Congress of Neurological Surgeons

GUIDELINES

CONGRESS OF NEUROLOGICAL SURGEONS SYSTEMATIC REVIEW AND EVIDENCE-BASED GUIDELINE ON THE MANAGEMENT OF PATIENTS WITH POSITIONAL PLAGIOCEPHALY: THE ROLE OF REPOSITIONING

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: Plagiocephaly, involving positional deformity of the calvarium in infants, is one of the most common reasons for pediatric neurosurgical consultation.

Objective: To answer the question: "what is the evidence for the effectiveness of repositioning for positional plagiocephaly?" Treatment recommendations are provided based on the available evidence.

Methods: The National Library of Medicine Medline database and the Cochrane Library were queried using MeSH headings and keywords relevant to repositioning as a means to treat plagiocephaly and brachycephaly. Abstracts were reviewed to identify which studies met the inclusion criteria. An evidentiary table was assembled summarizing the studies and the quality of evidence (Classes I-III). Based on the quality of the literature, a recommendation was rendered (Level I, II, or III).

Results: There were 3 randomized trials (Class I), 1 prospective cohort (Class II), and 6 retrospective cohort studies (Class III). Repositioning education was found to be equivocal to a repositioning device and inferior to a physical therapy program. Five out of the 7 cohort studies comparing repositioning to helmet reported helmets to be better and take less time.

Conclusion: Within the limits of this systematic review, repositioning education is effective in affording some degree of correction in virtually all infants with positional plagiocephaly or brachycephaly. Most studies suggest a molding helmet corrects asymmetry more rapidly and to a greater degree than repositioning education. In a Class I study, repositioning education was as effective as repositioning education in conjunction with a repositioning wrap/device. Another Class I study demonstrated a bedding pillow to be superior to physical therapy for certain infants. However, in keeping with The American Academy of Pediatrics' warning against the use of soft positioning pillows in the sleeping environment, the Task Force recommends physical therapy over any positioning device.

Short Title: Guideline on the Management of Patients with Positional Plagiocephaly: The Role of Repositioning

Key Words: infants; plagiocephaly; positional; practice guidelines; repositioning

RECOMMENDATION

1. Repositioning is an effective treatment for deformational plagiocephaly. However, there is Class I evidence from a single study and Class II evidence from several studies that repositioning is inferior to physical therapy and to use of a helmet, respectively.

Strength of Recommendation:

Level I—High clinical certainty (repositioning being inferior to physical therapy);

Level II—Moderate clinical certainty (repositioning being inferior to helmet use)

INTRODUCTION

Since the recommendation by the American Academy of Pediatrics (AAP) in 1992 that infants be placed on their back to sleep to reduce the risk of sudden infant death syndrome (SIDS), plagiocephaly, involving positional deformity of the calvarium in infants, has been one of the most common reasons for pediatric neurosurgical consultation.[1] There are 2 types of plagiocephaly. The most common is referred to as posterior plagiocephaly in which there is unilateral flattening of the parietooccipital region, resulting in a rhomboid-like shift of the calvarium with an anterior shift of the ipsilateral ear and bulging or bossing of the ipsilateral forehead. The second, less common variant is sometimes called brachycephaly, in which there is flattening of the entire occipital region, resulting in a foreshortened head in the anterior-posterior dimension. However, the term "brachycephaly" is also used in children with craniosynostosis. Henceforth, the authors will refer to non-synostotic calvarial positional deformity as plagiocephaly.

With very rare exception, plagiocephaly is a non-operative condition.[2] Treatments include observation; physical therapy, particularly in the presence of torticollis; repositioning education; or assistive devices and helmet therapy. High rates of parental satisfaction have been reported regardless of treatment.[3] Plagiocephaly has been the topic of numerous review articles.[4-10] The purpose of this systematic review is to address the question: "does repositioning (education or with an assistive device) provide effective treatment for plagiocephaly?"

