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| **CRITICALLY APPRAISED TOPIC** |

**FOCUSED CLINICAL QUESTION**

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| For a 3 month old boy with Torticollis/Plagiocephaly, does applying a Doc Band help improve symmetry in head shape as opposed to traditional physical therapy alone? |

**AUTHOR**

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**CLINICAL SCENARIO**

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| There are many cases of Torticollis and Plagiocephaly across several paediatric settings (outpatient paediatric clinics, early intervention, and in the hospital). There are varying levels of severity, and as cases become more severe, they are referred for physical therapy and have a potential need for Doc Banding. There is a small window of time for interventions to be effective, and if the child is not treated, it could cause developmental delays and other issues as they get older (aesthetics, being able to fit hats/glasses, vision problems, breathing problems, etc). During sessions for these patients, there is a lot of education for the parents on movements, positioning, and stretching to help their child. The clinical question at hand investigates whether applying a Doc Band helps to improve head symmetry of the patient better than physical therapy itself. |

**SUMMARY OF SEARCH**

[Best evidence appraised and key findings]

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| * Three electronic databases were searched and eight studies were found to meet the inclusion/exclusion criteria of the search, including four retrospective cohort studies, three systematic reviews, and one prospective longitudinal cohort study. Two of the systematic reviews with the highest quality of evidence, based on the ROBIS, were selected for detailed review in this analysis. * Both helmet therapy (Doc Band) and repositioning therapy (one aspect of physical therapy) appear to be effective in reducing head asymmetry in infants with torticollis and plagiocephaly, depending on the age of the infant and severity of the condition. Repositioning therapy with physical therapy intervention was seen to be more effective in infants <6 months of age with mild to moderate severity, while helmet therapy had better results for more severe cases and infants >6 months at the start of treatment. There was no harm found in starting one treatment over the other in terms of final results. * More research needs to be completed to better define and standardize outcome measurements, outline the specifics of the intervention protocols, and to account for cofounding variables. |

**CLINICAL BOTTOM LINE**

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| There is currently no evidence available that directly compares physical therapy intervention to Doc Band treatment. The best available evidence investigates repositioning therapy, a portion of physical therapy intervention, with different forms of orthotic interventions, including helmet therapy (with Doc Band being a specific type of helmet). The outcome measures, specific interventions, and timeline of treatments are poorly defined, making it difficult for clinicians to apply results to clinical practice. There are many biases in the current research, biasing for better results in repositioning therapy, thus it is nearly impossible to see the true effectiveness of Doc Banding in comparison to physical therapy intervention. Due to ethics of treatment limiting the use of higher quality studies like randomized controlled trials, evidence is limited to mainly retrospective and prospective cohort studies. Even so, both types of conservative treatments are seen to improve head symmetry in infants, with the potential to switch interventions if measurements do not improve over a few months. As long as the patients are treated within the first year of life, which is when the majority of cranial growth occurs, the child can benefit from either form of treatment, as determined by both the clinician and parental preference. Clinicians can use this evidence to help guide their treatment choices, while keeping in mind further high quality research is needed to understand the actual effectiveness of each treatment. |

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| ***This critically appraised topic has been individually prepared as part of a course requirement and has been peer-reviewed by one other independent course instructor*** |

*The above information should fit onto the first page of your CAT*

**SEARCH STRATEGY**

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| **Terms used to guide the search strategy** | | | |
| **P**atient/Client Group | **I**ntervention (or Assessment) | **C**omparison | **O**utcome(s) |
| Infant  Torticollis  Plagiocephaly | Doc Band  Helmet Therapy | Physical Therapy  Physiotherapy  Rehabilitation | Cervical Range of Motion |

**Final search strategy (history):**

*Show your final search strategy (full history) from PubMed. Indicate which “line” you chose as the final search strategy.*

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| --- | --- | --- |
| Search | Query | Items found |
| #10 | Search (#2 AND #3 AND #5) | 24 |
| #12 | Search (#2 AND #5 AND #6) | 16 |
| #11 | Search (#2 AND #3 AND #5 AND #6) | 6 |
| #7 | Search (#1 AND #2 AND #3 AND #4 AND #5 AND #6) | 1 |
| #6 | Search (head shape) | 718 |
| #5 | Search ("helmet therapy" OR "doc band") | 136 |
| #4 | Search "helmet therapy" | 133 |
| #3 | Search ("physical therapy" OR physiotherapy OR rehabilitation) | 601787 |
| #2 | Search (torticollis OR plagiocephaly) | 5261 |
| #1 | Search infant[MeSH Terms] | 1075605 |

*In the table below, show how many results you got from your search from each database you searched.*

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| --- | --- | --- |
| **Databases and Sites Searched** | **Number of results** | **Limits applied, revised number of results (if applicable)** |
| **CINAHL**  **Cochrane Library**  **PubMed** | **2**  **4**  **24** |  |

## INCLUSION and EXCLUSION CRITERIA

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| **Inclusion Criteria** |
| * Measured neck range of motion post intervention (either PT alone or with banding) * Infant less than 1 year old * Studied infants with positional plagiocephaly and torticollis |
| **Exclusion Criteria** |
| * Not in English * Abstract, dissertations, letters to editor, conference proceedings |

**RESULTS OF SEARCH**

**Summary of articles retrieved that met inclusion and exclusion criteria**

*For each article being considered for inclusion in the CAT, score for methodological quality on an appropriate scale, categorize the level of evidence, indicate whether the relevance of the study PICO to your PICO is high/mod/low, and note the study design (e.g., RCT, systematic review, case study).*

