the need for FDA classification for cranial orthoses as Class II devices requiring premarket notification. Removal of the regulations, which centralized production of the orthoses to larger companies and markedly increased charges, will probably eliminate much of the controversy and parental anxiety generated by marketing strategies. (DOI: 10.3171/2009.1.PEDS08330)

KEY WORDS • cranial banding • cranial headband • cranial helmet • cranial orthosis • craniosynostosis • deformational plagiocephaly

PLAGIOCEPHALY, derived from the Greek word “plagio,” meaning “bent, slanted, oblique,” and “kephale,” which means “head,” describes an asymmetrical, flattened deformity of the skull that can occur anteriorly or posteriorly.14 Decades ago, anterior flattening from prone positioning was more common, and 10% of healthy infants had plagiocephaly.42,52 Currently, the majority of anterior plagiocephaly cases are caused by unilateral craniosynostosis with premature fusion of the coronal suture, and rarely results from external molding forces. By contrast, the vast majority of occipital plagiocephaly cases are “positional” or “deformational” and result from external forces applied to the pliable infant skull in utero or postnatally. The prevalence of true lambdoid synostosis with premature fusion of the suture is estimated at 3 in 100,000 (0.003%).49 The prevalence of deformational plagiocephaly at 4 months was recently estimated at 19.7%, but others have suggested a prevalence of up to 48%.19,51

Nonsynostotic deformational plagiocephaly was recognized at least several decades ago, but the topic received relatively little attention due to its low prevalence (1 in 300 infants).8 In 1992, the AAP Task Force on Infant Positioning and SIDS recommended that healthy infants be positioned on the back or side when the child is put down for sleep.3 This “Back to Sleep” campaign resulted in a dramatic decrease in the incidence of SIDS.

Abbreviations used in this paper: AAP = American Academy of Pediatrics; CVA = cranial vault asymmetry; MDI = Mental Developmental Index; OFC = orbitofrontal head circumference; PDI = Psychomotor Developmental Index; SIDS = Sudden Infant Death Syndrome.
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from 1.2/1000 live births in 1992 to 0.56/1000 in 2001. A marked increase in the prevalence of deformational plagiocephaly was also noted, with the presence of cranial asymmetry in healthy newborn singletons in the US estimated at 13% in 2002. Therefore, deformational plagiocephaly is currently a relatively common problem faced by families and their physicians.

Deformational plagiocephaly results from either intrauterine forces or postnatal positioning. Unilateral deformational plagiocephaly occurs more often on the right side (54–71%), perhaps because the occipital anterior presentation is more common at birth. It may also be related to innate brain factors, similar to the higher prevalence of right-hand–dominant individuals. Risk factors are primiparity, maternal age ≥ 35 years, breech position, prolonged labor and assisted vaginal delivery, oligohydramnios, cephalohematoma, and male sex. The risk in twins or plural births is much higher than in singletons, with asymmetry found in 56%. Regardless of the initial cause, during sleep in the supine position the child's head repeatedly comes to rest on the same flat area, and without intervention the deformity is likely to persist or progress.

Any predilection for deformational plagiocephaly can be minimized by providing the infant with a minimum of 30 minutes of “tummy time” while the child is awake each day. Prior to 3–4 months of age, infants can be repositioned, but after this age the efficacy of this therapy is reduced due to the infant’s ability to regulate its own position. For those infants with associated muscular torticollis, neck stretching exercises often lead to improvement over several weeks. Repositioning and physical therapy were routinely used prior to the recent increase in the prevalence of deformational plagiocephaly, and these techniques continue to provide improvement for a subset of infants.

For infants who fail to improve with repositioning by 6 months of age and who continue to have a severe deformity, many pediatric neurosurgeons and plastic surgeons recommend that these children be treated with a cranial orthosis. Cranial banding devices, variously referred to as headbands, helmets, or orthotic devices, were first published in the modern era by Clarren. An individual mold or topographic scan is taken of the infant's head and a corresponding helmet is made. Passive helmets allow room for growth in the flattened areas while minimal pressure is applied in the areas with bossing. Active helmets actually apply compression to the bossed areas, with the theory that this allows for more rapid correction. The cranial bands, however, do not constrict normal cranial growth, but will minimize further bossing and allow the flattened areas to round out. Typically, the cranial bands are worn for 23 hours a day for 3 months. The band is reassessed every few weeks for passive designs and weekly for active designs, and it is adjusted to optimize the cranial shape and minimize skin irritation. Traditionally, pediatric craniofacial surgeons have worked in collaboration with various orthotic specialists to provide cranial orthoses to patients in need at affordable prices. In 1998, Cranial Technologies, a commercial entity, successfully petitioned the FDA to classify cranial orthoses as Class II devices requiring premarket approval, a “de novo” application, which remarkably also implied that their device was novel. Suddenly, orthotists who had been producing helmets successfully for decades were forced by the FDA to contract with large companies or obtain FDA approval if they wanted to continue to serve patients in need of cranial orthoses. This classification process and the associated marketing in the lay media resulted in a marked increase in both the anxiety among parents and the price of the cranial orthoses. Although the manufacturing costs remained stable, the charges increased at least 300–400%, and many third-party payers became reluctant to cover their insured patients. Most Medicaid patients were denied coverage. The use of cranial bands and the associated controversies around effectiveness, cost, and regulation has continued to generate significant discussion among pediatric neurosurgeons.

Methods

PubMed, a search engine used to access the MEDLINE database, was used to search for the following terms: “deformational plagiocephaly,” “positional plagiocephaly,” “cranial orthotic device,” “cranial orthosis,” “cranial banding,” “cranial helmet,” and “craniotosynostosis.” Relevant articles were selected and the reference lists from those articles were also reviewed for other relevant articles. Overall, 63 articles were read and evaluated for the quality of evidence presented and potential commercial bias. To judge the quality of the studies, the following classifications were used: Class I, evidence from a randomized controlled trial; Class II, evidence from a prospective trial that compared ≥ 2 treatments in a nonrandomized manner; Class III, evidence from a retrospective case series with historical controls; and Class IV, evidence from a prospective or retrospective case series with no control or comparison group. Studies were reviewed separately by each author.