METHODS

The Congress of Neurological Surgeons (CNS) and the Section on Pediatric Neurosurgery initiated a systematic review of the literature and evidence-based guideline

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 the National Library of Medicine/PubMed database and the Cochrane Library for the period from 1966 to 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 titles and abstracts to identify studies addressing the effectiveness of repositioning (education or device) in patients with deformational plagiocephaly compared to other treatment modalities such as physical or helmet therapy. A repositioning device was defined as any man-made device designed to prevent the infant from laying on the flattened part of their skull while asleep. Studies were excluded if there was no comparison group (uncontrolled), focus was on parental surveys, or if repositioning therapy was prematurely terminated at the discretion of the parents or providers before reaching its potential maximal benefit. Articles that met our criteria were independently reviewed by 2 of the authors and data compiled into an evidentiary table. The task force then reviewed this evidentiary table.

Search Results

Our search returned 38 articles; another 7 articles were found from a search through bibliographies (Figure 1). Twenty-four were excluded based on a review of the abstract. Eighteen full-length papers were reviewed; 8 were rejected for the following reasons: abstract for a presentation only and not full length paper,[11] contained no children who were treated with a

repositioning program or outcome data on these patients was lacking or unclear,[12,13] lack of a comparison group or data for the comparison group was unclear,[14,15] premature termination of repositioning treatment,[16,17] and potential significant degree of confounding introduced by co-intervention(s).[18] Therefore, 10 articles satisfied inclusion for this systematic review and meta-analysis (Table 1).[19-28]

There were 3 randomized trials, 1 prospective cohort, and 6 retrospective cohort studies. The comparisons were as follows: repositioning education vs physical therapy program (1 study), repositioning device vs physical therapy program (1 study), repositioning education vs repositioning device (1 study), and repositioning education vs helmet (7 studies). In only 2 papers was the individual gathering the post-treatment cranial data (anthropometric measurements or 3D digital images) blinded to the treatment allocation of the infant.[26,27]

DISCUSSION

Repositioning Education vs Physical Therapy Program

Van Vlimmeren et al[26] conducted a well-designed randomized trial evaluating repositioning education to a physical therapy intervention program. Sixty-five infants with positional preference were randomized to either repositioning education (n = 32), which consisted of a leaflet describing basic preventive measures, or to a 4-month physical therapy intervention program (n = 33), an 8-session program between 7 weeks and 6 months consisting of exercises to reduce positional preference as well as parental counseling. All children entered the study at 7 weeks of age with a blinded physical therapist measuring the Oblique Diameter Difference Index (ODDI). The primary outcome was severe deformational plagiocephaly (DP), defined as an ODDI of 104% or more. At 6 and 12 months, the percentage of infants with severe DP was less in the physical therapy group compared to repositioning education (30% vs 56% at 6 months; 24% vs 56% at 12 months).

Repositioning Device vs Physical Therapy Program

Wilbrand et al randomly assigned 50 infants of less than 5 months of age with plagiocephaly, brachycephaly, or both to either a commercially available bedding pillow or to education on cervical stretching exercises (to be performed 5 times a day) and instructions to provide “tummy time” while the child was awake during the day. Parents in the pillow group could not employ any other repositioning method, and the pillow was used for 6 weeks. As in the previous trial, anthropometric measurements (cranial index [CI] and cranial vault asymmetry

index [CVAI]) were performed following a standard protocol by an examiner who was blinded, and measurements were obtained immediately before and after 6 weeks of treatment (pillow vs stretching). Six patients were lost to follow-up and 2 used other nonorthotic treatment. Thus, 6 (12%) of the patients were excluded from analysis. The authors did not provide outcomes for the treatment groups as a whole but rather the 3 subgroups individually (plagiocephaly, brachycephaly, and combined deformity). The bedding pillow led to a statistically greater reduction in the CVAI in both the plagiocephaly (3.01%) and combined head deformity (2.86%) patients than stretching exercises (2.09% and 2.43%, respectively). Even though the pillow seemed to improve the CI to a greater degree in the brachycephalic (3.63% to 0.94%) and combined infants (3.23% to 2.24%), this did not reach statistical significance.

While both treatment groups demonstrated improvement and no significant complication was described, the use of the bedding pillow conflicts with the AAP's recommendation to avoid such soft bedding items in an infant crib in order to provide a safe sleeping environment.[29,30] The task force therefore recommends physical therapy as the preferred and safer treatment modality when considering these 2 options.

