Congress of Neurological Surgeons

GUIDELINES

CONGRESS OF NEUROLOGICAL SURGEONS SYSTEMATIC REVIEW AND EVIDENCE-BASED GUIDELINE ON THE ROLE OF CRANIAL MOLDING ORTHOSIS (HELMET) THERAPY FOR PATIENTS WITH POSITIONAL PLAGIOCEPHALY

Sponsored by

Congress of Neurological Surgeons (CNS) and the Section on Pediatric Neurosurgery

Endorsed by

Joint Guidelines Committee of the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS) and American Academy of Pediatrics (AAP)

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This clinical systematic review and evidence-based guideline was developed by a physician volunteer task force as an educational tool that reflects the current state of knowledge at the time of completion. The presentations are designed to provide an accurate review of the subject matter covered. This guideline is disseminated with the understanding that the recommendations by the authors and consultants who have collaborated in its development are not meant to replace the individualized care and treatment advice from a patient's physician(s). If medical advice or

assistance is required, the services of a physician should be sought. The recommendations contained in this guideline may not be suitable for use in all circumstances. The choice to implement any particular recommendation contained in this guideline must be made by a managing physician in light of the situation in each particular patient and on the basis of existing resources.

ABSTRACT

Background: No evidence-based guidelines exist on the role of cranial molding orthosis (helmet) therapy for patients with positional plagiocephaly.

Objective: To address the clinical question: "Does helmet therapy provide effective treatment for positional plagiocephaly?" and to make treatment recommendations based on the available evidence.

Methods: The US National Library of Medicine Medline database and the Cochrane Library were queried by using MeSH headings and key words relevant to the objective of this systematic review. Abstracts were reviewed, after which studies meeting the inclusion criteria were selected and graded according to their quality of evidence (Classes I-III). Evidentiary tables were constructed that summarized pertinent study results, and, based on the quality of the literature, recommendations were made (Levels I-III).

Results: Fifteen articles met criteria for inclusion into the evidence tables. There was 1 prospective randomized controlled trial (Class II), 5 prospective comparative studies (Class II), and 9 retrospective comparative studies (Class II).

Conclusion: There is a fairly substantive body of non-randomized evidence that demonstrates more significant and faster improvement of cranial shape in infants with positional plagiocephaly treated with a helmet as compared to conservative therapy, especially if the deformity is severe, and provided that helmet therapy is applied during the appropriate period of infancy. Specific criteria regarding the measurement and quantification of deformity and the most appropriate time window in infancy for treatment of positional plagiocephaly with a helmet remain elusive. In general, infants with a more severe presenting deformity and infants who are helmeted early in infancy tend to have more significant correction (and even normalization) of head shape.

Short Title: Guideline on the Role of Cranial Molding Orthosis Therapy for Patients with Positional Plagiocephaly

Key Words: cranial molding orthosis, infants, plagiocephaly, positional plagiocephaly

RECOMMENDATIONS

1. Helmet therapy is recommended for infants with persistent moderate to severe plagiocephaly after a course of conservative treatment (repositioning and/or physical therapy).

   Strength of Recommendation: Level II—uncertain clinical certainty

2. Helmet therapy is recommended for infants with moderate to severe plagiocephaly presenting at an advanced age.

   Strength of Recommendation: Level II—uncertain clinical certainty

INTRODUCTION

The incidence of non-synostotic positional calvarial deformity, heretofore referred to as positional plagiocephaly, has seen a dramatic rise ever since the 1992 American Academy of Pediatrics (AAP) recommendation that infants be placed on their back to sleep in order to reduce the risk of sudden infant death syndrome.[1] Pediatricians are increasingly referring patients with skull asymmetry to outpatient neurosurgical and craniofacial clinics for evaluation and management.

Plagiocephaly is a general term used for patients with cranial asymmetry that may arise in infants subject to intrauterine constraint or extrauterine compression and is perpetuated by postnatal sleeping position and concurrent torticollis or other neuromuscular conditions. The most common form of plagiocephaly is referred to as posterior plagiocephaly, in which there is unilateral flattening of the parieto-occipital region resulting in a compensatory anterior shift of the ipsilateral ear and bossing or bulging of the ipsilateral forehead. Brachycephaly, in which there is symmetrical flattening of the entire occipital region, resulting in a foreshortened antero-posterior dimension of the skull with or without an elevation of the skull vertex, is the less common variant.

There is no standard treatment for positional plagiocephaly. Depending on clinical factors such as age and the severity of the presenting deformity, options for management may include observation, active repositioning therapy, physical therapy, cranial molding orthosis (helmet) therapy, surgery, or various combinations thereof. Surgery is rarely considered as a viable treatment alternative; the principal management decisions revolve around the issue of whether conservative measures (observation, repositioning, physical therapy) should be tried, how long to

persist with conservative treatment prior to instituting helmet therapy, and the criteria that need to be met in order to proceed to helmet therapy.

Helmets are generally custom-fitted cranial orthoses that are designed to be worn 23 hours a day for several months, until the child has achieved satisfactory cosmetic correction or they have outgrown their helmet. Frequent regular assessments are required to assess for cranial growth and the presence of any adverse effects, as well as to make any necessary adjustments to the device to allow for continual growth and change in shape of the calvarium. These orthoses may be passive (allow room for growth in the flattened areas while minimal pressure is applied to the areas with bossing) or active (compression is applied to the bossed areas, possibly resulting in a more rapid deformity correction).

Despite numerous attempts at synthesis of the data regarding the effectiveness of helmet therapy in the treatment of positional plagiocephaly,[2-7] controversy remains. The purpose of this systematic review is to address the clinical question: Does helmet therapy provide effective treatment for positional plagiocephaly?

METHODS

The Congress of Neurological Surgeons (CNS) and the Section on Pediatric Neurosurgery initiated a systematic review of the literature relevant to the management of positional plagiocephaly. Additional details of the systematic review are provided below and within the introduction and methodology chapter of the guideline.

Potential Conflicts of Interest

All guideline task force members were required to disclose all potential conflicts of interest (COIs) prior to beginning work on the guideline, using the COI disclosure form of the Joint Guidelines Committee of the American Association of Neurological Surgeons (AANS) and the CNS. The CNS Guidelines Committee and guideline task force chair reviewed any disclosures and either approved or disapproved the nomination and participation on the task force. The CNS Guidelines Committee and guideline task force chair may approve nominations of task force members with possible conflicts and restrict the writing, reviewing, and/or voting privileges of that person to topics that are unrelated to the possible COIs.