Potential commercial bias is a significant concern for the literature on this topic. There is undoubtedly a financial impact related to the use of cranial orthoses that has the potential to bias the outcomes of studies. Indeed, many of the studies were written by individuals who are employees or consultants for some of the major helmet manufacturers. In addition, much of the literature was published prior to the current practices used to screen for conflict of interest in the publication and editorial review process. Commercial bias was not necessarily easily discernible in an objective manner, and needs to be accepted as a potential methodological flaw in the literature.

Results

Criteria for Diagnosis

Deformational plagiocephaly is characterized by unilateral occipital flattening accompanied by anterior displacement of the unilateral ear, contralateral parietal bossing, and often unilateral frontal bossing with contralateral frontal flattening; these characteristics give the head a parallelogram shape when it is viewed from the vertex. A subset of infants (13.1–31%) has asymmetry noted at birth.
although most develop the asymmetry during the first 2 months of life.\textsuperscript{36,44} Bilateral flattening occurs in 7–22% of infants with deformational cranial abnormalities.\textsuperscript{15,36,60} The majority of infants (79–84%) in many series have associated torticollis, whereas other series report a lower prevalence of associated torticollis (14.5–20%).\textsuperscript{8,31,32,36,39,57,59} A recent study of consecutive newborns in the Netherlands showed that 6.1% have asymmetry present at birth and that 22.1% of those with a normal shape at birth develop asymmetry by 7 weeks of age.\textsuperscript{60} Another study described a higher prevalence of asymmetry at birth.\textsuperscript{58} Bilateral flattening, or deformational brachycephaly, causes central occipital flattening with bilateral parietal bossing.\textsuperscript{4}

The diagnosis of deformational plagiocephaly is a clinical one made primarily by taking a patient’s history and performing an examination.\textsuperscript{2} In the past, plain radiographs or CT scans were obtained. These imaging studies are associated with radiation exposure and can be misleading due to sclerosis along the suture.\textsuperscript{45} As an alternative to procedures using ionizing radiation, ultrasound screening for fused cranial sutures has been used.\textsuperscript{48,59} Although ultrasound provides high sensitivity (100%) and specificity (89%), it has not been used frequently, most likely because the diagnosis is primarily made by clinical examination in most cases.\textsuperscript{39}

Proposed measures to document the severity of the cranial deformity include anthropomorphic measurements and grading scales based on visual inspection by experienced, nonbiased observers.\textsuperscript{4,31,37} Some authors also argue that the parent/caregiver’s perception should be included because the problem is a deformity in a child that is visible to others.\textsuperscript{6,46} Others are wary of including the parent’s perception due to multiple sources of bias. The treatment regimens for deformational plagiocephaly, either repositioning/physical therapy or cranial orthoses, require significant caregiver involvement. Their investment in the treatment regimen may influence their assessment of the outcome.

Anthropomorphic measurements are often obtained by using calipers to measure standard cranial diameters: CVA,\textsuperscript{25,27,37,38} diagonal difference,\textsuperscript{17} transcranial difference,\textsuperscript{50} and the transcranial diameter.\textsuperscript{59} Moss\textsuperscript{58} proposed defining severe deformity as a CVA measurement > 12 mm. Others have used this criterion to test the validity and reliability of the CVA obtained with calipers.\textsuperscript{37} Mortenson and Steinbok\textsuperscript{37} showed that experienced examiners achieved acceptable intrarater reliability (κ = 0.98 and 0.99), but only moderate interrater reliability (κ = 0.42). In addition, 1 study included < 38% of the total eligible patients in their series because they included only those patients who were measured pre- and posttreatment by a single examiner who was not blinded to the treatment course. To cope with the difficulty of obtaining reliable measurements with calipers, Loveday and de Chalain\textsuperscript{52} used an artist’s flexicurve tube to conform circumferentially around the infant’s head, and then they traced the outline. They reported reproducibility with this technique within 2 mm. They calculated the cranial index (cranial width divided by cranial length × 100 ± 4%; normal range 75–85%), and the CVA index (CVA index = the difference between the 2 cranial diagonals divided by the shorter diagonal × 100 ± 5%; normal < 3.5%). The authors argued that indices eliminate variations due to the cranial size (either because of natural variation or the age of the patient), which can be an issue with CVA. More recently Zonenshain et al.\textsuperscript{64} proposed using the cranial index of symmetry as an objective and convenient method of measurement. The cranial index of symmetry is 100% in children with a normal cranial shape; this index was consistently > 90% in all control infants (mean 96.3 ± 1.2%, 8 children) and < 85% in infants with deformational plagiocephaly (mean 81.9%, 8 children). Although this technique showed a significant difference between healthy infants and those with plagiocephaly, the reproducibility and interrater reliability have not been evaluated and the software is not widely distributed. Some newer technologies may lead to more objective and standardized measurements of cranial asymmetries. Plank and colleagues\textsuperscript{46} looked at the use of a 3D laser scanner to assess head shape and the response of plagiocephaly to treatment. Although these laser technologies show promise, currently their costs are prohibitive for clinicians and the devices are owned by the orthotic companies themselves.

Several authors have noted the poor correlation between anthropomorphic measurements and appearance.\textsuperscript{37,44} Argenta\textsuperscript{4} proposed a 5-point scale for patients with unilateral deformity and a similar 3-point scale for patients with bilateral flattening (deformational brachycephaly). For patients with a Type I deformity who are < 4 months old, he recommends repositioning and stretching exercises. For infants > 4 months in age or for those with asymmetrical ears (Type II), he recommends cranial orthosis therapy. A recent study from the Netherlands tested the reliability of this scale among various health-care providers, a group that included infant health-care physicians, pediatric physiotherapists, and manual therapists.\textsuperscript{55} Twenty infants with deformational plagiocephaly were rated by 9 clinicians trained in applying the scale. This study found overall moderate interrater reliability for Argenta’s scale (weighted κ = 0.54), although reliability scores for 2 of the 3 physician pairs fell within the substantial agreement range (κ = 0.6–0.8).\textsuperscript{54} The reliability of the Argenta scale has not been tested among pediatric craniofacial surgeons. Mortensen and Steinbok\textsuperscript{37} evaluated a 3-point visual scale and found poor reliability when comparing the severity category obtained from the CVA and the visual scale. Losee et al.\textsuperscript{31} used a 9-point visual scale, but no reliability studies have been performed using this scale.

