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| **CRITICALLY APPRAISED TOPIC** |

**FOCUSED CLINICAL QUESTION**

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| For a preterm infant in the neonatal intensive care unit (NICU) with cranial molding deformity (CMD), is a cranial molding orthotic device or a positioning program more effective for correcting head shape to achieve greater symmetry? |

**AUTHOR**

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**CLINICAL SCENARIO**

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| Since I have had only occasional observation experiences in the NICU, this clinical question is inspired more by my capstone project than by a specific patient encounter. My capstone will focus on determining the various cranial molding interventions that are currently being utilized in NICUs throughout the United States, as well as ways that head shaping deformities can be prevented. Though much of cranial molding research is focused on the outpatient setting, I want to look at the effectiveness of these interventions specifically for infants in the NICU, which represents an earlier stage of development than those who are receiving outpatient physical therapy. This topic is clinically important because head shape has an impact on brain growth and development; therefore, pediatric physical therapists need to be aware of the most effective interventions to correct deformities as efficiently as possible. |

**SUMMARY OF SEARCH**

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| * There are currently no published studies that directly compare the effectiveness of a cranial molding orthotic device versus a positioning program for improving head shaping outcomes in preterm infants in the NICU with cranial molding deformity. * Using more generalized inclusion/exclusion criteria than desired for answering the clinical question, 10 studies were identified that address cranial molding interventions in infants, including 3 systematic reviews, 2 randomized controlled trials, 3 prospective cohort studies, and 2 retrospective analyses. Three of these studies were selected for further review and discussion based on their relevance to the clinical question and methodological quality. * The cranial cup orthotic device seems to be a safe and potentially effective intervention for improving head shaping outcomes in infants with or at-risk for cranial molding deformity, including those who are premature, though the overall level of evidence is currently low. * Future research on this topic should include more randomized controlled trials with larger sample sizes, increased specificity regarding intervention protocols, long-term follow up of participants to assess outcomes over time, and a greater focus on preterm infants in the NICU environment. |

**CLINICAL BOTTOM LINE**

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| Based on the best available current research, there is a low level of evidence to suggest that the cranial cup orthotic device may be a safe and effective intervention for normalizing head shape in a preterm infant in the neonatal intensive care unit with cranial molding deformity, although ideal parameters of device use are currently undetermined. |

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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*** |

**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) |
| Preterm  Premature  Infant\*  Baby  Babies  Neonat\*  Newborn\*  Neonatal Intensive Care Unit  NICU  Cranial molding deformity  Cranial moulding deformity  CMD  Skull deformity  Plagiocephaly  Brachycephaly  Scaphocephaly  Dolichocephaly | Cranial molding helmet\*  Cranial moulding helmet\*  Plagiocephaly helmet\*  Cranial orthosis  Cranial orthoses  Cranial orthotic\*  Cranial helmet\* | Position\*  Reposition\* | Head symmetry  Head shape  Cranial symmetry  Cranial shape |

**Final search strategy:**

For PubMed:

1. (preterm OR premature) AND (infant\* OR baby OR babies OR neonat\* OR newborn) AND (neonatal intensive care unit OR NICU) 🡪 n=9880
2. “cranial molding deformity” OR “cranial moulding deformity” OR CMD OR “skull deformity” OR plagiocephaly OR brachycephaly OR scaphocephaly OR dolichocephaly 🡪 n=7916
3. cranial molding helmet\* OR cranial moulding helmet\* OR plagiocephaly helmet\* OR cranial orthosis OR cranial orthoses OR cranial orthotic\* OR cranial helmet\* 🡪 n=380
4. position\* OR reposition\* 🡪 n=505718
5. head symmetry OR head shape OR cranial symmetry OR cranial shape 🡪 n=14351
6. #1 AND #2 AND #3 AND #5 🡪 n=0
7. #1 AND #2 AND #4 AND #5 🡪 n=1
8. (infant\* OR baby OR babies OR neonat\* OR newborn) AND (neonatal intensive care unit OR NICU OR hospital) 🡪 n=321428
9. #8 AND #2 AND #3 AND #5 🡪 n=17
10. #8 AND #2 AND #4 AND #5 🡪 n=37
11. **#9 OR #10 🡪 n=40**