Literature Search

The task force collaborated with medical librarians to search for articles published in the US National Library of Medicine (PubMed/MEDLINE) database and the Cochrane Library for

the period January 1966 through October 2014, using the MeSH subject headings and PubMed search strategies provided in Appendix A. Manual searches of bibliographies were also conducted.

Article Inclusion/Exclusion Criteria

The task force reviewed the titles and abstracts to identify studies that would address the effectiveness of cranial remolding orthosis (helmet) therapy compared to other treatments for positional plagiocephaly (including no treatment). Studies in which there was no comparison group (uncontrolled) were excluded, as without a control or reference group, it is impossible to judge whether or not an intervention is effective. Studies that employed survey methodology were also excluded. Articles that met these criteria were independently reviewed by 3 of the authors, and appropriate studies were selected for inclusion into the evidence tables for this recommendation.

Search Results

The Medline plagiocephaly search (search #1) returned 88 abstracts, while the Medline brachycephaly (search #2) and Cochrane plagiocephaly/brachycephaly (search #3) searches returned 22 and 19 abstracts, respectively (Figure 1). After removal of duplicate results, 102 abstracts were screened in total. After review of the abstracts, 41 full-text articles were reviewed (38 articles were selected after reviewing the abstracts, and an additional 3 articles were obtained after examination of the bibliographies of the 38 initially selected articles). Of the 41 full-text articles reviewed, 26 were rejected for the following reasons: no comparison group,[8-28] use of a non-helmet orthosis,[29,30] comparison group did not have plagiocephaly,[31,32] and study used survey methodology.[33] Therefore, 15 articles satisfied our criteria for inclusion into the evidence tables.[34-48]

DISCUSSION

Of the 15 articles selected for inclusion into the evidence tables, there was one prospective randomized controlled trial (Class II), 5 prospective comparative studies (Class II), and 9 retrospective comparative studies (Class II). In general, the methodological quality of the studies was moderate; most suffered from similar design issues that affect the quality of data, and ultimately the strength of the inferences and recommendations that can be made.

Despite the size of the underlying population presenting for management of positional plagiocephaly, most studies were only able to enroll relatively small numbers of infants in each

treatment arm, which results in suboptimal statistical power. Moreover, convenience (non-randomized) sampling resulted in treatment groups that often had significant covariate imbalance with respect to important variables that relate to treatment outcome (such as patient age at initiation of treatment and severity of presenting deformity) as a result of treatment assignment being performed by physician or parent preference. This selection bias was pervasive in the non-randomized studies, and often resulted in a treatment effect against helmet therapy, as infants in the helmet therapy group tended to be older and tended to have more severe deformity than the comparison group.

Confounding of the principal treatment effect secondary to contamination of intervention(s) between treatment groups also led to difficulties in interpreting the data. Most often, this contamination took the form of infants entering the helmet group who previously underwent treatment with conservative therapy with less than satisfactory results. Bias as a result of contamination was present in several studies,[34,36,41] and, once again, would be expected to bias study results against helmet therapy, because of the older age and likely more severe deformity present at the time of initiating helmet therapy in the group of infants who crossed over.

There were also significant issues with respect to outcome ascertainment. Assessment of treatment outcome, whether it be change in 2- or 3-dimensional anthropometric measurements or subjective physician or parent evaluation, was done in a non-blinded fashion in all studies apart from the sole randomized controlled trial.[37] The absence of standardized criteria for the assessment of cranial asymmetry, both pre- and post-treatment, was clearly evident when one considers the heterogeneity of outcome measures used in the various studies. Moreover, the measurements chosen for analysis in any given study were not previously evaluated for their reliability and validity, making measurement bias a tangible concern when evaluating this body of literature. One could also be justified in questioning whether an observed statistically significant improvement in cranial asymmetry on the order of several millimeters has any clinical significance. Outcomes were often measured at different time points in the treatment (helmet) and comparison groups (usually when the infants were judged to have achieved an “acceptable cosmetic result”), further adding to the difficulty in determining the comparative effectiveness of different methods of treating positional plagiocephaly.

Despite these limitations, in aggregate, the body of evidence summarized in the evidence tables does allow for some general recommendations to be made. The significant heterogeneity

between studies with respect to critical elements of design, such as the study population, the nature of the intervention, and the assessment of treatment outcomes precludes, for the most part, any meaningful quantitative synthesis of the data; what follows is a largely qualitative review of the evidence relevant to this recommendation.

Helmet Therapy vs Conservative Therapy

A recently published randomized controlled trial[37] provided Class II evidence related to this recommendation (Table 1). Eighty-four infants aged 5-6 months were prospectively randomized to custom helmet therapy (n = 42) or to the "natural course of the condition" (n = 42). Importantly, all patients received physical therapy prior to randomization. The mean duration of therapy was 4 months. Outcomes were assessed at 2 years of age in a blinded fashion. Despite what appeared to have been an adequate block randomization schema, infants in the natural course group had more severe deformity, and infants in the helmet group had more brachycephaly. The overall conclusion of the trial was that helmet therapy has no added value in the treatment of moderate-severe positional plagiocephaly. This conclusion was based on the observations that no difference was seen in the primary outcome between the 2 groups, both on an intention-to-treat and per-protocol analysis; no significant differences between treatment groups were observed with respect to the secondary outcomes, including parental satisfaction; and that all parents reported one or more side effects of helmet therapy.

The conclusion of this trial stands in stark contrast to the remainder of the evidence uncovered during the course of this systematic review. The authors argue that their study has merit because it is one of the few that examined longer-term outcomes, focused on clinically meaningful differences in outcome measures rather than mere statistical significance, and because it comprehensively catalogued adverse effects related to helmet therapy.

The study does have some notable criticisms. The exclusion of infants with very severe deformity and those with neuromuscular issues, who are typical helmet candidates, limits the external validity of the results. Moreover, the study documented a very low participation rate, with only 21% of eligible participants being recruited into the trial. Although there was adequate power overall, the relatively small size of the treatment groups provides no insight into possible subgroup effects. There was no objective measure of compliance with helmet therapy, making it within the realm of possibility that the lack of efficacy of helmet therapy was because of suboptimal use of the device. Full normalization of head shape was observed in only 26% of

helmet therapy and 23% of natural course patients, a finding that once again alludes to possible suboptimal treatment of the presenting problem.

The Class II retrospective and prospective comparative studies summarized in Table 1 provide evidence in support of the notion that helmet therapy results in better outcomes than conservative therapy in infants with positional plagiocephaly. However, because of methodological deficiencies in the design of these studies and the relatively short duration of follow-up, the data are unable to prove that helmet therapy is, in fact, superior to alternative treatment modalities or the natural history of the condition with respect to improving an infant's head shape.