Natural History

Determining the efficacy of interventions in part depends on understanding the natural history of the disorder. In an observational epidemiology study from the Netherlands, 623 infants diagnosed with deformational plagiocephaly by infant care physicians from an original population of 7609 healthy infants were followed prospectively from early infancy for 2–3 years.\textsuperscript{7} The prevalence was 8.2%, with the highest prevalence at 4 months. Documentation showed that almost all parents (96%) received repositioning instructions. Although some children were lost to follow-up, including those released from the study at 1 year if the plagiocephaly had resolved, 45% of
the 129 children examined at 2–3 years had residual occipital flattening based on the physician’s evaluation. By extrapolating back to the original 623 infants who were diagnosed before 6 months of age, the authors estimated that 25% of the children with deformational plagiocephaly at 6 months had residual flattening at 2–3 years, or an overall prevalence of 2.4% at 3 years. Approximately 10% received physical therapy for plagiocephaly and/or torticollis, and only 3 children were treated with a cranial orthosis. Because this was an observational study, no attempt was made to compare the outcome of interventions. In another study in New Zealand, investigators prospectively followed every fourth infant from a pool of 1092 births, with an 87.7% enrollment rate, and 90.5% of enrolled infants were followed for 2 years. The researchers found an overall prevalence of residual plagiocephaly at 2 years of 3.3%. These results suggest that without treatment beyond repositioning and stretching exercises, 2–3% of children are left with a deformity of unknown severity as toddlers.

Developmental Delay and Other Impairments

Many families of infants with deformational plagiocephaly are concerned that the asymmetrical cranial shape will affect the child’s development. In several series, a subset of infants was classified as delayed, although the classification rarely was made using rigorous testing regimens that are standardized to detect subtle differences. For example, in multiple series of infants with deformational plagiocephaly, 11.6–12.8% of infants had reportedly had delayed milestone achievement. The researchers found an overall prevalence of residual plagiocephaly at 2 years of 3.3%. These results suggest that without treatment beyond repositioning and stretching exercises, 2–3% of children are left with a deformity of unknown severity as toddlers.

In addition to the decrease in the incidence of SIDS, pediatric primary care providers have noted that infants placed supine for sleep with minimal prone time while awake are likely to have a period of relatively delayed motor development that then resolves by 18 months. The early motor skills achievement tests focus on activities related to prone position and upper-body strength. In a prospective study of 351 infants recruited at < 2 months of age with an 87% follow-up rate, infants placed prone achieved early motor milestones earlier than those placed supine. No difference was noted in the achievement of later motor milestones, including sitting unsupported and ambulation. In a similar study, 343 full-term infants were evaluated at 4 and 6 months at the well-child visits with the Denver scale of neurodevelopment, and the scores were correlated with sleep position. At 4 months, infants who slept supine were less likely to roll over than those who slept prone (p < 0.0001). These studies suggest that any reports evaluating development in infants with deformational plagiocephaly need to account for sleep position to obtain an accurate comparison.

No studies have evaluated the developmental outcomes of infants with deformational plagiocephaly in a rigorous manner. Panchal et al. evaluated 42 infants with nonsynostotic plagiocephaly at a mean age of 8.4 months with the Bayley Scales of Infant Development-II (MDI and PDI) and compared their scores to standardized population norms rather than a local control group. In studies of this type, the Bayley scores are compared with a local control group matched for factors that influence developmental outcomes: sex, gestational age, birth weight, other neurodevelopmental disorders, socioeconomic status, and maternal education. The differences are typically presented using these means as well as by classification into the standard curve, with scores ≥ 85 defined as normal, 70–84 defined as borderline (mild) delay, and < 70 defined as severely delayed. This study did not present the means, and although the authors evaluated whether the type of medical insurance affected outcomes, they did not control for other influences that are known to affect infant development scores, such as maternal education. The authors found that infants with deformational plagiocephaly were slightly less likely than the population norm to have mild delay on the MDI (8.7 vs 12.5% of the standardized distribution), but more likely to have severe delay (8.7 vs 2.3%). If the proportion of infants with below-normal (< 85) versus normal (≥ 85) MDI scores were compared in a chi-square analysis of deformational plagiocephaly versus the population norm, no significant difference was present (p > 0.5). Infants with deformational plagiocephaly were more likely to have mild (19.6 vs 11.1% for norms) and severe delay (13 vs 1.6% for norms) on the PDI. The proportion of infants with a PDI score below normal was significantly more than the standardized population norm (p < 0.004, chi-square test). These results suggest that a subset of infants with deformational plagiocephaly may have delayed motor development. Because the infants in this study were tested during the period of early motor skills and were not compared with a local control group of supine sleepers, the difference in motor skills probably reflects the transient delay in motor development observed in infants with minimal prone awake time. This explanation is likely because infants with minimal “tummy time” are at higher risk for deformational plagiocephaly.

A recent study from the Netherlands using multivariate analysis found that the only independent predictive factor of deformational plagiocephaly was that infants exposed to prone positioning ≥ 3 times/day were at lower risk. Supine sleeping position did not show statistical significance as an independent risk factor, suggesting that other factors contribute substantially to the risk of deformational plagiocephaly. A more recent study used the Bayley infant development scales to assess delay in 173 infants with deformational plagiocephaly (110 consecutive prospective, and 63 retrospective cases); the authors did not account for sleep position. On the MDI, 90% of the infants had scores in the normal range, 7% had moderate delay, and 3% were delayed. On the PDI, 74% had scores in the normal range, 19% had moderate delay, and 7% had severe delay. Their finding that torticollis was associated with higher MDI scores suggests that methodological problems may have been present in the study. Importantly, for the 23 infants without the confounding factors that are known to predispose to delay, the MDI and PDI scores were in the expected range, leading the authors to conclude that “children without confounding factors do not have an increased incidence of development delay despite deformational plagiocephaly.” Together, these studies of early infant development do not suggest
that deformational plagiocephaly by itself is a risk factor for delayed development in infants.