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| **Databases and Sites Searched** | **Number of results** | **Limits applied, revised number of results (if applicable)** |
| **PubMed**  **CINAHL**  **PEDro** | **40**  **21**  **12** | **Search yielded 1 result initially; revised as indicated above to increase to 40.**  **- (preterm OR premature)**  **+ (OR hospital)**  **Search yielded 1 result initially; revised by combining terms more broadly: S8 AND (S2 OR S3 OR S5)**  **(Numbers correspond to final search strategy listed above.)**  **Therapy: orthoses, taping, splinting**  **Body Part: head or neck**  **Subdiscipline: paediatrics**  **Match all search terms (AND)** |

## INCLUSION and EXCLUSION CRITERIA

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| **Inclusion Criteria** |
| * Article in English * Peer-reviewed publications * Intervention involves cranial molding and/or positioning program |
| **Exclusion Criteria** |
| * Case studies or case series * Abstracts or dissertations * Studies involving individuals older than 12 months of age at the start of treatment |

**RESULTS OF SEARCH**

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

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| **Author (Year)** | **Study quality score** | **Level of Evidence** | **Study design** |
| **Bialocerkowski (2005)** | **7/11\*** | **1a** | **Systematic review of case series and comparative studies** |
| **DeGrazia (2015)** | **8/11\*\*\*** | **1b** | **Stratified, single-blind, randomized trial** |
| **Knorr (2016)** | **18/29\*\*** | **2b** | **Prospective descriptive research** |
| **Naidoo (2014)** | **12/29\*\*** | **3** | **Retrospective analysis** |
| **Paquereau (2013)** | **7/11\*** | **1a** | **Systematic review of cohort studies** |
| **Pollack (1997)** | **9/29\*\*** | **2b** | **Non-randomized prospective cohort** |
| **Rogers (2008)** | **12/29\*\*** | **2b** | **Non-randomized prospective cohort** |
| **Shamji (2012)** | **11/29\*\*** | **3** | **Retrospective analysis** |
| **Van Wijk (2014)** | **8/11\*\*\*** | **1b** | **Single-blind, randomized controlled trial** |
| **Xia (2008)** | **9/11\*** | **1a** | **Systematic review of cohort studies** |

\* AMSTAR

\*\* Downs and Black

\*\*\* PEDro Scale

**BEST EVIDENCE**

The following 3 studies were identified as the ‘best’ evidence and selected for critical appraisal. Reasons for selecting these studies were:

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| * **Rogers (2008) –** This non-randomized prospective cohort study compares both interventions of interest in my PICO question: cranial orthotics and positioning programs. Whereas most of the studies I located utilized a sample that included infants over 6 months of age (one of my original exclusion criteria), this article assessed only infants younger than 4 months old. Though the interventions were not applied to premature infants in the NICU setting, this article comes closest of the remaining studies to meeting my original inclusion/exclusion criteria. * **Knorr (2016) –** This prospective descriptive study is one of few that addresses head shaping interventions in both my setting of interest, neonatal intensive care units, and my population of interest, premature infants. It is the only article I located that completely meets all of my original inclusion criteria, and it is the highest scoring non-RCT on the Downs and Black checklist at 18/29. This study comes closest of all search results to matching the clinical scenario presented in my PICO question. * **DeGrazia (2015) –** This stratified, single-blind, randomized trial is one of few studies that addresses head shaping interventions in my setting of interest: neonatal intensive care units. Though it does not fully meet my original inclusion criterion of all participants being born prior to 37 weeks gestation, the data does show that the majority of participating infants had a gestational age of 31 weeks or fewer. Also, as a randomized trial, this study represents one of the higher levels of evidence on this topic (1b) with a high quality PEDro scale score as well (8/11). |