Several of these studies provide evidence that helmet therapy can result in equivalent or superior treatment outcomes compared to repositioning in a fraction of the overall treatment time. The study by Loveday et al[34] demonstrated similar changes in cranial vault asymmetry index (CVAI) in both the helmet and repositioning groups at the end of therapy, but the change was seen with a shorter duration of treatment in the helmet group. Since both groups commenced treatment at the same mean age, this result implies that helmet therapy results in a faster rate of improvement in head asymmetry. The fact that the mean age in the helmet group was 37 weeks, coupled with the fact that asymmetry was slightly worse in the helmet group at the initiation of therapy, may explain the relatively poor helmet results.

A retrospective comparison of 35 patients with positional plagiocephaly treated with active repositioning vs 35 patients treated with custom helmets published by Lipira et al[40] also demonstrated a statistically significant greater reduction in measures of asymmetry in the helmet group vs the repositioning group, specifically in the posterior head region. The mean duration of therapy was 5.2 months in the repositioning group vs 3.1 months in the helmet group.

In infants who were similar with respect to age at the initiation of treatment and the duration of treatment, Mulliken et al[42] reported significantly improved measures of asymmetry in those who were helmeted as compared to those who were treated with repositioning exercises. A high rate of loss to follow-up, as evidenced by the fact that pre- and post-treatment measures were available for only 17/63 infants in the repositioning group and 36/51 infants in the helmet group, limits the strength of these data. They recommended helmet treatment in infants less than 1 year of age, although no relationship was observed between the age at helmet initiation and the ultimate degree of correction.

Vles et al[46] studied 105 patients with positional plagiocephaly, 39 of whom were treated with repositioning and 66 who received helmet therapy. No anthropometric measures were used; rather, a subjective unvalidated deformity rating scale, scored by the infant's caregiver, was used. Although the pre-treatment severity was significantly worse in the helmet group, likely because the choice of treatment was made by the parents (selection bias), the final outcome was better in the infants who received a helmet. Moreover, treatment time with the helmet was only one-fifth as long as the repositioning treatment. The most improvement was seen in those infants with the most severe presenting deformity. No correlation was observed between the age at helmet initiation and the degree of correction.

A recent study by Kim et al[35] also alludes to a greater effect of helmet therapy vs repositioning therapy in infants with more severe deformity. Likewise, the study by Plank et al,[39] which examined 224 infants with moderate-severe positional plagiocephaly, the overwhelming majority of whom were treated with helmet therapy, demonstrated improved treatment outcomes in the helmet (n = 207) vs repositioning (n = 17) groups. This latter study in particular is suggestive of the notion that, in the subgroup of infants presenting with moderate-severe positional plagiocephaly, helmet therapy should be preferred over repositioning therapy.

Two similar retrospective studies by Graham, one in infants with brachycephaly[38] and the other in infants presenting with plagiocephaly,[36] also suggest that infants treated with helmet therapy had improved outcomes compared to those treated with repositioning therapy, despite the fact that in both studies, the initial deformity was more severe in the helmet group and the infants were older in the helmet group (patients in the helmet group did require a longer duration of treatment). In addition, subgroup analyses showed that early helmeting (<8 months) resulted in better outcomes compared to late helmeting (>8 months). The effect of age on helmet treatment outcomes has been validated in 2 recent prospective studies (Table 2).

Two studies, one by Clarren[43] and the other by Wilbrand,[45] examined the effect of helmet therapy on infants with positional plagiocephaly when compared to physical therapy. Whereas the study by Clarren was able to show improved outcomes in infants treated with a helmet based on a subjective outcome measure, a more formal outcome assessment by Wilbrand, using 3D photogrammetry, demonstrated improvement in asymmetry in helmeted infants, but at the end of treatment, no significant difference in the degree of asymmetry between helmeted and unhelmeted

infants was observed.

A very recent prospective, non-randomized longitudinal study by Kluba[44] examined treatment outcomes in 62 patients with plagiocephaly treated with a custom helmet vs 66 patients treated without a helmet. Patients in both groups were asked to continue with any previously instituted therapy (physical therapy, repositioning). However, details of previously initiated (and ongoing) non-helmet therapy were not recorded and may have differed between groups, thereby confounding the primary result of this study. In both groups, a statistically significant decrease in asymmetry was observed. Although children in the helmet group had more severe deformity at baseline, they showed significantly better improvement than the comparison group when the outcome was adjusted for the degree of initial deformity. In both groups, a weak positive correlation was observed between the extent of initial asymmetry and the extent of improvement, a finding that was also suggested by the work of Kim et al.[35]

Recommendation

1. Helmet therapy is recommended for infants with persistent moderate to severe plagiocephaly after a course of conservative treatment (repositioning and/or physical therapy).

   Strength of Recommendation: Level II – uncertain clinical certainty

Age at Initiation of Helmet Therapy and Outcome

Two prospective studies serve to clarify the relationship between age at initiation of helmet therapy and treatment outcomes that was suggested by some of the methodologically weaker retrospective studies.[36,38] Both studies examined patients with "significant" cranial asymmetry who appear not to have undergone any prior conservative treatment. The results of both studies were similar, although the recommended age cut-off between those infants who were expected to achieve a satisfactory treatment response and those expected to have a suboptimal response was slightly different between the 2 studies (Table 2).

Seruya et al prospectively assessed the results of custom helmet therapy in 346 patients in 7 pre-defined age groups ranging from <20 weeks to >40 weeks.[47] The degree of calvarial asymmetry was similar in all groups at the beginning of therapy. They found that all patients achieved normal calvarial symmetry at the end of helmet therapy, except those helmeted at >36

weeks of age. Improvement was seen even in infants aged >12 months at time of helmet therapy initiation. Duration of helmet therapy was positively correlated with age.

Similarly, Kluba et al[48] undertook a prospective comparison of the results of helmet therapy in 24 infants with plagiocephaly helmeted at age <6 months vs 38 helmeted at age >6 months. The degree of asymmetry was similar in both groups at the commencement of therapy, and a significant reduction in asymmetry was seen in both groups. Younger patients (<6 months) showed a greater decrease in asymmetry and attained values considered "normal." Children starting therapy later (>6 months) showed significantly less absolute improvement and did not attain values considered "normal." Duration of therapy was statistically significantly shorter in the younger patients.

Although the data were not robust enough to definitively determine the optimal time window in infancy for treatment of positional plagiocephaly with helmet therapy, it does appear that the earlier an infant is placed in a helmet, the better the treatment outcome. That being said, it must be remembered that young infants with positional plagiocephaly may see an improvement in cranial symmetry with conservative therapy or simply observation.