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| --- | --- | --- | --- | --- |
| **Author (Year)** | **Risk of bias (quality score)\*** | **Level of Evidence\*\*** | **Relevance** | **Study design** |
| **Steinberg et al. (2015)** | **QUIPS:**  **Study participation – low**  **Study attrition – high**  **Prognostic factor measurement – low**  **Outcome measurement – low**  **Study confounding – moderate**  **Statistical analysis & reporting - low** | **2b** | **Moderate** | **Retrospective cohort study** |
| **Teichgraeber et al. (2004)** | **QUIPS:**  **Study participation – moderate**  **Study attrition – moderate**  **Prognostic factor measurement – low**  **Outcome measurement – low**  **Study confounding – moderate**  **Statistical analysis & reporting - moderate** | **2b** | **Low - Moderate** | **Retrospective cohort study** |
| **Kim et al. (2013)** | **QUIPS:**  **Study participation – low**  **Study attrition – moderate**  **Prognostic factor measurement – low**  **Outcome measurement – low**  **Study confounding – high**  **Statistical analysis & reporting - low** | **2b** | **Moderate** | **Retrospective cohort study** |
| **Flannery et al. (2012)** | **ROBIS:**  **Domain 1 – low**  **Domain 2 – low**  **Domain 3 – low**  **Domain 4 – high**  **Phase 3 Risk of Bias - low** | **2a – review included systematic reviews, RCT, cohort, retrospective cohort, prospective cohort, & case-control studies**  **Most of the studies were cohort** | **High** | **Systematic Review** |
| **Bialocerkowski et al. (2005)** | **ROBIS:**  **Domain 1 – low**  **Domain 2 – low**  **Domain 3 – low**  **Domain 4 – low**  **Phase 3 Risk of Bias - low** | **3a – review included case series, prospective & retrospective case series, & comparative studies**  **Most of the studies were case series** | **High** | **Systematic Review** |
| **Kluba et al. (2011)** | **Downs and Black Checklist – 15/29** | **2b** | **Moderate** | **Prospective longitudinal (cohort) study** |
| **Xia et al. (2008)** | **ROBIS:**  **Domain 1 – low**  **Domain 2 – low**  **Domain 3 – low**  **Domain 4 – low**  **Phase 3 Risk of Bias - low** | **2a – systematic review of cohort** | **High** | **Systematic Review** |
| **Lam et al. (2017)** | **QUIPS:**  **Study participation – low**  **Study attrition – high**  **Prognostic factor measurement – low**  **Outcome measurement – low**  **Study confounding – low**  **Statistical analysis & reporting - low** | **2b** | **Moderate** | **Retrospective cohort study** |

\*Indicate tool name and score

\*\*Use Portney & Watkins Table 16.1 (2009); if downgraded, indicate reason why

**BEST EVIDENCE**

The following 2 studies were identified as the ‘best’ evidence and selected for critical appraisal. Rationale for selecting these studies were:

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| * 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. doi:10.1001/archpedi.162.8.719. * This systematic review looked at studies that compared helmet therapy to traditional therapy as opposed to a lot of the other studies that did not intend to directly compare the treatments. It included potential confounding variables and attempted to limit bias. It included statistical analyses of each study and looked at validity and clinical applicability. * Flannery ABK, Looman WS, Kemper K. Evidence-based care of the child with deformational plagiocephaly, part II: management. *J. Pediatr. Health Care* 2012;26(5):320-331. doi:10.1016/j.pedhc.2011.10.002. * This systematic review also had the other highest level of evidence and was most relevant to the clinical question. While it had higher bias in synthesis/findings, it was more recent in time than the other systematic review not chosen and had more studies included. |

**SUMMARY OF BEST EVIDENCE**

**(1) Description and appraisal of Nonsurgical treatment of deformational plagiocephaly: a systematic review by Xia JJ, Kennedy KA, Teichgraeber JF, Wu KQ, Baumgartner JB, Gateno J. 2008.**