**SUMMARY OF BEST EVIDENCE**

**(1) Description and appraisal of *Comparison of a Modifiable Cranial Cup versus Repositioning and Cervical Stretching for the Early Correction of Deformational Posterior Plagiocephaly* by Rogers GF, Miller J, and Mulliken JB (2008).**

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| **Aim/Objective of the Study/Systematic Review:** |
| The purpose of this study was to compare the effectiveness of two treatment strategies for the correction of deformational posterior plagiocephaly in infants less than 4 months of age: a custom-made occipital orthotic device and repositioning combined with cervical stretching techniques. |
| **Study Design** |
| This study was a non-randomized prospective cohort trial with a historical control group. There was no blinding of subjects, therapists, or assessors due to the nature of the interventions and study design. Outcomes for both groups were measured by a single assessor at baseline and following the intervention period (average of 56.3 days for treatment group and 61.6 days for control group). Follow up sessions were not conducted beyond the time of final evaluation at the end of treatment. |
| **Setting** |
| Though the setting of this study was not explicitly stated, it appears that the interventions for both groups were implemented by the parents of infant subjects in their home environment. Initial and final evaluation measures were obtained at the practice location of the primary author, Gary F. Rogers, which is associated with the Children’s Hospital in Boston, Massachusetts. |
| **Participants** |
| All participants (N = 51 total) were referred to the same practice location for treatment of deformational posterior plagiocephaly. There are no additional details provided with respect to recruitment procedure, though it appears that consecutive purposive sampling may have been used.  Treatment Group:   * N = 28 (Only 24 infants were included in analysis due to failure of 4 participants to obtain the cranial cup device.) * Received intervention between August of 2003 and June of 2004 * Gestational age at birth = 38.2 +/- 2.8 weeks * Age at initial evaluation (baseline) = 96.5 +/- 28.7 days   Historical Control Group:   * N = 23 * Received intervention between August of 2002 and June of 2003 * Gestational age at birth = 39.3 +/- 1.8 weeks * Age at initial evaluation (baseline) = 88.4 +/- 20.9 days   Of the 47 infants included in analysis, 35 had right-sided head flattening, 32 were male, and 15 were female. There was no mention of the gender makeup of each group. Groups were similar at baseline for the characteristics of gestational age at birth and age at initial visit. |
| **Intervention Investigated** |
| *Control* |
| The historical control group for this study received repositioning and cervical stretching exercises including side bending and rotation for the management of their deformational plagiocephaly. The infants’ parents were instructed in the performance of these techniques, and the article implies that the intervention was carried out in the home environment. In addition, parents were permitted to utilize any commercially available devices for head shaping as part of the treatment as well. Specific details in relation to positions, exercises, and other devices used, along with their frequency, were not provided in the article; however, the average treatment duration for this group was 61.6 days. |
| *Experimental* |
| The experimental group for this study utilized a custom-made, adjustable cranial cup device for the management of their deformation plagiocephaly. Though not explicitly stated, it appears that use of this intervention was facilitated by parents in the home environment. Each device was made of foam and consisted of a concave portion to allow for head growth, a neck support, and a torso support that can be attached with velcro. The cranial cups were made by a licensed orthotist and individually fitted to each infant. As with the control group, the specific details and frequency of use were not clearly defined; however, the average treatment duration for this group was 56.3 days. |
| **Outcome Measures** (Primary and Secondary) |
| The primary and secondary outcome measures for this study were transcranial difference and head rotational asymmetry, respectively. These outcomes were measured by a single assessor, author Gary F. Rogers, at his practice location during initial (baseline) and final evaluation (following treatment period).  Transcranial difference (millimeters)   * Difference between right anterior-posterior and left anterior-posterior measurements   + These measurements represent the diagonal lengths of the infant’s head based on specific anterior landmarks * Measured using a large cranial caliper   + This method has been standardized through the use of specific anatomical landmarks. * Average of two measurements was recorded * Goal = 0 mm difference, indicating cranial symmetry   Active head rotational asymmetry (degrees)   * Measured with the infant in supine; visual and/or auditory stimulation was used to facilitate active cervical rotation in each direction   + After multiple attempts, the difference in angular rotation between sides was recorded * A tool for rotation measurement was not mentioned, and visual estimation is implied   + Estimation to the nearest 10 degrees * Goal = 0 degrees, indicating rotational symmetry |
| **Main Findings** |