Recommendation

2. Helmet therapy is recommended for infants with moderate to severe plagiocephaly presenting at an advanced age.

   Strength of Recommendation: Level II – uncertain clinical certainty

CONCLUSION

There is a fairly substantive body of non-randomized evidence that demonstrates more significant and faster improvement of cranial asymmetry in infants with positional plagiocephaly treated with a helmet as compared to conservative therapy, especially if the asymmetry is severe, and provided that helmet therapy is applied during the appropriate period of infancy. As outlined above, specific criteria regarding the measurement and quantification of deformity and the most appropriate time window in infancy for treatment of positional plagiocephaly with a helmet remain elusive. In general, infants with a more severe presenting deformity and infants who are helmeted early in infancy tend to have better correction (and even normalization) of head shape.

The only randomized study pertaining to this recommendation provided data that showed no benefit of helmet therapy in the treatment of positional plagiocephaly in infants. Issues with

the design and execution of this study may explain why the randomized data conflicts with the majority of the non-randomized evidence.

When judging the totality of the evidence, it appears that currently accepted management of positional plagiocephaly in infants—using conservative therapy (repositioning and physical therapy) for the treatment of mild/moderate deformity in younger infants and reserving helmet therapy for more severe deformity, especially in those older infants who have failed to see improvement with conservative measures—can be justified by the data. Evidence in favor of helmet use must be tempered by the lack of data regarding the extent of natural improvement of positional plagiocephaly, the long-term effects of helmet therapy (and of "untreated" plagiocephaly), and the costs associated with helmet therapy.

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REFERENCES

1. American Academy of Pediatrics AAP Task Force on Infant Positioning and SIDS: Positioning and SIDS. *Pediatrics.* 1992;89(6 Pt 1):1120-1126.

2. Bialocerkowski AE, Vladusic SL, Howell SM. Conservative interventions for positional plagiocephaly: a systematic review. *Dev Med Child Neurol.* 2005;47(8):563-570.

3. Paquereau J. Non-surgical management of posterior positional plagiocephaly: orthotics versus repositioning. *Ann Phys Rehabil Med.* 2013;56(3):231-249.

4. Rekate HL. Occipital plagiocephaly: a critical review of the literature. *J Neurosurg.* 1998;89(1):24-30.

5. Robinson S, Proctor M. Diagnosis and management of deformational plagiocephaly. *J Neurosurg Pediatr.* 2009;3(4):284-295.

6. Xia JJ, Kennedy KA, Teichgraeber JF, Wu KQ, Baumgartner JB, Gateno J. Nonsurgical treatment of deformational plagiocephaly: a systematic review. *Arch Pediatr Adolesc Med.* 2008;162(8):719-727.

7. Mortenson P, Steinbok P, Smith D. Deformational plagiocephaly and orthotic treatment: indications and limitations. *Childs Nerv Syst.* 2012;28(9):1407-1412.

8. Lee WT, Richards K, Redhed J, Papay FA. A pneumatic orthotic cranial molding helmet for correcting positional plagiocephaly. *J Craniofac Surg.* 2006;17(1):139-144.

9. Kelly KM, Littlefield TR, Pomatto JK, Manwaring KH, Beals SP. Cranial growth unrestricted during treatment of deformational plagiocephaly. *Pediatr Neurosurg.* 1999;30(4):193-199.

10. Teichgraeber JF, Ault JK, Baumgartner J, et al. Deformational posterior plagiocephaly: diagnosis and treatment. *Cleft Palate Craniofac J.* 2002;39(6):582-586.

11. 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(2):127-130.

12. Lee RP, Teichgraeber JF, Baumgartner JE, et al. Long-term treatment effectiveness of molding helmet therapy in the correction of posterior deformational plagiocephaly: a five-year follow-up. *Cleft Palate Craniofac J.* 2008;45(3):240-245.

13. Teichgraeber JF, Seymour-Dempsey K, Baumgartner JE, Xia JJ, Waller AL, Gateno J. Molding helmet therapy in the treatment of brachycephaly and plagiocephaly. *J Craniofac Surg.* 2004;15(1):118-123.

14. Yoo HS, Rah DK, Kim YO. Outcome analysis of cranial molding therapy in nonsynostotic plagiocephaly. *Arch Plast Surg.* 2012;39(4):338-344.

15. Littlefield TR, Beals SP, Manwaring KH, et al. Treatment of craniofacial asymmetry with dynamic orthotic cranioplasty. *J Craniofac Surg.* 1998;9(1):11-17; discussion 18-19.

16. Ripley CE, Pomatto J, Beals SP, Joganic EF, Manwaring KH, Moss SD. Treatment of positional plagiocephaly with dynamic orthotic cranioplasty. *J Craniofac Surg.* 1994;5(3):150-159; discussion 160.

17. Kluba S, Schreiber R, Kraut W, Meisner C, Reinert S, Krimmel M. Does helmet therapy influence the ear shift in positional plagiocephaly? *J Craniofac Surg.* 2012;23(5):1301-1305.