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| **Aim/Objective of the Study/Systematic Review:** |
| The study aimed to address whether repositioning or molding helmet therapy is more effective in treating infants with deformational plagiocephaly, accounting for severity and age at the start of treatment. |
| **Study Design**  [e.g., systematic review, cohort, randomised controlled trial, qualitative study, grounded theory. Includes information about study characteristics such as blinding and allocation concealment. When were outcomes measured, if relevant]  Note: For systematic review, use headings ‘search strategy’, ‘selection criteria’, ‘methods’ etc. For qualitative studies, identify data collection/analyses methods. |
| **Systematic review of cohort studies (6 prospective, 1 retrospective)**   * **Search Strategy:** the authors followed the Cochran Handbook for Systemic Review of Intervention guidelines. They used “plagiocephaly, lambdoid, synostosis, craniosynostosis, cranial suture, positional molding, skill molding, flat head syndrome, and deformational skull deformity” as search words through titles, abstracts, and keywords lists.1 They searched the Cochrane Library initially with no results. Then searched MEDLINE databases from January 1978 to August 2007. The authors also included plagiocephaly, nonsynostotic as a MeSH term. In addition, they searched the following databases: ISI Web of Science, ScienceDirect, and Journals@Ovid. Lastly, the authors conducted a manual search for conference proceedings of nonsurgical treatment for deformational plagiocephaly. * **Selection Criteria:** **1)** infants had deformational plagiocephaly with/without torticollis **2)** infants did not have any other conditions that would affect treatment of deformational plagiocephaly [craniosynostosis, congenital craniofacial deformities, or genetic conditions like Down syndrome] **3)** infants were never treated before study enrollment **4)** studies compared 2 nonsurgical treatments, head repositioning and molding therapy, for effectiveness * **Methods:** 2 reviewers appraised the selected studies for methodological quality using a Critical Appraisal Skills Programme (CASP) critical review form for cohort criteria. Three questions were used to categorize the critical review: “Are the results of the study valid?”, “What are the results?”, and “Will the results help me locally?”.1 Lastly, the magnitude of benefit/effect was evaluated using a point estimate with confidence interval. * **Test for Heterogeneity:** the authors tested for heterogeneity using the chi-square test (X2), with *p*-value < 0.05 determining significance. |
| **Setting**  [e.g., locations such as hospital, community; rural; metropolitan; country] |
| Although the location of the cohort studies being reviewed did not explicitly state their locations in the systematic review itself, the individual studies indicated that 2 of the studies were conducted at an outpatient clinic and 5 of the studies were at a hospital setting.2–8 |
| **Participants**  [N, diagnosis, eligibility criteria, how recruited, type of sample (e.g., purposive, random), key demographics such as mean age, gender, duration of illness/disease, and if groups in an RCT were comparable at baseline on key demographic variables; number of dropouts if relevant, number available for follow-up]  Note: This is not a list of the inclusion and exclusion criteria. This is a description of the actual sample that participated in the study. You can find this descriptive information in the text and tables in the article. |
| Seven full-length journal articles were selected for review.  Recruitment: All of the infants in the studies were diagnosed with deformational plagiocephaly.  Severity of disease: in 3 studies, severity of the molding group was more severe than repositioning group. In article 1, the physician gave all the pariticpants the molding group option, but 10 with mild to moderate severity opted for the repositioning group leaving 28 participants with more severe plagiocephaly in the molding group. In 3 studies the baseline severity of the molding group was higher than repositioning group due to infants switching from repositioning group to modling group due to failure of treatment.  All infants were <12 months at start of treatment. 4 of the studies had both groups at comparable ages.   * Article 1:2 * 38 total participants, 28 in molding therapy group and 10 in repositioning group * Mean age at start of treatment: 5.5 months, ranging 4-10 months * Both groups comparable at baseline * Article 2:3 * 335 total participants, 159 in molding therapy group and 176 in repositioning group * Mean age at start: 6.6 months (SD 1.7) for molding therapy group, 4.8 months (SD 1.7) for repositioning group * Article 3:4 * 74 total participants, 29 in molding therapy group and 45 in repositioning group * Mean age at start of treatment: 8.5 months for molding group and 8.8 months for repositioning group * Article 4:5 * 112 total participants, 47 in molding therapy group and 66 in repositioning group\* * Mean age at start of treatment: 5.9 months for molding group and 6.4 months for repositioning group * Article 5:6 * 114 total participants, 51 in molding therapy group and 63 in repositioning group * Mean age at start of treatment: 5.4 months for molding group and 5.6 months for repositioning group * Article 6:7 * 103 total participants, 34 in molding therapy group (had failed at previous repositioning group) and 69 in repositioning group (35 with this therapy alone) * Mean age at start of treatment: <6 months for 35 infants and 6-12 months for 34 infants in repositioning group, infants in molding therapy group were 2-3 months later when repositioning failed * Article 7:8 * 105 total participants, 66 in molding therapy group and 39 in repositioning group * Mean age at start of treatment: <10 months old for both groups   In all the studies, follow-up measurements occurred at the end of treatment. In article 5, only 71% of the molding therapy group and 27% of the repositioning therapy group were available for follow-up.6  No other participant information was included in this systematic review.  \*the chart providing the information on number in each group from the systematic review switched the numbers on the table. The actual numbers were found within the study itself. |
| **Intervention Investigated**  [Provide details of methods, who provided treatment, when and where, how many hours of treatment provided] |
| *Control – repositioning therapy* |
| Allocation of treatment groups were determined by physician recommendation or parent preference (depending on age and severity) for 3 of the studies. One study treated mild to moderate severity with repositioning therapy and compared to retrospective data of molding therapy at the same institution. In one study, all participants underwent repositioning therapy and then switched if asymmetry did not improve after 2-3 months. In 3 studies, infants who did not improve after completion of repositioning therapy were crossed to molding therapy.  In all of the studies, repositioning therapy was described briefly, but no specific techniques were outlined. 3 studies had physiotherapy administered in addition to repositioning therapy. Treatment duration, in months, for each of the studies for the repositioning therapy group were 5.3, 4.2 (SD 2.2), 5.1, 4.3, 4.6, no duration indicated, and 1.2 (SD 0.9).2–8 |
| *Experimental – molding therapy* |
| In all of the studies, the molding therapy group had the infant fitted for a helmet, to be worn for the majority of the day (average 23 hours/day). There was no indication as to who completed the fitting for the helmet. Treatment duration, in months, in each of the studies were 5.3, 3.5 (SD 3.5), 14.7, 4.5, 4.8, 2-3, and 5.6 (SD 6.2).2–8 |
| **Outcome Measures**  [Give details of each measure, maximum possible score and range for each measure, administered by whom, where] |
| In 5 of the studies, outcomes were measured either subjectively or objectively. Articles 1 and 2 used both subjective and objective mesurements.2,3 No blinding of outcome assessments were mentioned in any of the studies. Article 5 did not administer anthropometric measurements for the entire cohort.6  Overall, outcome measures were the anthropometric measurements, taken by the physician in the clinic or hospital, using various instruments and by visual interpretation. No details were provided for which anthropometric measurements that were specifically taken. Best possible outcome was indicated through being within normal range of the head shape using anthropometric measurements or visual judgment. No range for each measure was indicated. |