| * At baseline, the transcranial difference for the treatment group was 11.2 +/- 4.4 mm and for the control group was 9.0 +/- 3.8 mm. * At baseline, the head rotational asymmetry for the treatment group was 44.4 +/- 19.5 degrees and for the control group was 38.2 +/- 14.8 degrees. * There was no significant difference in the baseline values between groups for transcranial difference (p = 0.08) or head rotational asymmetry (p = 0.24), indicating that the groups were similar for these characteristics. * Following the intervention period (average of 56.3 days), the transcranial difference for the treatment group was 3.5 +/- 3.0 mm and for the control group was 8.0 +/- 3.5 mm.   + The effect size of the cranial cup intervention on transcranial difference was 7.7 mm (improvement).   + The effect size of the control intervention on transcranial difference was 1.0 mm (improvement). * Following the intervention period (average of 61.6 days), the head rotational asymmetry for the treatment group was 15.6 +/- 8.4 degrees and for the control group was 13.9 +/- 5.1 degrees.   + The effect size of the cranial cup intervention on head rotational asymmetry was 28.8 degrees (improvement).   + The effect size of the control intervention on head rotational asymmetry was 24.3 degrees (improvement). * There was no significant difference in the final values between groups for head rotational asymmetry (p = 0.40), indicating that neither intervention was superior to the other for improving head rotational asymmetry. * There was a statistically significant difference in the final values between groups for transcranial difference (p = 0.000), with greater improvement in the difference in final cranial shape for the treatment group compared to the control group. |
| **Original Authors’ Conclusions** |
| Based on the results of this study, the authors concluded that the adjustable cranial cup device is significantly more effective at improving cranial symmetry than repositioning and cervical stretching for infants less than 4 months of age with deformational posterior plagiocephaly. |
| **Critical Appraisal** |
| **Validity** |
| In order to assess the methodological quality of this study, I used the Downs and Black checklist since it is appropriate for non-randomized trials. The article scored 12/29 points and demonstrated weaknesses in a variety of areas including reporting, internal validity, and power as follows:  Reporting:   * A primary limitation in terms of reporting is that the authors did not clearly define or describe the intervention protocols for each group. For the treatment group, the composition of the cranial cup device itself was explained, but there was no reported frequency of use. For the historical control group, not only was a specific protocol for positioning and stretching not mentioned, but the authors also stated that parents of infant participants were free to select any other commercially available device to use as part of the treatment program. Therefore, the reader has no way to know what specific interventions the control group actually received.   Internal Validity:   * There was no blinding of participants due to the nature of the interventions, and there was also no blinding of assessors due to the study design and use of a historical control group. * Also, since a historical control was utilized, the study subjects were not recruited or treated over the same period of time. * There was no randomization of subjects into groups and no opportunity for concealed allocation, again due to the design of the study. * There was no report of compliance for either group, which also limits the credibility of results. * The method of determining head rotational asymmetry left a good deal of room for measurement error and bias since there was no mention of a measurement tool, and it appears to have been visually estimated to the nearest 10 degrees. Therefore, these measurements may have had poor accuracy and precision.   Power:   * There was no power analysis reported in this study. * Sample sizes were small for each group (n = 24 and n = 23), and there was no justification for how and why the sample sizes were selected.   Overall, the strengths of this study were that the researchers used a standardized procedure for the primary outcome measure (calvarial asymmetry) and that they reported mean, standard deviation, p-values, and standard error values for each of the measures. Additionally, the similarity of the groups at baseline for important characteristics such as gestational age at birth, age at initial visit, and initial head symmetry is another strength of the study. |
| **Interpretation of Results** |
| The results of this study suggest that there was a significantly greater treatment effect for the cranial cup group compared to the control group in terms of transcranial difference with a between group difference of 6.7 mm. Although this effect size seems to be clinically meaningful due to its magnitude, my interpretation is that the findings cannot be fully trusted due to the numerous methodological flaws in study design. As a physical therapist, I would not be able to replicate either the treatment or control intervention with my patients based on the details provided in this article, and this is an important characteristic for clinical relevance and applicability. In addition, there were several factors that introduced bias into the study including the non-randomization, lack of blinding, and lack of specific intervention protocols. If both groups had received intervention over the same period of time, then it would have been possible to randomly assign participants to groups, as well as blind the assessor who was taking the head shape and rotation measurements, and these changes would have decreased bias and improved internal validity, thereby increasing the credibility of the results.  From my reading and review of the study, the findings suggest to me that the custom-made cranial cup may be effective for improving cranial symmetry in infants less than 4 months of age with deformational posterior plagiocephaly. I do not feel confident about making any conclusions in relation to the historical control group since there is no way for me to know which interventions and protocols that parents chose to utilize with this group of infants. |