Fowler et al.\(^9\) compared detailed neurological examinations of 49 infants with deformational plagiocephaly to 50 age-matched controls with normal cranial shape. The only difference was that “altered” tone (not specifically hypertonia or hypotonia) was associated with deformational plagiocephaly. No difference was noted in gross or fine motor scales, and the study did not control for sleep position. This study is reassuring because it failed to detect any difference in motor achievement.

Three studies describing the developmental outcome of older children who had deformational plagiocephaly as infants also were not performed in a rigorous manner. Miller and Clarren\(^56\) used a survey to evaluate developmental outcomes of older children who were treated as infants for deformational plagiocephaly. From a pool of 254 patients, 181 parents/caregivers were invited to participate in the study, and 63 (37.6%) responded (that is, only 24.8% of the original 254 participated). Cranial orthoses were used to treat 36%, and repositioning with stretching was used for the others. Families reported that 39.7% of the children with a history of deformational plagiocephaly received some special therapy services in school and that 34.9% had an individualized educational plan, whereas only 7.7 and 6.6%, respectively, of controls (non–age-matched siblings) received such support. The authors believed that treatment with a cranial orthosis was not a risk factor for delay, nor did it improve developmental outcome. No standard level or type of delay was noted.\(^9\) In another questionnaire type of study conducted to assess long-term outcome in infants with deformational plagiocephaly, Steinbok et al.\(^57\) found similar results. Per parental report, 33% of the children had received long-term learning assistance and 14% were in special classes. Similar to the other studies, no difference in long-term delay, as assessed by the need for educational accommodations, was noted between the group treated with repositioning and that treated with cranial orthosis. Interestingly, in a recent validated questionnaire study from the Netherlands,\(^16\) no delay was reported by parents 3.3 ± 0.6 years after cranial orthotic treatment compared with healthy controls.

In addition to cognitive delay and neurological function, concern about vision development in infants with deformational plagiocephaly has been raised. In a Class III/IV study, Siatkowski et al.\(^53\) examined 40 consecutive infants with deformational plagiocephaly who were referred to the ophthalmology clinic. The authors found that constriction of ≥ 1 hemifields by at least 20° occurred in 35% of the infants. They found no correlation between the laterality of visual deficit and of the plagiocephaly. They also relied on normative standards for comparison rather than a control group from their own clinic, which can be problematic because the reliability of visual field testing in infants can be quite variable.

Mandibular asymmetry has also been raised as a potential issue. A recent Class IV study described orthodontic abnormalities in 28 children randomly selected from a pool of 111 with deformational plagiocephaly.\(^25\) Because no control group was used to define the prevalence and severity of these abnormalities compared with other children, the impact of these abnormalities remains unclear.

A primary reason for treating deformational plagiocephaly is to minimize disfigurement and the associated negative social consequences. Steinbok et al.\(^57\) used a survey to assess the long-term impact in children in western Canada. From a consecutive pool of 278 infants, 65 families responded to a questionnaire. According to the authors, the nonresponders did not differ from responders. The mean age of the patients at the time of the questionnaire was 8.9 years. Of the 65 children, 18 were treated as infants with cranial orthoses, and the remainder with repositioning. At long-term follow-up of at least 5 years after the initial diagnosis, no difference in parental perception of aesthetic outcome was noted between patients in the 2 treatment regimens. Parents reported a “very abnormal” appearance in 2 (3%), and a “mildly abnormal” appearance in 25 (39%), with the remainder “normal.” Parents also reported that 7.7% of the children had commented on their own asymmetry and that 4.6% reported occasional teasing. In a study from the Netherlands, quality of life outcomes were assessed using a validated questionnaire. No difference was found at long-term follow-up between those treated with cranial orthoses for Argenta deformity type ≥ 3 and healthy controls. This survey included mood, behavior problems, anxiety, social functioning, motor function, and communication.\(^16\) Although the methodology of these studies is not optimal, together they suggest that the long-term impact of deformational plagiocephaly on self-image and quality of life affects a small percentage of children.

Repositioning and Physical Therapy

No Class I study has been performed to document the efficacy of supervised repositioning and physical therapy compared with no intervention. In a Class III study, Moss\(^58\) prospectively treated 66 patients with mild to moderate deformity, which was defined as a CVA < 12 mm, with repositioning and therapy. Only 1 infant failed to improve and eventually required treatment with a cranial orthosis; this result suggests that repositioning effectively treats mild to moderate deformity. Similarly, in a Class IV retrospective case series, Hellbusch et al.\(^18\) found that active repositioning improves cranial asymmetry.

A recent study by Rogers et al.\(^50\) describes using a cranial cup (a modifiable, individualized, relatively inexpensive device made by orthotists) to optimize the cranial shape in infants < 4 months old. In a Class III study with historical controls, they found that the cup was more effective than repositioning and stretching exercises (p < 0.001), by using the transcranial difference obtained in a nonblinded manner as the outcome parameter.

Some infants with associated torticollis will have concomitant improvement in cranial shape with the resolution of torticollis, whereas other infants will have a persistent cranial deformity despite the improvement in torticollis.\(^13\) Although much discussion has occurred about the primary cause of deformational plagiocephaly versus torticollis, the issue of primary versus secondary does not affect management, because both issues need to be addressed if they are present.\(^35\)
Cranial Orthoses

A subset of infants with deformational plagiocephaly will fail to show significant improvement by 6 months of age, even with an adequate trial of repositioning.47 No Class I studies have been performed to compare cranial orthotic treatment with repositioning and therapy. A few authors have attempted a meta-analysis of the deformational plagiocephaly literature.6,34,40,49,51 Uniformly, they have noted the lack of quality studies in the field, including the lack of blinding, the use of different measurement techniques without proven reliability or validity, and inadequate nonrandomized control groups. Bialocerkowski et al.6 surveyed the English literature published between 1983 and 2003 and identified 16 papers, all of which used Class III or IV data. In 12 papers, no comparison groups were included. The remaining 4 papers compared cranial orthotic treatment to repositioning and physical therapy by using nonrandomized groups. These authors determined that potential commercial bias was present in 37.5% of the papers, but these assessments are subjective. Despite these limitations that precluded a formal meta-analysis, the authors concluded that the trends of using repositioning and therapy for effective treatment of mild to moderate deformity and cranial orthoses for severe deformity are consistently supported in the literature. The more recent studies continue to note the same deficiencies in evidence quality.34,40,51