18. Couture DE, Crantford JC, Somasundaram A, Sanger C, Argenta AE, David LR. Efficacy of passive helmet therapy for deformational plagiocephaly: report of 1050 cases. *Neurosurg Focus.* 2013;35(4):E4.
19. Bruner TW, David LR, Gage HD, Argenta LC. Objective outcome analysis of soft shell helmet therapy in the treatment of deformational plagiocephaly. *J Craniofac Surg.* 2004;15(4):643-650.
20. Moghaddam MB, Brown TM, Clausen A, DaSilva T, Ho E, Forrest CR. Outcome analysis after helmet therapy using 3D photogrammetry in patients with deformational plagiocephaly: the role of root mean square. *J Plast Reconstr Aesthet Surg.* 2014;67(2):159-165.
21. Thompson JT, David LR, Wood B, Argenta A, Simpson J, Argenta LC. Outcome analysis of helmet therapy for positional plagiocephaly using a three-dimensional surface scanning laser. *J Craniofac Surg.* 2009;20(2):362-365.
22. Schaaf H, Malik CY, Streckbein P, Pons-Kuehnemann J, Howaldt HP, Wilbrand JF. Three-dimensional photographic analysis of outcome after helmet treatment of a nonsynostotic cranial deformity. *J Craniofac Surg.* 2010;21(6):1677-1682.
23. Shamji MF, Fric-Shamji EC, Merchant P, Vassilyadi M. Cosmetic and cognitive outcomes of positional plagiocephaly treatment. *Clin Invest Med.* 2012;35(5):E266.
24. Pollack IF, Losken HW, Fasick P. Diagnosis and management of posterior plagiocephaly. *Pediatrics.* 1997;99(2):180-185.
25. Steinbok P, Lam D, Singh S, Mortenson PA, Singhal A. Long-term outcome of infants with positional occipital plagiocephaly. *Childs Nerv Syst.* 2007;23(11):1275-1283.
26. Govaert B, Michels A, Colla C, van der Hulst R. Molding therapy of positional plagiocephaly: subjective outcome and quality of life. *J Craniofac Surg.* 2008;19(1):56-58.
27. Elwood ET, Petronio J, Wood RJ. Parental satisfaction with the CranioCap: a new cranial orthosis for deformational plagiocephaly. *Cleft Palate Craniofac J.* 2005;42(4):340-343.
28. Katzel EB, Koltz PF, Sbitany H, Girotto JA. Treatment of plagiocephaly with helmet molding therapy: do actual results mimic perception? *The Cleft palate-craniofacial journal : official publication of the American Cleft Palate-Craniofacial Association.* 2011;48(2):205-209.
29. Rogers GF, Miller J, Mulliken JB. Comparison of a modifiable cranial cup versus repositioning and cervical stretching for the early correction of deformational posterior plagiocephaly. *Plast Reconstr Surg.* 2008;121(3):941-947.
30. Seruya M, Oh AK, Sauerhammer TM, Taylor JH, Rogers GF. Correction of deformational plagiocephaly in early infancy using the plagio cradle orthotic. *J Craniofac Surg.* 2013;24(2):376-379.
31. Meyer-Marcotty P, Bohm H, Linz C, et al. Head orthesis therapy in infants with unilateral positional plagiocephaly: an interdisciplinary approach to broadening the range of orthodontic treatment. *J Orofac Orthop.* 2012;73(2):151-165.
32. Schweitzer T, Bohm H, Linz C, et al. Three-dimensional analysis of positional plagiocephaly before and after molding helmet therapy in comparison to normal head growth. *Childs Nerv Syst.* 2013;29(7):155-1161.
33. Naidoo SD, Cheng AL. Long-term satisfaction and parental decision making about treatment of deformational plagiocephaly. *J Craniofac Surg.* 2014;25(1):160-165.

34. Loveday BP, de Chalain TB. Active counterpositioning or orthotic device to treat positional plagiocephaly? *J Craniofac Surg.* 2001;12(4):308-313.
35. Kim SY, Park MS, Yang JI, Yim SY. Comparison of helmet therapy and counter positioning for deformational plagiocephaly. *Ann Rehabil Med.* 2013;37(6):785-795.
36. Graham JM, Jr., Gomez M, Halberg A, et al. Management of deformational plagiocephaly: repositioning versus orthotic therapy. *J Pediatr.* 2005;146(2):258-262.
37. van Wijk RM, van Vlimmeren LA, Groothuis-Oudshoorn CG, Van der Ploeg CP, Ijzerman MJ, Boere-Boonekamp MM. Helmet therapy in infants with positional skull deformation: randomised controlled trial. *Bmj.* 2014;348:g2741.
38. Graham JM, Jr., Kreutzman J, Earl D, Halberg A, Samayoa C, Guo X. Deformational brachycephaly in supine-sleeping infants. *J Pediatr.* 2005;146(2):253-257.
39. Plank LH, Giavedoni B, Lombardo JR, Geil MD, Reisner A. Comparison of infant head shape changes in deformational plagiocephaly following treatment with a cranial remolding orthosis using a noninvasive laser shape digitizer. *J Craniofac Surg.* 2006;17(6):1084-1091.
40. Lipira AB, Gordon S, Darvann TA, et al. Helmet versus active repositioning for plagiocephaly: a three-dimensional analysis. *Pediatrics.* 2010;126(4):e936-945.
41. Losee JE, Mason AC, Dudas J, Hua LB, Mooney MP. Nonsynostotic occipital plagiocephaly: factors impacting onset, treatment, and outcomes. *Plast Reconstr Surg.* 2007;119(6):1866-1873.
42. Mulliken JB, Vander Woude DL, Hansen M, LaBrie RA, Scott RM. Analysis of posterior plagiocephaly: deformational versus synostotic. *Plast Reconstr Surg.* 1999;103(2):371-380.
43. Clarren SK. Plagiocephaly and torticollis: etiology, natural history, and helmet treatment. *J Pediatr.* 1981;98(1):92-95.
44. Kluba S, Kraut W, Calgeer B, Reinert S, Krimmel M. Treatment of positional plagiocephaly--helmet or no helmet? *J Craniomaxillofac Surg.* 2014;42(5):683-688.
45. Wilbrand JF, Hagemes F, Wilbrand M, et al. Nonsynostotic Cranial Deformity: A Six-Month Matched-Pair Photogrammetric Comparison of Treated and Untreated Infants. *Cleft Palate Craniofac J.* 2014;51(6):632-638.
46. Vles JS, Colla C, Weber JW, Beuls E, Wilmink J, Kingma H. Helmet versus nonhelmet treatment in nonsynostotic positional posterior plagiocephaly. *J Craniofac Surg.* 2000;11(6):572-574.
47. Seruya M, Oh AK, Taylor JH, Sauerhammer TM, Rogers GF. Helmet treatment of deformational plagiocephaly: the relationship between age at initiation and rate of correction. *Plast Reconstr Surg.* 2013;131(1):55e-61e.
48. Kluba S, Kraut W, Reinert S, Krimmel M. What is the optimal time to start helmet therapy in positional plagiocephaly? *Plast Reconstr Surg.* 2011;128(2):492-498.

Table 1 Helmet vs Conservative Treatment

Author (Year)	Title	Study Description	Data Class, Quality, and Reasons	Results and Conclusions
Van Wijk et al (2014)	Helmet Therapy in Infants with Positional Skull Deformation: Randomized Controlled Trial	84 infants aged 5-6 months prospectively randomized to custom helmet therapy (n = 42) or to the "natural course of the condition" (n = 42) All patients received physical therapy Mean duration of therapy was 4 months Outcome: change in skull shape from baseline to 24 months, as assessed by 2D anthropometric measures, including oblique diameter difference index	Class II Randomized controlled trial Block randomization schema—infants in the natural course group had more severe deformity and infants in the helmet group had more brachycephaly (significant differences) Blinded outcome assessment Outcome subject to measurement bias Intention-to-treat and per-protocol analysis (7 infants did not start their assigned therapy after randomization) 5 patients lost to follow-up 21% of eligible participants agreed to participate (limits external validity)	No difference in primary outcome between the 2 groups (intention-to-treat and per-protocol analysis similar) No significant differences between treatment groups in secondary outcomes, including parental satisfaction All parents reported one or more side effects of helmet therapy Helmet therapy has no added value in the treatment of moderate-severe positional plagiocephaly