| **Main Findings**  [Provide summary of mean scores/mean differences/treatment effect, 95% confidence intervals and p-values etc., where provided; you may calculate your own values if necessary/applicable. Use a table to summarize results if possible.] |
| Findings were taken from the Summary of Results table on pages 723 and 724 of the systematic review. Group A indicates the molding therapy group and group B indicates the repositioning group.   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | Source | Magnitude of Net Benefit of Interventiona | *P* Value | Relative Risk (95% CI) | Efficacy (95% CI) | Number Needed to Treat (95% CI) | | Clarren, 19812 | A. Effective in 19 infants, noneffective in 9.  B. Noneffective in all 10 infants. | .001 | 14.793 (0.974-224.568) | 0.627 (0.416-0.838) | 2 (1-2) | | Graham et al., 20053 | A. Effective in 122 infants, noneffective in 9.  B. Effective in 139 infants, noneffective in 37.  Anthropometric measurement (in cranial diagonal difference) reduction for group A was significantly larger than group B at 0.71 cm and 0.55 cm, respectively. | <.001 | 1.264 (1.170-1.365) | 0.208 (0.147-0.269) | 5 (4-7) | | Loveday and de Chalain, 20014 | Both treatments were effective and anthropometric improvements were comparable. Repositioning group had 3 times longer treatment duration than molding group. Molding group also consisted of many failed repositioning group infants. |  |  |  |  | | Moss, 19975 | A: Cranial vault asymmetry improved on average from 8.9mm to 4mm  B: Cranial vault asymmetry improved an average of 10.6mm to 5.5mm  The two groups could not be compared due to differences in anthropometric definitions between the groups. |  |  |  |  | | Mulliken et al., 19996 | Both treatments were effective. Improvement in the molding group was statistically significantly greater. |  |  |  |  | | Pollack et al., 19977 | All infants started with repositioning therapy. After 2-3 months, 34 infants’ head shapes did not improve and crossed over to the molding therapy group. Normal to nearly normal head shape was achieved in all but 5 infants (who were all >6 months old at start of intervention). |  |  |  |  | | Vles et al., 20008 | The molding group had more severe differences at beginning of treatment, but still had significantly greater improvement in head symmetry. Treatment time for repositioning group was 4.6 times longer than molding group, showing statistical significance. |  |  |  |  |   aEffectiveness determined by being within normal range of head shape either by visual interpretation or anthropometric measurements  Biases within several of the studies made comparison between groups only possible in 5/7 studies. Treatment for both groups was around 6 months for all except one study. Repositioning therapy was significantly longer in 2 of the studies.  Calculation of magnitude of effect: 3 of the studies did not provide enough information of results to compare magnitude of effect. One study had significant measurement bias. Another was not clear on whether they administered repositioning therapy or simply observed the comparison group. One study had participants cross over after failure of repositioning group, and was not included in the calculation. Only article 2, the Graham et al. study, was able to determine magnitude of treatment effects through calculation. The study resulted that improvement was 1.3 times more likely with molding therapy than repositioning therapy. Absolute risk reduction for proportion of infant improvement was determined at 0.21 (0.15-0.27, 95% CI), favouring molding therapy over repositioning therapy. |
| **Original Authors’ Conclusions**  [Paraphrase as required. If providing a direct quote, add page number] |
| The authors noted significant bias towards repositioning therapy, potentially underestimating the benefit of using molding therapy over repositioning therapy. Even with bias towards the repositioning therapy group, molding therapy was seen to be more effective in the majority of the studies. The authors of the review stated a great need for further research to help determine the true efficacy of molding therapy in terms of nonsurgical treatment strategies. |
| **Critical Appraisal** |
| **Validity**  [Summarize the internal and external validity of the study. Highlight key strengths and weaknesses. Comment on the overall evidence quality provided by this study.] |
| * ROBIS risk of bias in systematic reviews score: * Domain 1 (study eligibility criteria) – low * Domain 2 (identification and selection of studies) – low * Domain 3 (data collection and study appraisal) – low * Domain 4 (synthesis and findings) – low * Phase 3 Risk of Bias – low * Key strengths of this systematic review include * The authors used multiple data sources to search for appropriate articles * Eligibility criteria was clearly defined * 2 reviewers completed the appraisal of evidence to help limit bias * The authors noted any biases and differences they found in the studies, and attempted to limit bias of their statistical analyses throughout the review * All of the studies included were directly related to the clinical question * Key weaknesses of this systematic review include * The only demographics shared in the review was the average age of participants at the beginning of the study * The authors did not share the intervention methods of the two different treatments * There was a lot of bias within the individual studies they reviewed – lack of blinding, lack of objective measurement consistency, selection bias, lack of taking into account cofounding factors, cross over in groups, significant difference in timing within each group, different severities within the groups, follow-up only occurred at the end of the treatment * Overall, the quality of evidence the study provided was low to moderate. Even though the authors did their best to limit bias in their review, the quality of the evidence within the studies they were reviewing were overall poor, thus limiting the ability to quantitatively compare effectiveness of the different treatments. |
| **Interpretation of Results**  [This is YOUR interpretation of the results taking into consideration the strengths and limitations as you discussed above. Please comment on clinical significance of effect size / study findings. Describe in your own words what the results mean.] |
| While the authors took the best steps possible to limit bias within the review, the biases within the individual studies made the effectiveness of the two interventions difficult to access. The authors compared all cohort studies, assisting in objectively comparing results. The review determined the effect size to be 5 (4-7, 95% CI). This means that 5 infants need to be treated with molding therapy to effectively improve plagiocephaly. Clinically, that is a very good number considering a paediatric therapist can see more patients with plagiocephaly than than within a single business day. Even though the biases favored the repositioning group, the molding group still had overall better results. This means that more severe cases of plagiocephaly saw better cranial symmetry over a shorter period of time. Clinically, this can be useful in giving parents options for non-surgical treatments for their child. |
| **Applicability of Study Results**  [Describe the relevance and applicability of the study to your clinical question and scenario. Consider the practicality and feasibility of the intervention in your discussion of the evidence applicability.] |
| This systematic review has good relevance the the clinical question presented as it compared molding therapy, another term for doc band, to repositioning therapy, which is a part of physical therapy intervention. Unfortunately, the studies were somewhat unclear as to how much physical therapy influenced the repositioning therapy group, making it harder to apply directly to the clinical scenario presented. However, in descriptions of repositioning therapy, a lot of the same techniques are applied as with physical therapy, so some of the results can be applied to clinical practice. The review noted that the more severe cases of plagiocephaly had greater benefits when in the molding group, but the repositioning group still saw significant results for more mild to moderate cases. Therefore, perhaps it would be beneficial to start the infant on repositioning therapy and switch over to molding as needed, as helmets can be quite expensive. There was no evidence to say infants who switched from repositioning to molding therapy had worse outcomes than infants who started on molding therapy initially, therefore it would not necessarily harm the infant if they began with repositioning therapy alone. As repositioning therapy is considered to be less invasive, the parent may prefer to chose this route, keeping in mind the potential to switch to molding therapy. |