Repositioning Education vs Repositioning Device

In the randomized trial by Hutchison et al[19], children with plagiocephaly or brachycephaly were randomized to receive education only about repositioning strategies (n = 61) or education and the use of sleep repositioning device (n = 65). The randomization sequence was computer-generated, and the individual result was sealed by an outside party and concealed to both researcher and parent until after the parent signed the consent form to participate. Three cranial measurements were obtained (cephalic index [CI], oblique cranial length ratio [OCLR], and transcranial diameter difference [TCD]) from a 2-dimensional digital photograph of a headband placed around the child's maximum occipitofrontal circumference. Neck dysfunction, defined as head tilt or limited range of motion, was also measured. Analysis was performed at baseline and at 3, 6, and 12 months by 1 researcher. However, there was no mention whether that researcher knew which treatment the child was receiving (ie, no mention that the researcher was blinded). At 12 months, there was no difference in the average measurements between treatment groups. Overall, 20% of children were categorized as having poor improvement, but only 17% of parents were "very concerned" (2%) or "somewhat concerned" (15%) about their child's head shape.

Repositioning Education vs Helmet

Loveday et al[21] compared 45 children (average age 38.1 weeks) who were treated with active counter positioning (ACP, ie, education only, no device used) to 29 (average age 36.6 weeks) with a helmet. Two anthropometric measurements were obtained by placing a rubber tube filled with lead and silicon around the child's head. The cranial index (CI) was the cranial width divided by the cranial length. The cranial vault asymmetric index (CVAI) is the percent difference between 2 diagonal measurements obtained 30 degrees from the anterior-posterior pole. Asymmetry was defined as a CVAI > 3.5%. The average management time for ACP was 63.7 weeks, but for the helmet was 21.9 weeks. Head tracings were obtained every 3 to 12 months, but there is no mention as to who did the measurements and whether they were blinded. At last follow-up, the average cranial measurements (CVAI and CI) were similar to slightly better for the ACP group, although no statistical analysis was provided. It is unclear whether this was a retrospective (we assume) or prospective study, and there was no information on how children were selected for one treatment over another. The authors stated that there were some patients who were initially managed with ACP but failed to improve and were then treated with a helmet, but there is no information on how many cross-overs there were and if these patients were included in the analysis, although we assume they were.

Using a 4-pod stereophotogrammetric imaging system, Lipira et al[20] found that infants who were helmeted (n = 35) had statistically greater improvement in asymmetry in a shorter period of time (3.1 vs 5.2 months) compared to parents who received repositioning instructions (n = 35). Children were matched at the outset for cranial vault asymmetry (CVA), were of similar age at the onset, and treatment decision was made by the parents.

Graham et al[28] reported on infants with brachycephaly. Ninety-six infants were treated by repositioning from an average starting age of 4.6 months to 7.7 months; 97 were treated with a helmet from an average age of 6.0 months to 10.3 months. There was no mention of any patients that crossed over from repositioning to helmet. However, it is unclear how treatment was allocated, and no definition of repositioning was provided. The change in the cranial index for children who were repositioned was not significant (86.3% to 85.7%), whereas the change for the helmet group was (91.5% to 88.4%).

Comparing their results to a study they had previously performed using a headband, Moss et al[22] found that repositioning achieved similar results. Using cranial vault asymmetry

measurement (CVA), the mean CVA went from 10.6 mm to 5.5 mm over a 4.5-month period in children who were repositioned (n = 72, average age 6.6 months) compared with 8.9 to 4.0 mm in the headband group (n = 72, average age 5.9 months). Although selection bias seemed to be present as the authors favored repositioning in infants with mild to moderate deformity (CVA < 12 mm) and a headband in those with more severe asymmetry (CVA > 12 mm), the repositioning group had a greater average starting asymmetry (10.6 mm vs 8.9 mm).