Author (Year)	Title	Study Description	Data Class, Quality, and Reasons	Results and Conclusions
Kluba et al (2014)	Treatment of Positional Plagiocephaly—Helmet or No Helmet	Prospective analysis of treatment outcomes in 62 patients with plagiocephaly treated with a custom helmet vs 66 patients treated without Brachycephaly patients excluded Patients in both groups asked to continue with any previously instituted therapy (PT, repositioning) Mean age at institution of helmet therapy was 6.3 months Mean duration of helmet therapy was 4 months Outcome: cranial vault asymmetry index at end of therapy	Class II Prospective comparative study Selection bias—groups different at baseline with respect to severity of plagiocephaly at baseline (more severe in the helmet group) Details of previously instituted (and ongoing) non-helmet therapy were not recorded, and may have differed between groups Outcome subject to measurement bias Outcome assessed at different times in the 2 treatment groups (patients in helmet group were assessed at age 10.2 months whereas patients in control group were assessed at 18.5 months)	In both groups, a statistically significant decrease in asymmetry was observed Although children in the helmet group had more severe deformity at baseline, they showed significantly better improvement than the comparison group when the outcome was adjusted for the degree of initial deformity In both groups, a weak positive correlation was observed between the extent of initial asymmetry and the extent of improvement Clinical significance of observed treatment effect unclear

Author (Year)	Title	Study Description	Data Class, Quality, and Reasons	Results and Conclusions
Plank et al (2006)	Comparison of Infant Head Shape Changes in Deformational Plagiocephaly Following Treatment With a Cranial Remolding Orthosis Using a Noninvasive Laser Shape Digitizer	Prospective comparison of 207 patients with moderate-severe positional plagiocephaly treated with helmet to 17 patients treated without helmet Mean age of patients in both groups not documented Mean duration of therapy in both groups not documented Outcome: an assortment of 3D anthropometric measurements, including CVAI	Class II Prospective comparative study Selection bias—control group comprised of patients who refused helmet. Several control patients later decided to pursue helmet therapy and left the control group Details of therapy provided to control group patients not clearly specified Limited generalizability of laser scan results	Helmet therapy results in statistically significant changes in head shape and symmetry when compared to the control group Clinical significance of observed effect on outcomes is unclear

Author (Year)	Title	Study Description	Data Class, Quality, and Reasons	Results and Conclusions
Mulliken et al (1999)	Analysis of Posterior Plagiocephaly: Deformational versus Synostotic	Prospective comparison of 36 patients treated with a helmet and 17 patients treated with repositioning Mean age at initiation of helmet therapy was 5.5 months Mean duration of helmet therapy was 4.9 months Outcome: change in oblique transverse cranial diameter pre/post therapy	Class II Prospective comparative study High rate of loss to follow-up; - pre- and post-treatment measures were available for only 17/63 infants in the original repositioning group and 36/51 infants in the original helmet group Measurement bias	Improvement occurred in 52/53 patients Correction of asymmetry was better in those treated with a helmet compared to those managed with repositioning Age at initiation of helmet therapy was unrelated to the degree of improvement

Author (Year)	Title	Study Description	Data Class, Quality, and Reasons	Results and Conclusions
Kim et al (2013)	Comparison of Helmet Therapy and Counter Positioning for Deformational Plagiocephaly	Retrospective chart review of 27 patients with positional plagiocephaly, 21 who had helmet therapy and 6 who underwent counterpositioning Mean age at therapy initiation: 5.6 months for both groups Mean duration of therapy: 4.3 months for helmet vs 4.1 months for counterpositioning Outcome: change in CVAI and other 3D anthropometric measurements	Class II Retrospective comparative study Selection bias—therapy determined by parental preference Exclusion of some populations (eg, neurodevelopmental disabilities) vulnerable to positional plagiocephaly limits generalizability	Statistically significant change in CVAI seen in the helmet group but not in the counterpositioning group Subgroup analysis shows greater effect of helmet in severe vs moderate deformity group Helmet therapy results in more favorable outcomes than counterpositioning in moderate-severe positional plagiocephaly

Wilbrand et al (2013)	Nonsynostotic Cranial Deformity: A Six-Month Matched-Pair Photogrammetric Comparison of Treated and Untreated Infants	Retrospective comparison of 40 patients with positional plagiocephaly treated with helmet vs 40 controls not treated with helmet Physiotherapy and "bedding maneuvers" were recommended to the unhelmeted patients Mean age at baseline evaluation was 6.5 months in the treated group vs 6.8 months in the control group Mean length of helmet therapy was 5.2 months. Outcome was assessed at 5.6 months in the control group Outcome: An assortment of 3D anthropometric measures including cranial vault asymmetry index (CVAI) at the end of therapy	Class II Retrospective comparative study Attempt to match for severity of initial deformity, but initial 3D measures of asymmetry were different in the 2 groups Selection bias—most patients in the control group were not treated with helmet because of advanced age at presentation, mild-moderate deformity, or parental request Outcome assessed at different time points in the 2 groups Limited generalizability of laser scan results	Improvement in asymmetry is seen in helmeted infants, but at the end of treatment, no significant difference is seen in asymmetry between helmeted and unhelmeted infants Nonsynostotic cranial deformity shows some spontaneous correction

Author (Year)	Title	Study Description	Data Class, Quality, and Reasons	Results and Conclusions
Lipira et al (2010)	Helmet Versus Active Repositioning for Plagiocephaly: A Three-Dimensional Analysis	Retrospective comparison of 35 patients with positional plagiocephaly treated with active repositioning vs 35 custom orthoses Mean age at intake: 4.8 months in repositioning group vs 4.9 months in helmet group Mean duration of therapy was 5.2 months in repositioning group vs 3.1 months in helmet group Helmet prescribed for 23 h/day Outcome: change in 3D anthropometric measure (mean and maximum asymmetry) pre/post therapy	Class II Retrospective comparative study Matched for severity of initial deformity Selection bias—treatment decision was guided by parental preference Selection bias—an additional 17 patients were assigned to repositioning arm but 13 elected to switch to helmet therapy in the midst of treatment, and 4 were lost to follow-up (all of these patients were excluded from analysis) Outcome assessed at different time points in the treatment groups (cessation of treatment guided by parent/clinician satisfaction) Limited generalizability of laser scan results	Statistically significant greater reduction in measures of asymmetry in the helmet group vs the repositioning group, specifically in the posterior head region Mean duration of therapy was shorter in the helmet group No difference in average head growth between the 2 groups at end of treatment Clinical significance of observed effect on outcomes unclear (very small treatment effects)