**(2) Description and appraisal of Evidence-based care of the child with deformational plagiocephaly, part II: management by Flannery ABK, Looman WS, Kemper K. 2012.**

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| **Aim/Objective of the Study/Systematic Review:** |
| The aim of the systematic review was to guide primary care clinical decision making on non-synostotic deformational plagiocephaly (DP) by gathering the most current and relevant clinical management evidence. |
| **Study Design**  [e.g., systematic review, cohort, randomised controlled trial, qualitative study, grounded theory. Includes information about study characteristics such as blinding and allocation concealment. When were outcomes measured, if relevant]  Note: For systematic review, use headings ‘search strategy’, ‘selection criteria’, ‘methods’ etc. For qualitative studies, identify data collection/analyses methods. |
| **Systematic review of systematic reviews (3), case-control studies (6), cohort studies (15), and randomized control trials (RCT) (2) for treatment of deformational plagiocephaly.**   * **Search strategy:** the authors searched 2 different online databases. MEDLINE was searched using MeSH heading of “plagiocephaly, non-synostotic” and CINAHL was searched using major subject “deformational plagiocephaly”. * **Selection criteria:** The search was limited to peer-reviewed research reports published in 2000 and later. Exclusion criteria included: letters, comments, or editorials; duplicates; non-English; not focused on primary non-synostotic plagiocephaly; historical/anthropological; patient handouts; or non-human. After exclusion criteria was applied, 26 of the 73 remaining articles were specifically related to deformational plagiocephaly management. 3 were systematic reviews and 23 were research articles. * **Methods:** the articles were graded for strength and quality using 2 different methods. The studies were first rated on strength of evidence through the Fineout-Overhold, Melnyk, Stillwell, and Williamson described hierarchy. This hierarchy rates level of evidence as I-VII, with systematic reviews and meta-analyses rating as I and expert opinion or consensus as VII. The studies were then rated in quality by the Critical Review Form for quantitative studies. The tool gives a point for each criteria the study has: “purpose clearly stated; literature review relevant; research design appropriate to answer aims; no bias introduced into the study; sample described in detail; sample size justified; informed consent gained; reliable outcome measures used; validated outcome measures used; intervention described in detail; results reported in terms of significance; analysis appropriate; clinical importance reported; conclusions appropriate; clinical implications reported; and acknowledgement of limitations of the study” (page 321). The articles were additionally put into categories based on treatment timing, positioning and/or physical therapy interventions, surgical intervention, and orthotic device intervention using either helmets, cups, or pillows. |
| **Setting**  [e.g., locations such as hospital, community; rural; metropolitan; country] |
| The locations of the studies were not explicitly stated in the systematic review, however, based on the information provided it can be assumed that the treatments occurred in either a hospital setting or an outpatient clinic. |
| **Participants**  [N, diagnosis, eligibility criteria, how recruited, type of sample (e.g., purposive, random), key demographics such as mean age, gender, duration of illness/disease, and if groups in an RCT were comparable at baseline on key demographic variables; number of dropouts if relevant, number available for follow-up]  Note: This is not a list of the inclusion and exclusion criteria. This is a description of the actual sample that participated in the study. You can find this descriptive information in the text and tables in the article. |
| All of the infants in the included studies had a diagnosis of deformational plagiocephaly, which varied in severity of mild, moderate, or severe.  Number of participants in the non-systematic review studies were reported as:   * Carson et al. (2000) – 68 participants wore an assistive device * David & Menard (2000) – 204 infants (84 mild, 90 moderate, 30 severe) had positioning therapy +/- PT, 19 severe cases had surgery * de Ribaupierre et al. (2007) – 260 infants had helmet therapy * Elwood et al. (2005) – 81 infants were treated with an orthotic device * Govaert et al. (2008) – 46 infants had molding therapy and were compared to 251 healthy control subjects * Graham, Gomez et al. (2005) – 176 infants were treated with repositioning and 159 were treated with helmet therapy * Graham, Kreutzman et al. (2005) – 96 infants treated with repositioning and 97 treated with helmet therapy * Hutchison et al. (2010) – 126 total infants randomly assigned to positioning or device group * Jalaluddin et al. (2001) – 303 infants were treated; 166 infants were in repositioning and neck stretching group and 137 in orthotic (headband or helmet) group * Lee et al. (2006) – no number given * Lee et al. (2008) – no total number given, but 28 infants were reported to have significant improvements within the helmet therapy group * Lipira et al. (2010) – 70 total infants, 35 in repositioning group and 35 in helmeting therapy group * Losee et al. (2007) – 145 total infants, 45 in helmeting after repositioning therapy group and 100 in repositioning alone * Loveday & de Chalain (2001) – 74 total infants, 45 in counter-positioning group and 29 in helmet therapy group * Marchac et al. (2011) – 30 infants diagnosed with severe DP were treated with corrective surgery * Plank et al. (2006) – 207 infants with moderate to severe DP were treated with helmet therapy and compared to control subject who received no treatment (N was not reported) * Rogers et al. (2008) – 47 total infants, 24 received a modifiable cranial cup and 22 received repositioning and PT * Steinbok et al. (2007) – 18 children received orthotic intervention and 47 received repositioning therapy +/- PT * Teichgraeber et al. (2002) – 125 infants with moderate to severe DP received helmet therapy +/- PT * Terpenning (2001) – total participants not reported, 12 infants who underwent helmet therapy had significant results * Thompson et al. (2009) – 116 infants received helmet therapy * van Vlimmeren et al. (2008) – 68 total infants were randomly assigned to either 4 months of PT intervention or usual care (control group) * Vles et al. (2000) – 105 total infants, 85 received helmet therapy and 20 control group (no helmet)   Age (in months) of the infants at treatment time for each of the studies were 1.5-12, 1.5-24, 3-18, <12, 6.6 +/- 2.2, 1-6, 3-12, <12, 2-7, <12, <12, 2-7, 3-14, 6-12+, 15-34, 3-12, <4, 3-16, <12, 5-14, 1-12, 2-6, and not reported. In the majority of the studies, the infants were less than 12 months at the start of treatment time. No other demographic information was provided.  No other participant information was provided in this systematic review. |
| **Intervention Investigated**  [Provide details of methods, who provided treatment, when and where, how many hours of treatment provided] |
| *Control – repositioning therapy* |