Vles et al[25] compared therapy with a soft molding cranial helmet (n = 66) to head positioning (n = 39) and found that cosmetic head deformity was better and more quickly corrected by helmet therapy. A subjective deformity scale was used, which ranged from 0-10 (0, severely abnormal; 10, normal) and was scored by the patient's caregivers before and after treatment. No anthropometric measurements were collected. The caregivers were given the choice of helmet or repositioning therapy at the time of initial evaluation. The average pretreatment deformity score was slightly less in the helmet group (4.2 vs 4.7). The authors found that all patients improved, but the helmet group had significantly better average improvement (3.3 vs 1.6) and final outcome scores (7.4 vs 6.2) that were achieved in a much shorter time period (5.3 weeks vs 24.1 weeks) compared to the head positioning group.

The study by Plank et al[24] also suffered from selection bias in that they only included patients with moderate to severe plagiocephaly. The orthotic group far outnumbered the repositioning group (n = 207 vs 17), but there was no difference in the average degree of cranial asymmetry or age at presentation. Head shape was determined by a 3D laser data acquisition system; scans were obtained at baseline and every 2 weeks for 4 months. At the end of the 4 months, the authors found that the helmet group had improved in all 25 cranial measurements whereas the control group had improved in only 12, which the authors attributed to head growth rather than any real correction. The authors found that 5 measures were the best predictors of asymmetry: Posterior Symmetry Ratio (PSR), Overall Symmetry Ratio (OSR), Cranial Vault Asymmetry Index (CVAI), Radial Symmetry Index (RSI), and the Cephalic Index (CI). It is notable that the company that made the helmet also made the 3D laser scanner, and the authors provided no conflict of interest statement.

Mulliken et al[23] showed that helmet therapy was superior to repositioning education in a prospective cohort study. Infants who were put into a helmet (n = 36) had a greater reduction of their transcranial diameter difference (1.2 cm to 0.6 cm) compared to those who were given

repositioning education (n = 17, 1.2 cm to 1.0 cm, $p < 0.001$), which consisted of posturing the infant on foam wedges. The groups were similar in terms of starting age and duration of treatment.

RECOMMENDATION

1. Repositioning is an effective treatment for deformational plagiocephaly. However, there is Class I evidence from a single study and Class II evidence from several studies that repositioning is inferior to physical therapy and to use of a helmet, respectively.

Strength of Recommendation:

Level I—High clinical certainty (repositioning being inferior to physical therapy);

Level II—Moderate clinical certainty (repositioning being inferior to helmet use)

CONCLUSION

Positional plagiocephaly and brachycephaly are very common nowadays. This systematic review has demonstrated that either repositioning therapy or devices may be effective as sole therapy, improving cranial asymmetry, particularly for mild to moderate deformity. Three randomized trials were included in our review. Each study compared different pairs of treatments. One trial found no difference between repositioning education and a repositioning device, and another found repositioning education was inferior to a physical therapy intervention program. Even though there is a European randomized trial that suggested a bedding pillow was superior to daily stretching exercises in certain forms of positional deformity, the Task Force cannot at this time endorse any sleep positioning device, as it would be contrary to the repeated recommendations set forth by the American Academy of Pediatrics Task Force on Sudden Infant Death Syndrome to avoid placing any soft surface bedding in the infant's crib.[30] Seven out of 10 articles that were included in this review evaluated repositioning education (without a specified device) as compared with a helmet or headband. The majority of these cohort studies (1 prospective, 6 retrospective) demonstrated that helmet therapy provides a greater degree of correction in a shorter period of time than repositioning. Thus, helmets should be the preferred treatment for severe positional deformity.