Author (Year)	Title	Study Description	Data Class, Quality, and Reasons	Results and Conclusions
Losee et al (2007)	Nonsynostotic Occipital Plagiocephaly: Factors Impacting Onset, treatment and Outcomes	Retrospective comparison of 55 patients treated with conservative repositioning to 45 patients who failed conservative treatment and were subsequently placed in a helmet Mean age at initiation of helmet therapy was 7.5 months Mean duration of helmet therapy was 3.7 months Outcome: subjective surgeon assessment of head shape	Class II Retrospective comparative study Selection bias—parents decided whether to undergo repositioning or helmet therapy Measurement bias—subjective outcome assessed by a single craniofacial surgeon	Improvement in head shape was statistically significantly better in the helmet vs repositioning group

Author (Year)	Title	Study Description	Data Class, Quality, and Reasons	Results and Conclusions
Graham et al (2005)	Deformational Brachycephaly in Supine Sleeping Infants	Retrospective review of 193 brachycephalic infants, 96 of whom were treated with repositioning and 97 who were treated with a custom orthosis Mean age at therapy initiation was 4.6 months for repositioning and 6.0 months for helmet Mean duration of therapy was 3.1 months for repositioning and 4.3 months for helmet Outcome: change in CI pre/post treatment	Class II Retrospective comparative study Selection bias—initial deformity more severe in helmet group Outcome subject to measurement bias Outcome assessed at different times in the 2 treatment groups	Change in CI for the patients treated with helmet was statistically significant, whereas it was not significant for those treated with positioning For those treated with helmet, treatment at a younger age resulted in more improvement in the CI Clinical significance of observed effect on outcome is unclear

Author (Year)	Title	Study Description	Data Class, Quality, and Reasons	Results and Conclusions
Graham Jr et al (2005)	Management of Deformational Plagiocephaly: Repositioning Versus Orthotic Therapy	Retrospective review of 298 plagiocephalic infants, of whom 176 underwent repositioning and 159 underwent helmet therapy Thirty-seven patients initially treated with repositioning eventually received helmet Mean age at initiation of therapy was 4.8 months in repositioning group vs 6.6 months in helmet group Mean duration of therapy was 3.5 months in repositioning group vs 4.2 months in helmet group Outcome: reduction in diagonal difference pre/post therapy	Class II Retrospective comparative study Selection bias—initial deformity more severe in helmet group *(P* = .08) Helmet was recommended for infants >6 months with severe deformity. Patients <4 months were given repositioning. Patients 4-6 months were offered either treatment Outcome subject to measurement bias Outcome assessed at different times in the 2treatment groups	Infants treated with helmet had improved outcome compared to those treated with repositioning Infants treated with helmet were older and required a longer treatment period Early helmeting (<8 months) resulted in better outcomes compared to late helmeting (>8 months) Clinical significance of observed effect on outcomes is unclear

Author (Year)	Title	Study Description	Data Class, Quality, and Reasons	Results and Conclusions
Loveday et al (2001)	Active Counterpositioning or Orthotic Device to Treat Positional Plagiocephaly	Random sample of 74 infants with positional plagiocephaly selected from clinic records Forty-five were repositioned and 29 received helmet Mean age at initiation of therapy: 38 weeks for repositioning vs 37 weeks for helmet Mean duration of therapy—64 weeks for repositioning vs 22 weeks for helmet Initial CVAI: 7.3% for repositioning vs 8.0% for helmet Outcome: change in CVAI pre/post treatment	Class II Retrospective comparative study Selection bias—selection to treatment group based on severity of deformity and preference of surgeon Some (n = ?) repositioning patients went on to get a helmet and were analyzed as part of the helmet group Outcome assessed at different times in the 2 treatment groups Outcome subject to measurement bias No statistical presentation of results	Change in CVAI similar for both groups at the end of therapy, but change effected with shorter duration of treatment in helmet group Mean age in helmet group was 37 weeks, which may explain relatively poor helmet results Clinical significance of findings unclear

Author (Year)	Title	Study Description	Data Class, Quality, and Reasons	Results and Conclusions
Vles et al (2000)	Helmet versus Nonhelmet Treatment in Nonsynostotic Positional Posterior Plagiocephaly	Retrospective comparison of 66 patients treated with a helmet and 39 patients treated with repositioning Mean age at initiation of helmet therapy was 5.1 months Outcome: change in parental rating of the severity of skull deformity	Class II Retrospective comparative study Selection bias—choice of treatment alternative made by the parents. This resulted in pre-treatment severity score being significantly worse in the helmet group	Improvement was seen in all patients, although the improvement was significantly better in the helmet group Improvement in the helmet group was seen at a mean of 5.3 weeks after initiation of therapy, vs 24.1 weeks after initiation of therapy in the repositioning group No correlation between age at initiation of helmet treatment and outcome Within the helmet group, more improvement was seen in those with the worse presenting deformity