| In general, repositioning was taught by the physician or physical therapist. It is outlined as alternating head position when putting infant to sleep in supine, spending as little time as possible in car seats, supervised tummy time as frequent as possible with a goal of at least 30 minutes a day, active repositioning during sleep, positioning the crib and changing table opposite of the infant’s preferred position, and placing toys on the side the infant is limited. Neck exercises were given with the presence of torticollis in addition to plagiocephaly. It was recommended the exercises were completed for 2 minutes during each diaper change. Exercises include: rotating infant’s chin towards both shoulders and tilting the infant’s head in attempt to touch their ear to their shoulder. |
| *Experimental – orthotic (helmet) therapy* |
| Cranial orthotics are fitted for the individual by either the physician or qualified professional, providing dynamic pressure to certain areas of the skull in order to promote growth in flattened areas. The helmet was worn between 20-23.5 hours a day. Other cranial orthotics included in the systematic review were positioning wrap worn during sleep, and a cranial cup when the infant is in supine. The orthotics were worn for a duration between 3 months to a year.  \*surgery protocol is not going to be included in the intervention details as it is rarely indicated, is not a conservative treatment method, not administered nor monitored by physical therapists, and is not related to the clinical question at hand |
| **Outcome Measures**  [Give details of each measure, maximum possible score and range for each measure, administered by whom, where] |
| Outcome measures within the studies were either anthropometric measurements or visual inspection of head shape symmetry. The head shape assessments were completed by the physicians at the end of the treatment time. Best outcome was defined as complete head symmetry. When the measurements were taken varied across the studies. |
| **Main Findings**  [Provide summary of mean scores/mean differences/treatment effect, 95% confidence intervals and p-values etc., where provided; you may calculate your own values if necessary/applicable. Use a table to summarize results if possible.] |
| Findings of the review were gathered from the table provided on pages 324-326.9   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | |  | | | | Intervention Provided | | | | Authors/year | **Design & level of evidence** | **Quality score (0-16)** | **Main findings** | **Positioning +/- PT** | **Surgery** | **Device** | | Bialocerkowski et al. (2005) | Systematic review (I) | N/A | Moderate to poor evidence; no criterion standard in skull asymmetry outcome measure assessment; skull deformity can improve with either helmet therapy or counter-positioning +/- PT |  |  |  | | Robinson & Proctor (2009) | Systematic review (I) | N/A | Methodological bias limited the level of evidence; mild deformity better treated with repositioning and PT, in more severe cases helmet therapy was more effective |  |  |  | | Xia et al. (2008) | Systematic review (I) | N/A | Methodological bias limited the level of evidence; infants </= 4 months with non-severe DP better treated with repositioning therapy; infants >/= 6 months better treated with molding therapy; between 4-6 months there is uncertainty in treatment choice; overall molding therapy may improve skull symmetry over repositioning therapy |  |  |  | | Carson et al. (2000) | Case-control (IV) | 7 | Good-excellent results in 62/68 infants wearing an AD during sleep who had moderate to severe DP; infants > 7 months saw less effectiveness |  |  | AD | | David & Menard (2000) | Cohort (IV) | 5 | 94% of infants of both positioning +/- PT and surgical intervention was subjectively significant improvements; with 2 surgical and 1 conservative treatment patients having no noticeable improvement by parent report | X | X |  | | de Ribaupierre et al. (2007) | Cohort (IV) | 5 | Treatment duration similar for infants treated before and after 6 months old; single helmet intervention improve TDD measurements in 147/260 patients; 98 and 15 patients had good results after 2 and 3 helmets |  |  | Helmet | | Elwood et al. (2005) | Cohort (IV) | 9 | All parents indicated recommendation to use the helmet to others; head shape improvement rated 4.06/5 on a Visual Analog Scale in 81 infants |  |  | Helmet | | Govaert et al. (2008) | Case-control (IV) | 8 | After 4-8 year follow-up, children had similar quality of life rating to healthy control subjects |  |  | Helmet | | Graham, Gomez et al. (2005) | Retrospective cohort (IV) | 12 | Helmet therapy was more statistically significant in improvement of DP, but both repositioning and helmet therapy groups saw improvement; helmet therapy was administered later and treatment lasted longer | X |  | Helmet | | Graham, Kreutzman et al. (2005) | Retrospective cohort (IV) | 12 | Cephalic index change for helmet therapy group was significant, but not for repositioning group; infants starting at a younger age saw greater improvement | X |  | Helmet | | Hutchison et al. (2010) | RCT (II) | 12 | Infants randomized in either positioning or sleep positioning wrap device groups; no difference at 12 month follow up for head shape outcomes between the groups; quickest improvement seen at 3 months of treatment | X |  | AD | | Jalaluddin et al. (2001) | Case-control (IV) | 3 | At 3 to 5 year follow-up, both repositioning and stretching were seen as effective as orthotic devices on long-term outcomes | X |  | AD, Helmet | | Lee et al. (2006) | Cohort (IV) | 11 | Infants undergoing helmet therapy had significant improvements from baseline |  |  | Helmet | | Lee et al. (2008) | Cohort (IV) | 11 | Helmet therapy significantly improving head shape symmetry over 6 months; no significant changes at 5.6-year follow-up of helmet therapy group |  |  | Helmet | | Lipira et al. (2010) | Case-control (IV) | 13 | Between helmet therapy and active repositioning infants with DP, the helmet group had significantly greater improvements in head symmetry, as assessed by 3D scans | X |  | Helmet | | Losee et al. (2007) | Retrospective cohort/case control (IV) | 8 | The addition of cranial molding helmet therapy after completion of repositioning therapy was more effective than repositioning therapy by itself; outcomes not influenced by age at start of treatment | X |  | Helmet | | Loveday & de Chalain (2001) | Retrospective cohort (IV) | 6 | Helmet therapy group had comparable treatment outcomes to repositioning group, but treatment time 3x shorter | X |  | Helmet | | Marchac et al. (2011) | Retrospective cohort (IV) | 7 | Infants with severe DP had surgical intervention, with poor to excellent results at 1 year follow-up after correction |  | X |  | | Plank et al. (2006) | Case-control (IV) | 12 | Moderate to severe cases of DP underwent helmet therapy and were compared to a no treatment group; significant improvement in 96% of the helmet group and 30% worsening in the control group in terms of head asymmetry |  |  | Helmet | | Rogers et al. (2008) | Prospective cohort with historical control subjects (IV) | 8 | Repositioning with PT was compared to cranial cup administration in infants with DP; while the cup was more effective in head shape correction, both groups improved in balance of the cervical muscles | X |  | AD | | Steinbok et al. (2007) | Case-control (IV) | 10 | Children who received orthotic intervention