Class III and IV studies of varying quality have been reported that compare repositioning and physical therapy regimens to treatment with cranial orthoses. Most studies used a treatment algorithm that generally mimics clinical practice. In most studies, the infants with persistent severe deformational plagiocephaly at a certain age (typically 6 months) or those in whom a trial of repositioning and stretching fails are treated with cranial orthoses in a standardized algorithm rather than initial prospective randomization. In an early study, Clarren8 offered helmet therapy to 43 infants with deformational plagiocephaly (Class III). Fifteen families declined to use the helmet and formed the control group of patients who were treated with therapy and repositioning. The outcomes were quantified using a 2-point grading scale based on cranial measurements, with a ratio > 0.9 considered normal (2+). Three patients ceased helmet therapy due to dermatitis (in 1 infant) or dissatisfaction with the helmet (in 2 infants). Using the grading scale, 76% of the 25 helmet-treated patients had an excellent outcome, compared with none in the group treated without helmets. Although the study has limitations in its design and methodology, a strong trend demonstrating improved efficacy of cranial orthoses over control is suggested.

More recent studies have all shown similar trends: for example, Pollack et al.47 reported a prospective series of infants treated with a standardized algorithm, a Class IV study. Half of the infants improved to a normal cranial shape with repositioning. The remaining half, consisting of patients who failed to improve with repositioning, was treated with cranial orthoses. In a Class IV retrospective study by O’Broin et al.,48 85% of families completed a questionnaire after cranial orthosis treatment and reported significant improvement. Littlefield (the director of Research and Development for Cranial Technologies, the maker of the DOC Band) et al.22 documented the efficacy of cranial orthosis in a Class IV study with several significant limitations, including selected inclusion of only 37.5% of treated patients. In another study, Kelly and colleagues23 published a Class IV series describing 190 patients selected from a pool of 477. In a third Class IV study, Teichgraeber et al.60 reported retrospectively on 132 patients treated with positioning and 292 treated with cranial orthoses, and showed that the cranial orthoses significantly decreased asymmetry. In a recent Class IV study of long-term outcomes of parental satisfaction measured using a 10-point scale, those children treated with cranial orthoses improved from a mean pretreatment score of 3.6 to a posttreatment score of 7.5.50 The Class IV studies all had limited methodologies.

In a Class III study, Mulliken et al.29 reported outcomes of 114 patients treated with repositioning (63) or cranial orthosis (51). Pretreatment and posttreatment cranial measurements were available for only 27% of the infants treated with repositioning and for 71% of the cranial orthosis patients. These investigators found that the cranial asymmetry decreased by 6 mm in the cranial orthosis group, compared with 2 mm in the repositioning group. In a second Class III study, Vles et al.52 compared orthoses with repositioning in a prospective study of 105 infants in whom the choice of therapy was decided by the parents. The outcome was assessed according to a 10-point scale assigned by the parents. In this study, the pretreatment deformity score was significantly worse for infants who received a helmet than for those treated with repositioning (p = 0.018), the outcome score was better for those treated with a cranial orthosis (p < 0.01), and the helmet treatment period took one-third of the time needed for repositioning. In a third Class III study, Loveday and de Chalain32 compared the outcomes of 45 infants treated with repositioning and therapy to 29 treated with cranial orthotic helmets. The therapy regimen was determined by the physician’s recommendation, not by randomization, and the follow-up period varied. There was no difference in outcomes between the 2 techniques, but the infants who underwent repositioning were treated ~ 3 times longer than the infants treated with cranial orthoses. Given that the infants entered treatment at approximately the same age, this implies that the orthotic devices rounded the skull more quickly than repositioning with stretching. In a fourth Class III study, 298 consecutive infants were treated according to a standardized algorithm.17 If significant asymmetry was present at 6 months, or if repositioning failed to improve the cranial shape, the child was treated with a cranial orthosis. These investigators found that significantly better improvement occurred with the cranial orthosis than with repositioning (p < 0.007); they used the diagonal difference as the outcome parameter. A fifth retrospective Class III study of 105 infants treated based on a standard algorithm showed that 45% failed to improve with repositioning and were treated with a cranial orthosis.33 Using a 9-point visual scale (nonblinded to treatment type), the authors found that significantly better improvement occurred with cranial orthoses compared with repositioning and stretching (p < 0.05).31

Plank et al.46 recently did a prospective study of 225...
patients to assess the effect of orthoses versus repositioning therapy. All patients in the study were referred for the orthosis, and the control group was the 17 patients for whom the parents declined this treatment option. Their assessment was performed with a 3D laser scanner (OrthoAmerica STARscanner), and all patients in the treatment arm received a STARband. Looking at 25 measurement variables, the investigators found that the treatment group had improvement in all 25 parameters, whereas the control group had improvement in only those 12 parameters attributed to growth of the head. Although the laser scanning technique may have promise for assessing the condition, the methodology of this study does not allow for accurate comparisons, due to the small and nonrandomized control group.

In contrast to these short-term studies, 2 retrospective Class III long-term outcome studies suggest that after several years there may be no significant difference between repositioning and cranial orthotic therapy, although both studies had significant methodological issues. Jalaluddin et al. reevaluated 303 children from an initial pool of 447 between 3 and 5 years of age (mean 4 years old) after either repositioning or cranial orthosis treatment as infants by using CVA measurements. The method of determining which therapy was used was not reported, and both groups had mild to moderate asymmetry (mean CVA < 12 mm) before treatment. At long-term follow-up, no difference was found in the mean CVA between the repositioning and cranial orthosis groups. This study suggests that there is no difference in long-term outcome for mild to moderate plagiocephaly with the 2 types of treatment. In a small Class IV study no pretreatment improvement of growth-adjusted CVA was found in 28 patients with a 5-year follow-up. The non–growth-adjusted pretreatment CVA and an estimate of those with severe plagiocephaly was not reported. The lack of improvement probably reflects the small sample size and other study design issues. Although these studies have methodological issues, they support the generally accepted practice that cranial orthoses are not superior to repositioning and therapy for mild to moderate plagiocephaly.

Surgery for deformational plagiocephaly is rarely indicated, and there are few, if any, recent publications that address outcomes. Surgical therapy will not be discussed further.