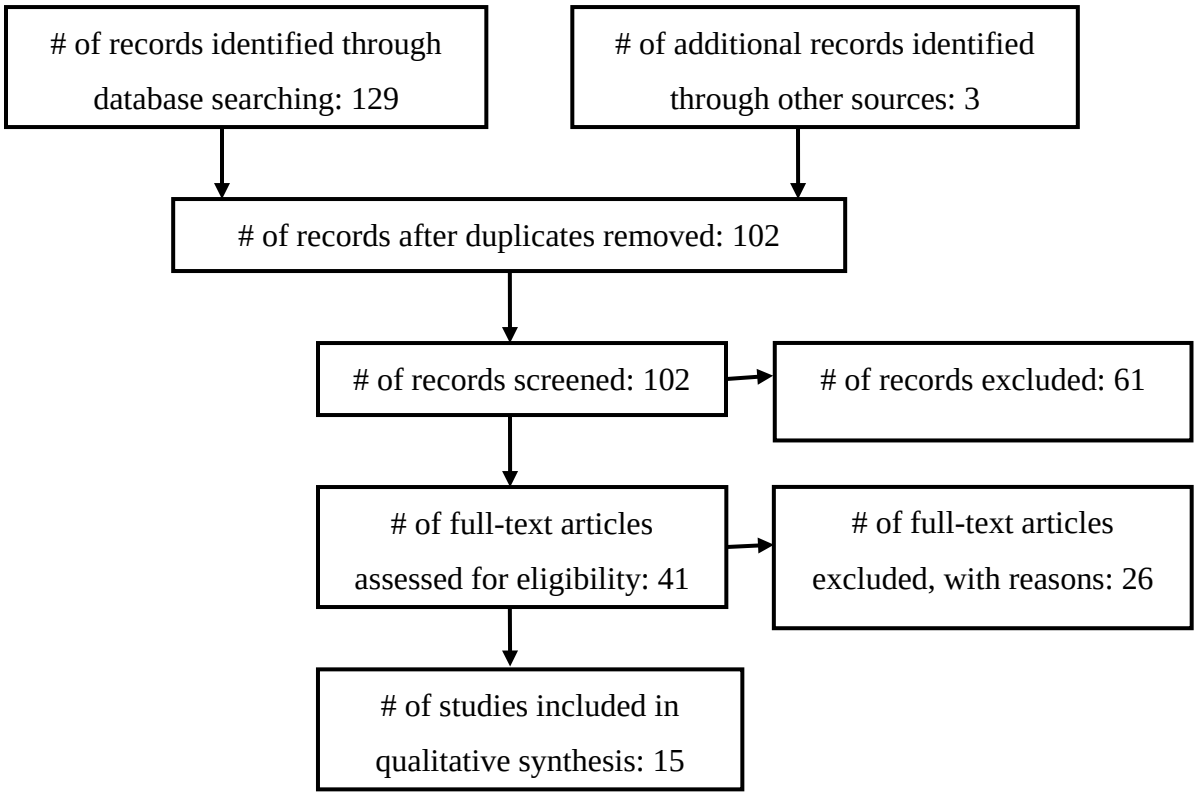
Author (Year)	Title	Study Description	Data Class, Quality, and Reasons	Results and Conclusions
Clarren (1981)	Plagiocephaly and Torticollis: Etiology, Natural History and Helmet Treatment	Retrospective comparison of 25 infants who completed helmet therapy to 10 infants whose family declined helmet therapy Control infants received passive neck stretching exercises Mean age at initiation of helmet therapy was 5.5 months Mean duration of helmet therapy was 5.3 months Outcome: subjective (surgeon) assessment of head shape	Class II Retrospective comparative study Selection bias—control infants were those who declined helmet Twenty-five of 28 patients in helmet group actually completed therapy Measurement bias	Nineteen patients in the helmet group and 0 patients in the control group achieved a normal head shape An improvement in head shape (but not normalization) was seen in 6/25 of the helmet group and 4/10 of the control group

Table 2 Effect of Age

Author (Year)	Title	Study Description	Data Class, Quality and Reasons	Results and Conclusions
Seruya et al (2012)	Helmet Treatment of Deformational Plagiocephaly: The Relationship Between Age at Initiation and Rate of Correction	Prospective comparison of the results of custom helmet therapy in 346 patients in 7 pre-defined age groups ranging from <20 weeks to >40 weeks Similar degree of deformity in both groups at outset of therapy Median duration of helmet therapy ranged from 7.8-13 weeks across groups Median helmet compliance was 22 h/day Outcome: transcranial difference in oblique diameters measured at end of therapy	Class II Prospective comparative study Outcome assessed at different times in the treatment groups (treatment discontinued when transcranial difference <5mm) Outcome subject to measurement bias	All patients achieved normal calvarial symmetry at the end of helmet therapy, except those helmeted >36 weeks of age Duration of helmet therapy was positively correlated with age Improvement was still seen even in infants aged >12 months at time of helmet therapy initiation

Author (Year)	Title	Study Description	Data Class, Quality and Reasons	Results and Conclusions
Kluba et al (2011)	What is the Optimal Time to Start Helmet Therapy in Positional Plagiocephaly?	Prospective comparison of the results of helmet therapy in 24 infants with plagiocephaly helmeted at age <6 months vs 38 helmeted at age >6 months Similar degree of deformity in both groups at outset of therapy Helmet therapy started between 4-11 months of age Instructed to wear helmet 23 h/day Mean duration of helmet therapy was 14 weeks in those <6 months vs 18 weeks in those >6 months Outcome: change in cranial vault asymmetry index (CVAI) pre/post therapy	Class II Prospective comparative study Outcome assessed at different times in the 2 treatment groups Outcome subject to measurement bias (no exactly reproducible landmarks)	A significant reduction in asymmetry was seen in both groups Younger patients (<6 months) showed a greater decrease in CVAI and attained values considered "normal" Children starting therapy later (>6 months) showed significantly less absolute improvement and did not attain values considered "normal" Duration of therapy was statistically significantly shorter in the younger patients Clinical significance of observed treatment effect unclear

Figure 1 Flow diagram showing the selection of studies for inclusion in the systematic review



APPENDIX A

Search # 1 – Medline plagiocephaly / orthotic therapy

1. "Plagiocephaly, Nonsynostotic"[Mesh terms]
2. "nonsynostotic plagiocephaly" OR "Positional plagiocephaly" OR "deformational plagiocephaly" OR "flat head" OR “posterior plagiocephaly” or “positional posterior plagiocephaly” or “deformational posterior plagiocephaly” or “occipital plagiocephaly” or “nonsynostotic plagiocephaly” or “non-synostotic plagiocephaly”
3. “Plagiocephaly” [All Fields]
4. 1 OR 2 OR 3
5. 4 AND "orthotic devices"[Mesh terms] OR orthotic OR "cranial orthoses" OR "orthotic treatment” OR "head protective devices"[MeSH Terms] OR "head protective devices"[All Fields] OR "helmet"[All Fields] OR "helmets"[All Fields] OR “Helmet treatment” [All Fields]

Limits: “NOT animals”, English language, NOT Comment [publication type], NOT Letter [publication type]

Search # 2 – Medline brachycephaly / orthotic therapy

1. brachycephaly[tiab] OR brachiocephaly OR brachycephalic[tiab] OR brachycephalies[tiab]
2. 1 AND "orthotic devices"[Mesh terms] OR orthotic OR "cranial orthoses" OR "orthotic treatment” OR "head protective devices"[MeSH Terms] OR "head protective devices"[All Fields] OR "helmet"[All Fields] OR "helmets"[All Fields]

Limits: “NOT animals”, English language, NOT Comment [publication type], NOT Letter [publication type]

Search # 3 – Cochrane Library plagiocephaly and brachycephaly / orthotic therapy

1. MeSH descriptor: [Plagiocephaly, Nonsynostotic] explode all trees
2. Title, Abstract, Keywords: “positional plagiocephaly” OR “deformational plagiocephaly” OR “nonsynostotic plagiocephaly” OR “flat head”
3. Title, Abstract: “brachycephaly”

4. 1 or 2 or 3

Limit to English, Humans