were compared to non-orthotic intervention at a 5 years or more; no difference in either cosmetic or developmental outcomes were found | X |  | Helmet | | Teichgraeber et al. (2002) | Retrospective cohort (IV) | 10 | Helmet therapy was administered with or without PT in moderate to severe DP cases; age did not predict outcomes; both cranial vault and cranial base symmetry improved | X |  | Helmet | | Terpenning (2001) | Cohort (IV) | 6 | Beginning treatment at 6 months saw best treatment outcomes; infants treated with helmet therapy saw significant improvements in skull asymmetry |  |  | Helmet | | Thompson et al. (2009) | Cohort (IV) | 6 | Infants initially treated with helmet therapy between 4-8 months old had best treatment outcomes; significant improvement in majority of infants treated with helmet therapy |  |  | Helmet | | van Vlimmeren et al. (2008) | RCT (II) | 16 | Infants had DP and a positional preference at start of treatment; no positional preference indicated at 12 months in either group; infants undergoing 4-months of standardized PT intervention demonstrated significant improvement in comparison to the usual care (control) group | X |  |  | | Vles et al. (2000) | Prospective cohort (IV) | 9 | Cosmetic improvement was significant for helmet group in comparison to the non-helmet group |  |  | Helmet |   AD = Assistive Device (band, foam pillow, cup, or wedge)  Overall, it was found repositioning was more beneficial in infants <4 months old, with helmet therapy being more effective for older infants (>6 months old) and more severe cases of plagiocephaly.  The authors found minimal long-term effects in children who have had resolved plagiocephaly. |
| **Original Authors’ Conclusions**  [Paraphrase as required. If providing a direct quote, add page number] |
| The authors determined different treatment approaches for deformational plagiocephaly depends on 2 factors: age of the infant at start of treatment and the magnitude of head asymmetry. As shown in their review, evidence for treatment has improved in recent years, having RCTs and better design in studies. If started early, conservative treatment strategies of repositioning and helmet therapy can help improve head symmetry in infants. Cranial molding therapy is highly successful if treatment starts by the time the infant is 6 months old and has no indication of harm in choosing this intervention. However, helmet therapy may not be covered by insurance and can be very expensive. Therefore, regular patient visits to the primary care physician and close monitoring of measurements over time will best help choose management strategies for deformational plagiocephaly. |
| **Critical Appraisal** |
| **Validity**  [Summarize the internal and external validity of the study. Highlight key strengths and weaknesses. Comment on the overall evidence quality provided by this study.] |
| * ROBIS risk of bias in systematic reviews score: * Domain 1 (study eligibility criteria) – low * Domain 2 (identification and selection of studies) – low * Domain 3 (data collection and study appraisal) – low * Domain 4 (synthesis and findings) – high * Phase 3 Risk of Bias – low * Key strengths of this systematic review include * The authors assessed the quality of the studies through validated measures and provided a chart outlining results * The eligibility criteria were clearly defined * The authors used terms likely to retrieve as many relevant results as possible * The authors provided methods for the different interventions being analysed * All of the studies were related to the clinical question * Key weaknesses of this systematic review include * The review did not state how many reviewers conducted the finding and appraisal of evidence * The authors only used 2 databases for searching and did not use any methods in addition to database searching to identify relevant reports * The authors did not identify any effort in minimizing error in risk of bias assessment * The study did not include any mean baseline measurements nor normative values for healthy population * The authors did not conduct a sensitivity analysis to demonstrate whether findings were robust * Statistical and clinical significance was not defined in the review * There was a mixture of types of studies in the review, making it difficult to be able to compare results * The only demographics shared in the review was the average age of participants during treatment   Overall, the quality of evidence was moderate, with the majority of the studies receiving mid-range scores on the Critical Review form. The quality of evidence seemed to improve in later years, as demonstrated by their quality rating scores. Only one study, one of the RCTs received a 12/12 on the rating system, indicating a great need for further research. |
| **Interpretation of Results**  [This is YOUR interpretation of the results taking into consideration the strengths and limitations as you discussed above. Please comment on clinical significance of effect size / study findings. Describe in your own words what the results mean.] |
| The review did a good job of including all relevant studies for analysis. The different type of studies in the review reflected the increasing level of evidence the different treatments have in effectiveness. The interventions were explained in more detail than a lot of other research studies surrounding the topic, making it easier to apply to clinical practice. Although many of the patient demographics were not given, it can be drawn that both repositioning therapy +/- physical therapy and orthotic (helmet) device use are effective in improving head symmetry of infants with plagiocephaly with/without torticollis. As shown in the results of the various studies, infants at a younger age and with mild to moderate plagiocephaly would benefit from attempting repositioning therapy initially, with the potential to switch to helmet therapy if head symmetry did not improve adequately. This systematic review did not include an effect size to indicate the magnitude of the interventions. |
| **Applicability of Study Results**  [Describe the relevance and applicability of the study to your clinical question and scenario. Consider the practicality and feasibility of the intervention in your discussion of the evidence applicability.] |
| This systematic review does have applicability to the current clinical question/scenario. It provides various options for families to choose as interventions for their child with plagiocephaly/torticollis. Not all of the studies compared helmet therapy to repositioning therapy, and not all of the repositioning therapy groups had physical therapy integrated. Therefore, it is difficult to fully assess whether one treatment is superior to the other in correcting infant head shape. However, the findings were mostly consistent throughout the studies in that good results were found with both types of treatment, with repositioning therapy (+/- PT) being more effective in younger, more mild cases and helmet therapy more effective in older, more severe cases. There was no harm indicated in using either method, and the child can be switched based on effectiveness of treatment. With helmet therapy tending to be quite expensive and often not being covered by insurance, a therapist could feel safe in offering either method to families without high risk of poor outcomes. |