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Disclosures

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FIGURE

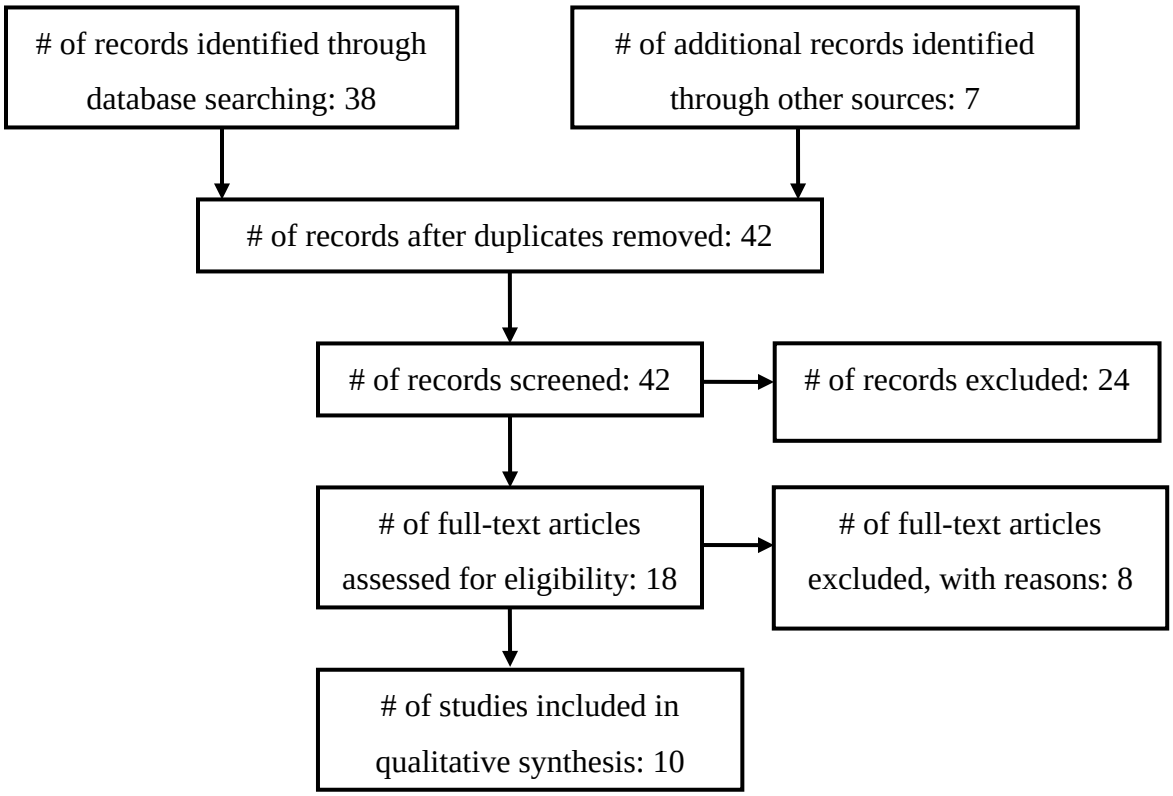

Figure 1: Flow diagram showing the selection of studies for inclusion in the systematic review

TABLE

Table 1: Characteristics of the 10 studies critically evaluated for this review

Author (Year)	Study Design	Assessment of Cranial Deformity	Data Class, Quality and Reasons	Results	Conclusions
Loveday et al (2001)	Active counterpositioning (n = 45) compared to helmet (n = 24).	Cranial index (CI) and cranial vault asymmetry index (CVAI).	II—Retrospective cohort study	Helmet group had improvement in average CVAI (8.0 to 6.2%) and CI (89.6 to 87.8%) over 21.9 weeks; ACP improvement in CVAI (7.3 to 5.4) and CI (88.2 to 86.2) over 63.7 weeks.	ACP and helmet treatment results similar, but ACP takes much longer.
Hutchison et al (2010)	Randomized to education about repositioning education (n = 61) vs repositioning education plus device (Safe T Sleep positioning wrap, n = 65).	Using a digital photograph, 1 researcher measured the cephalic index (CI), the oblique cranial length ratio (OCLR), and the transcranial diameter (TCD). Neck dysfunction was also assessed.	I—Prospective RCT	At 12 months, there was no difference between the treatment groups for mean CI, mean OCLR, or mean RCD.	No difference in head shape improvement for those using a sleep positioning wrap versus repositioning strategies alone.