**Discussion**

*Current Practices for Diagnosis and Prevention of Deformational Plagiocephaly*

Current practices among the majority of pediatric neurosurgeons are presented to offer a framework within which to evaluate the current literature and to formulate recommendations. The diagnosis of deformational plagiocephaly can usually be made from the history and examination of the patient. Because deformational plagiocephaly is so prevalent now, many pediatric primary care physicians are comfortable with the diagnosis in patients seen routinely. If there are any concerns, the child can be evaluated by a pediatric specialist with expertise in craniofacial disorders and neurodevelopment. These specialists include pediatric neurosurgeons, pediatric plastic surgeons, or a pediatric craniofacial team clinic, although in many areas pediatric specialist resources may be limited. A timely evaluation within a few weeks is optimal because the interventions are time dependent, but evaluation for plagiocephaly may not be necessary before 3–4 months of age because many cases self-correct by this age. In cases for which the origin of a cranial shape irregularity is unclear, early referral should be considered so that surgical options such as endoscopic release can be considered. In addition, deformational plagiocephaly may occur in the presence of true craniosynostosis. An assessment by a pediatric neurosurgeon or plastic surgeon is especially necessary in such patients, because surgical treatment is often required for the true craniosynostosis.

Although radiographs or CT scans were routinely obtained in the last decade to assist with making the diagnosis, imaging studies are now usually only necessary if an additional concern or issue arises. In general, to minimize the exposure of infants to unnecessary radiation and sedation, imaging studies should only be ordered by a specialist, who will be able to establish the diagnosis on clinical grounds alone, without imaging, in the vast majority of patients. That is, imaging need not be obtained routinely by the primary care physician. Most craniofacial surgeons now only obtain plain radiographs in a small minority of patients (those with some atypical finding), and proceed directly to CT scans with 3D reconstructions for that subset of infants undergoing surgical repair for true craniosynostosis. Besides the radiation exposure, plain radiographs and standard CT scans can provide misleading information that suggests possible true lambdoid synostosis, and this misinformation can cause additional, unwarranted concern for parents. Similarly, radiographs or other imaging studies are rarely indicated for infants with torticollis, unless there is progressive torticollis with other clinical findings to suggest a rare process.

*Current Practices for Prevention and Nonorthotic Management of Deformational Plagiocephaly*

Treatment practices vary due to physician preference and geography. A typical management paradigm is presented to provide the basis for the interpretation of the literature that follows. The prevalence of deformational plagiocephaly peaks at 4 months, and it can be minimized or prevented by an informed positioning program (see Appendix). These recommendations are reviewed here because they are the most effective method to minimize deformational plagiocephaly before it becomes problematic. We would like to stress that the most effective way to eradicate the problem of deformational plagiocephaly is to educate primary care physicians and parents about proper infant positioning.

*Current Practices for Cranial Orthoses*

Despite a vigorous effort (see Appendix) to minimize cranial asymmetry in infants, some will probably develop
persistent plagiocephaly due to supine sleeping. Fortunately, approximately half of all infants with prominent deformational plagiocephaly present at 4 months will have significant improvement by 6 months of age. During this period, most infants begin spending much less time resting on the occiput as they sit up and move about more. Because many infants will have marked improvement in the cranial shape by 6 months of age, many clinicians do not routinely begin cranial orthotic treatment prior to 6 months, except for exceptionally severe deformities. A subset of infants with deformational plagiocephaly will fail to show significant improvement by 6 months of age, even with an adequate trial of repositioning and therapy. Some infants with associated torticollis will have concomitant improvement in cranial shape with the resolution of torticollis, whereas other infants will have a persistent cranial deformity despite the improvement in torticollis. For infants with severe deformational plagiocephaly despite conservative treatment and improvement in torticollis, a cranial molding helmet can provide significant improvement in the cranial shape and minimize disfigurement. Infants typically show significant improvement after the initial several weeks in the cranial orthoses, and achieve most of the correction by 3 months.

Management Controversies

For several reasons, these general recommendations for management of deformational plagiocephaly are fraught with controversy, even though they are supported by literature. Issues and areas of uncertainty include the natural history of the disorder without treatment, distinguishing mild and moderate from severe deformity, the efficacy of cranial orthoses, the financial implications of treatment, and the relative lack of quality studies. Deformational plagiocephaly is unlike many other disorders treated by pediatric neurosurgeons in that it does not cause potentially life-threatening or debilitating neurological deficits. Nevertheless, one cannot underestimate the significant concern this condition can cause to parents/caregivers and primary care providers.

Natural History

One source of controversy is the natural history of the deformity without treatment. Two recent epidemiological studies found a prevalence of residual plagiocephaly of 3.3% at 2 years and 2.4% at 3 years. The prevalence may continue to diminish over time, although this has not been documented. We estimate that ~0.5–1% of children probably enter school with noticeable plagiocephaly. No studies of early infant development have shown that those with deformational plagiocephaly are at higher risk of developmental delay. Two long-term outcome studies conducted using questionnaires suggest that children who had deformational plagiocephaly as infants are at higher risk for special services in school, but both studies had significant methodological limitations. A more recent study performed using a validated questionnaire detected no differences between children with a history of deformational plagiocephaly and a control group. Better long-term studies to assess developmental outcomes are warranted, because developmental achievement is crucial to becoming an independent, productive adult.

Assessing Degree of Severity

Another issue is the lack of an agreed-upon system to distinguish infants with a mild to moderate deformity from those with a severe deformity or quantifying the deformity. As with other types of craniosynostosis, there is no standard valid and reliable measurement of the cranial deformity in deformational plagiocephaly. Various anthropomorphic measurements are available, but are not universally applied and may not accurately convey the degree of deformity and subsequent posttreatment correction. To place this discussion in context, consider the reliability of OFC measurements. Pediatric neurosurgeons routinely use these measurements to evaluate management issues in our patients. Multiple examiners obtain OFC measurements, and substantial to excellent interrater agreement has been found in reliability studies. Yet the range of error for OFC measurements, even though the statistical reliability is high in studies designed to assess reliability, may be enough to affect the outcome of research studies that use these measurements. Obtaining precise measurements to document cranial asymmetry with calipers in squirming infants is much more difficult than obtaining the OFC, and the issues with statistical analysis may obscure the assessment of true deformity or its improvement. Other techniques to quantitate the deformity have been developed to determine the severity of plagiocephaly, but no measurement technique that is widely available has established reliability or validity. Newer technologies such as laser scanning may also be of use in the future.