**SYNTHESIS AND CLINICAL IMPLICATIONS**

[Synthesize the results, quality/validity, and applicability of the two studies reviewed for the CAT. Future implications for research should be addressed briefly. Limit: 1 page.]

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| **Evidence Synthesis**  The reviewed evidence indicates that infants with plagiocephaly could benefit from either repositioning therapy or molding (helmet) therapy in order to improve cranial symmetry. The majority of the studies within each systematic review outlined that infants less than 6 months of age and mild to moderate severity were better off beginning with repositioning therapy with/without physical therapy, and could switch to helmet therapy if there was no improvement in head symmetry after 2-3 months. Infants older than 6 months and had more severe deformity would see better reduction in asymmetry through helmet therapy, even if initially starting with repositioning therapy. There was no indication of harm in using either of the treatment methods, with the majority of infants achieving within normal range of head shape symmetry by 2 to 3 years of age.  In terms of quality of evidence, the two systematic reviews mainly consisted of studies of moderate to poor quality. While the reviews themselves took the necessary steps in limiting the risk of bias in their analysis, the poor quality of evidence made appraisal and comparison nearly impossible. There is an overall lack of criterion standard in measuring cranial asymmetry, making it difficult to compare studies. The majority of evidence is through retrospective cohort studies, thus lacking randomized controlled trials (RCT) contain methodological biases. However, higher quality studies like RCT design may not be suitable for this patient population. A couple of the studies showed no improvement in head symmetry in untreated infants, therefore randomly allocating infants to be in a control group with no intervention would be unethical in practice. Retrospective analysis, or cohort studies providing different interventions with varying degrees of involvement may be the best possible evidence for this type of condition. Even with this, the current research has an overall lack of analysis on drop-out nor is there much description of the physical therapy interventions used. There is an emphasis on the efficacy of the helmet therapy as opposed to comparing directly helmet therapy and physical therapy/repositioning as interventions. While the standardization and evidence quality improves over time, there is an overall lack evidence for this clinical question.  **Clinical Implications**  Clinicians can take the the evidence provided in the studies and apply them to their clinical practice. While the actual efficacy is unknown for the two different interventions, both seem to be appropriate to administer to patients with relatively little risk. Both options can be presented to parents, showing them that repositioning therapy with or without physical therapy may be a better option for younger, less severe cases and helmet therapy is more applicable for older, more severe asymmetries. At the time of the research studies, helmet therapy is often not covered by insurance and is very expensive. The reason for lack of coverage is the lack of relevant evidence from research showing the effectiveness in treating plagiocephaly.10 Therefore, parents may opt for the repositioning treatment route initially. As neither treatment show significant side-effects or relative risks, a clinician may feel comfortable with either choice to start with, given current evidence. Though, depending on the severity and age of the infant, the clinician may suggest one over the other.  As of 2016, new guidelines from the American Academy of Pediatrics (AAP) suggest physical therapy to be administered in all cases in addition to repositioning therapy in order to yield better outcomes.11 However, there is not a consensus among literature as to the best timing for initiation, duration of treatment, and particular stretches/exercises to achieve the best results.  **Implications for Future Research**  Further research is indicated across many areas of this clinical topic. More studies should focus on comparison of helmet therapy to other noninvasive interventions for infants across similar domains. Current evidence lacks direct comparison of treatments for infants possessing comparable demographics. Secondly, the majority of the research did not take into account confounding factors, such as craniosynostosis, congenital craniofacial deformities, or genetic conditions like Down syndrome, that could affect treatment. Many cases of plagiocephaly and torticollis have underlying conditions that may affect treatment, therefore inclusion of such factors will help further apply evidence.1 There should also be more clear definitions of treatment and measurement criterion in order to generalize treatment in the plagiocephaly/torticollis population.  Current evidence indicates that infants with plagiocephaly may benefit from helmet therapy, particularly in more severe cases and at a later diagnosis, but it is unclear as to the true efficacy and clinical significance of such treatment. In clinical practice, parents may choose not to apply a Doc Band due to costs and resources, potentially limiting effectiveness of treatment. As insurance often relies on research evidence for coverage, it is vital for more research to be conducted investigating the efficacy of using helmet therapy on infants with plagiocephaly/torticollis. |

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[List all references cited in the CAT]

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