Author (Year)	Study Design	Assessment of Cranial Deformity	Data Class, Quality and Reasons	Results	Conclusions
Lipira et al (2010)	Active repositioning (n = 35) compared to helmet (n = 35) matched for cranial vault asymmetry (CVA).	Used whole-head 3D asymmetry analysis at each visit.	II—Retrospective cohort study	Greater reduction in the mean and maximal asymmetry in the helmeted group than the repositioned group in a shorter period of time (3.1 vs 5.2 months).	Orthotic helmet provides superior improvement in head asymmetry in a shorter period of time.
Graham et al (2005)	Children with brachycephaly were treated with repositioning (n = 96) or helmet (n = 97).	The cranial index (CI) was calculated 3 times and averaged by 1 pediatric nurse practitioner.	II—Retrospective cohort study	The change in CI for children who were repositioned was not significant (86.3% to 85.7%), whereas the change for the helmet group was (91.5% to 88.4%).	Repositioning was less effective than cranial orthotic therapy for brachycephaly.
Moss et al (1997)	Repositioning (n = 72) compared to prior helmeted group (n = 47).	Cranial vault asymmetry (CVA)	III—Retrospective cohort study with historical control. Results compared to prior study evaluating headband from same authors.	Over 4.5 months, the mean CVA went from 10.6 mm to 5.5 mm.	Repositioning and external orthotic treatment result in similar improvements in CVA.

Author (Year)	Study Design	Assessment of Cranial Deformity	Data Class, Quality and Reasons	Results	Conclusions
Plank et al (2006)	Repositioning program (n = 17) compared to helmet (n = 207) in infants with moderate to severe deformity.	3D head shape analysis using laser data acquisition system. This was able to calculate 25 measurements. Scans done every 2 weeks for about 4 months.	II—Prospective cohort study	For the orthotic group, significant differences were found in all 25 variables. For the repositioning group, significant differences were found in 12 of the 25 variables, but this was attributable to head growth.	Cranial symmetry improved significantly more with helmet therapy than without.
Mulliken et al (1999)	Repositioning (n = 17) compared to helmet (n = 36).	Transcranial diameter difference measured 3 times by the primary author at 3-month intervals until therapy completed.	II—Prospective cohort study	The reduction in the transcranial difference was greater in the helmet group (1.2 cm to 0.6 cm) compared to the repositioning group (1.2 cm to 1.0 cm).	Helmet therapy superior to repositioning.
Vles et al (2000)	Positioning (n = 39) compared to helmet (n = 66)	Cosmetic deformity score (0, severely abnormal; 10, normal) at initiation and completion of treatment	II—Retrospective cohort (no mention whether it was retro or prospective)	Helmet group had better average improvement (3.3 vs 1.6) and final outcome score (7.4 vs 6.2) in a shorter treatment period (5.3 vs 24.1 weeks).	Helmet therapy superior to repositioning and takes less time.

Author (Year)	Study Design	Assessment of Cranial Deformity	Data Class, Quality and Reasons	Results	Conclusions
van Vlimmeren et al (2008)	Repositioning education (n = 32) compared to a 4-month physical therapy intervention program (n = 33)	Oblique Diameter Difference Index (ODDI) measured at 6 and 12 months	I—Prospective RCT	Physical therapy intervention group had significantly less severe plagiocephaly at 6 (30%) and 12 months (24%) compared to repositioning education (56% and 56%).	A 4-month physical therapy program led to significantly reduced risk of severe deformational plagiocephaly compared with education.
Wilbrand et al (2013)	Repositioning device (n = 25) compared to stretching exercises (n = 25)	Cranial index (CI) and cranial vault asymmetry index (CVAI) before and after 6 weeks of treatment.	I—Prospective RCT	Bedding pillow showed superior CVAI improvement to daily stretching exercises in the plagiocephaly and combined deformity patients; there was improvement in the CI for the brachycephaly and combined infants, but it did not reach statistical significance.	Bedding pillow is more effective at correcting cranial asymmetry than stretching exercise program.

APPENDIX A

PubMed—Plagiocephaly

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 repositioning OR reposition* OR “positional therapy”

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

PubMed—Brachycephaly

1. brachycephaly[tiab] OR brachiocephaly OR brachycephalic[tiab] OR brachycephalies[tiab]
2. 1 AND repositioning OR reposition* OR “positional therapy”

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

Cochrane Library

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