Visual scales, such as the one proposed by Argenta, are promising tools for the assessment of plagiocephaly, although the single reliability study for this scale that was performed among primary care physicians and other ancillary health-care providers in the Netherlands, who had minimal experience assessing craniofacial deformity, may not reflect the results that would be expected in the US if the reliability was tested among experienced pediatric craniofacial surgeons. Infants with severe cranial deformity who are referred to a craniofacial team (second-line health care) are not routinely seen by the health-care providers who participated in this study. In addition, the sample size was small and may have been underpowered to reflect the reliability statistic accurately. The evaluators did not consistently rate the cranial shape as abnormal and also doubted the existence of Grade 5 (where vertical cranial growth is found in addition to the parallelogram with facial scoliosis). Although Grade 5, fortunately, occurs much less frequently than the milder grades, it is not uncommon in the craniofacial clinics in the US. A study testing the reliability of Argenta’s or a similar scale among experienced pediatric craniofacial surgeons with adequate power and prevalence is warranted.

At the current time, the diagnosis of deformational plagiocephaly remains primarily a clinical decision and should be made by an experienced clinician. Due to the prevalence of deformational plagiocephaly, many pedi-
atric primary care providers are competent to diagnose this condition. If there are any concerns that the child has more than typical deformational plagiocephaly, a referral to a pediatric craniofacial surgeon is often appropriate. Reliance on anthropomorphic measurements instead of clinical judgment to validate the diagnosis may be inappropriate, but a grading scale that is both objective and easily reproducible needs to be established and widely accepted. Given the lack of a standard reliable measurement, most pediatric craniofacial surgeons currently classify patients into mild, moderate, and severe categories based more on clinical judgment than any other criteria.56

Treatment Options

The use of cranial orthotics in older infants or in infants with other neurological issues is another area of controversy. Approximately 85% of cranial growth occurs during the 1st year.47 Because infants typically can remove the helmet themselves by 1 year, and because the rate of cranial growth and thus reshaping slows tremendously during the 2nd year,23 infants rarely have much improvement with treatment after 1 year of age.45 Although some pediatric craniofacial surgeons will treat infants up to 18 months, most do not initiate cranial orthotic treatment after 1 year. One paper published by Littlefield et al.29 presented 4 selected patients > 1 year of age who achieved some improvement with cranial orthoses. The paper did not state the total number of infants who began treatment at > 1 year of age from whom these 4 were selected. Some clinicians are also hesitant to prescribe the helmet in a child with microcephaly. Although clinical experience and 1 study have shown that the cranial orthoses do not restrict normal cranial growth, the influences on growth and pressure gradients may be different for those with limited brain growth, such as former preterm infants with microcephaly from encephalomalacia.23

The rate of complications from cranial orthoses is low. Few authors have published reports of complications,8,16,32 but these have included poorly fitted helmets, skin rash, and skin pressure ulcers. Anecdotally, we have used multiple cranial orthotic suppliers, with consistent results. Less than 1% of our patients have experienced contact dermatitis or skin breakdown. At the time of classification of cranial orthoses as Class II devices by the FDA, the potential complications cited in addition to skin-related problems were head and neck trauma, impairment of brain growth and development, asphyxiation, and eye trauma. Except for the rare patient with contact dermatitis or skin breakdown, none of the other complications have been reported in the literature or have been mentioned during extensive discussions at our multiple national meetings. Because the prevalence of deformational plagiocephaly is so high and cranial orthoses have been widely used for > 20 years, it is unlikely that these other complications have occurred without any mention in the literature.

Cost Considerations

Much of the controversy surrounding cranial orthoses has been due primarily to the financial impact that occurred when they were classified as Class II medical devices. For at least 2 decades prior to 1998, cranial orthoses were made by local orthotists (similarly to other orthotic devices) without reports of any complications except rare pressure ulcers or contact dermatitis. The request to the FDA for classification as a Class II device (requiring premarket notification) rather than a Class III device was made by Cranial Technologies (FDA 21 CFR Part 882, docket # 98N-0513). After the FDA ruling, the costs for cranial orthoses increased up to 10-fold in some markets. The cascade of the effects from the inflated costs, such as the reluctance of third-party payers and Medicaid to cover the treatment, has had the net result that infants from economically disadvantaged families are denied treatment available to other children.

Unfortunately, the high cost for cranial orthoses has markedly affected perception and discussion. It has distorted the discussions about the indications for and efficacy of orthoses and brought undue industry pressure into what should be a medical deliberation. In 2006 the American Association of Neurological Surgeons/Con- gress of Neurological Surgeons Joint Section on Pediatric Neurological Surgery submitted a petition to the FDA to exempt cranial orthoses as Class II medical devices and thereby reduce their price and make them more available to infants. Multiple parties (including the pediatric neurosurgical leadership and several small orthotic providers) supported the petition for exemption because the costs associated with the process have restricted access for economically challenged families. A few entities with major commercial interests challenged the petition to protect their financial position. They argued that the increase in price was related to the additional time spent with the infants in follow-up to adjust the orthoses and was not due to manufacturing costs, although prior to the FDA requirements, orthotists routinely provided the same service intensity at a much lower cost. Other orthotic devices that treat children with established major disabilities, such as spine and extremity orthotic devices for children with open spina bifida, are not subject to the same premarket notification requirements and have not been associated with the same price inflation and marketing strategies. The FDA rejected the petition, primarily on the grounds that the complications of orthotic use were not adequately discussed. In fact, no literature to support serious adverse events exists, and the extensive experience of the pediatric neurosurgical community also supports the safety profile of the devices. The FDA, despite many requests, failed to produce a single medical device report outlining a complication or complaint related to helmet therapy. The orthotic manufacturing industry introduced tremendous commercial bias into the petition process by hiring a large law firm to defend the Class II status, and thereby ensured that prices for these devices will remain high. We contend that the FDA classification and major price increases were due to the involvement of a large national corporation that saw a financial benefit to regulation of the device. They succeeded in persuading the FDA to regulate the orthoses, despite opposition from the clinicians with the most expertise in caring for these children. The ones who suffered in this process were the children who need the devices the most.
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Limitations of Current Literature

There are no studies with Class I data for the treatment of deformational plagiocephaly, and this is unlikely to change in the near future. As discussed above, no reliable measurement or visual scale to assess deformity over time in a blinded manner has been established. Although treatment with cranial orthoses generates anxiety among families and lively discussion among medical professionals, the resources to conduct a multicenter study to obtain Class I data are limited. Financial support by orthotic device companies for these studies, except as an unrestricted grant, is inappropriate. Because these devices are already approved by the FDA, there is no incentive for industry to study them further. Therefore, such a study would require federal funds that are increasingly scarce. Because both funding and professional resources available to pediatric neurosurgeons are quite limited, these precious resources are currently directed toward life-threatening and debilitating problems such as brain tumors, hydrocephalus, epilepsy, and trauma. Most pediatric neurosurgeons and plastic surgeons generally follow the recommendations mentioned above to treat only those with persistent severe deformational plagiocephaly with cranial orthoses.

Class I studies are ideal, but are not essential to provide optimal care for our patients. For example, the recommendations for a supine sleeping positioning and the associated marked reduction in SIDS were not based on Class I evidence, and performance of a randomized trial of sleep position at this time is not ethically justifiable. Similarly, the algorithm of active repositioning and therapy for young infants or infants with mild to moderate deformity, and cranial orthoses for persistent severe deformity have been practiced widely in the US for 3 decades, with widespread efficacy and safety. The summation of evidence, including the natural history that half of infants will improve between 4 and 6 months with repositioning and therapy and that the optimal time to initiate cranial orthosis treatment for persistent severe deformity is ~ 6 months, argues against randomization in most contexts.

Commercial bias has had an impact in this arena and can make the results difficult to interpret. This methodological flaw was discussed earlier in this article. It is our opinion that studies with potential commercial bias were more likely to find utility in the use of the orthosis. However, although potential commercial bias appears to have affected the treatment regimen in some series, studies without potential commercial bias clearly show that the cranial orthoses were effective for a subset of infants with persistent severe deformational plagiocephaly. In national forums, most pediatric neurosurgeons report prescribing cranial orthoses for approximately one-third of the patients evaluated in their practices.

Conclusions

Although many of the individual studies in this field might be considered of suboptimal quality in this era of evidence-based medicine, when they are considered en masse, substantial evidence for guidelines emerge. We believe that parental education is one of the keys to prevention and treatment of this condition, and it needs to be instituted by the primary caregivers at a very early age. All infants should be placed supine in a safe environment for sleep to minimize the risk of SIDS and suffocation. Parents and caregivers should be encouraged to provide at least 30 minutes of supervised “tummy time” daily, especially for infants < 6 months old. If an infant has significant cranial asymmetry, true craniosynostosis should be excluded (usually by a detailed physical examination) and a program of repositioning and often physical therapy and/or stretching exercises should be initiated. If the infant demonstrates persistent severe deformity at 6 months, treatment with a cranial orthosis will probably improve the cranial shape at a faster pace, and more effectively, than active repositioning and therapy. Currently, the literature has not shown convincingly that children with deformational plagiocephaly are at higher risk for developmental delay, but families and health-care providers need to be vigilant about providing children with all educational opportunities and services that are needed. As with all areas of pediatric neurosurgery, the child’s best interest must remain the central premise of care.

Much of the controversy over these treatments has been generated and sustained by commercial involvement in cranial orthoses. Diminishing the financial contribution to the controversy by exempting cranial orthoses from Class II premarket notification will not endanger the safety of infants, but will decrease the associated costs, and thus minimize the 2-tier access to standard treatment that has evolved for economically disadvantaged children.

Appendix

Current Practices to Minimize the Prevalence and Severity of Deformational Plagiocephaly

Sleep Position. As part of the neonatal discharge instructions, the recommendation to place the infant supine in its own bed for sleep should be reviewed with the parents and caregivers by the hospital team. The 1992 AAP recommendations suggested a supine or a side sleeping position for healthy infants, with some exclusions for preterm infants and others.3 As more data became available, the guidelines were revised in 2000.2 The option of side sleeping was removed because infants positioned on the side can roll prone and suffer SIDS, and the exclusions were removed. It is currently recommended that all infants be placed supine for sleep.2 If the infant had medical problems that required prone positioning while in the hospital, such as very early preterm infants in incubators in the neonatal intensive care unit, parents should be reminded at hospital discharge that the recommendations for the home-going infant are to sleep supine and not to mimic the position used by the hospital staff at one point during the infant’s hospitalization.1 Parents should be encouraged to share the positioning recommendations with other childcare providers who may not be aware of the AAP recommendations.1

Supervised Prone Positioning. Examination of the SIDS outcomes data has also shown that the occasional prone position can be particularly dangerous for infants usually placed supine, with an 18-fold increase in SIDS found for infants placed prone who are routinely placed supine for sleep.3 Infants also should not sleep with an adult, especially on a couch or in a chair.1 As part of these instructions, it should be reinforced that the supine position is for sleep and that an infant should have at least 30 minutes a day of supervised prone time while awake. Prone “tummy time” speeds the acquisition of some early motor skills,33 and awareness of this enhancement of
motor development may encourage parents to focus more on prone time while awake. These recommendations should be reviewed and reinforced at the early “well-infant” visits. At the well-infant visits, the cranial shape can readily be assessed at the time of the head circumference measurement.

Repositioning and Physical Therapy. If an infant has early occipital flattening up to 4 months of age, repositioning recommendations should be reviewed, reinforced, and, in selected cases, physical therapy may be beneficial. Many infants have associated torticollis, and instructions for neck stretching exercises can be given. The combination of instruction from the primary physician’s office plus reinforcement by physical therapy is a more effective approach for many families. If the infant resists repositioning measures, parents should be reassured that many infants are recalcitrant to repositioning efforts, because many new parents especially harbor the angst of being considered an inadequate parent. With neck exercises, torticollis typically resolves or markedly improves within several weeks. Progression of torticollis despite compliance with a stretching program may indicate that the child needs additional evaluation.

Disclaimer

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

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