**(2) Description and appraisal of *Use of the Cranial Cup to Correct Positional Head Shape Deformities in Hospitalized Premature Infants* by Knorr A, Gauvreau K, Porter CL, Serino E, and DeGrazia M (2016).**

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| **Aim/Objective of the Study/Systematic Review:** |
| The purpose of this study was to determine the effectiveness of the cranial cup for correcting head shape in hospitalized premature infants with visible deformational plagiocephaly, as well as to assess the feasibility and safety of utilizing this orthotic device. |
| **Study Design** |
| This study was a prospective descriptive design in which all subjects received the experimental treatment. There was no blinding of participants, clinicians, or assessors due to the nature of the intervention and study design. Head shaping outcomes were measured at baseline and at hospital discharge (median of 22 days enrolled in the study; range of 7-62 days), and daily logs were kept by nurses to record position changes, use of the device, and adverse events for each infant. Follow up sessions were not conducted beyond the time of hospital discharge. |
| **Setting** |
| This study was conducted at two different hospital locations: an urban Level IV neonatal intensive care unit and a suburban Level II special care nursery. |
| **Participants** |
| Participants were selected by convenience sampling of premature infants with visibly abnormal head shape who were admitted to either of the study locations between May of 2012 and June of 2013. All infants were in the convalescent phase of hospitalization, meaning that they were no longer considered to be critically ill. There were no dropouts that occurred during the study.  Sample Characteristics:   * N = 23 * Male = 14, Female = 9 * Gestational age at birth: median of 26.6 weeks; range of 23.6-35.1 weeks * Corrected gestational age at study enrollment: median of 34.6 weeks; range of 30.0-44.5 weeks * Cranial measurement generalizations at study enrollment:   + Deformity = 19 infants   + No deformity = 3 infants   + Data not obtained = 1 infant |
| **Intervention Investigated** |
| *Control* |
| There was no control group utilized in this study. |
| *Experimental* |
| All participants in this study utilized an adjustable cranial cup orthotic device in the hospital setting for the management of their deformational plagiocephaly. This device is made up of a plastic base overlaid with up to four layers of polyethylene foam that can be removed to adjust the fit of the device as the infant grows. The cranial cup has a concave portion for the head in order to encourage normal cranial development, and it supports the infant’s body in both supine and semi-side-lying positions. Participants were intended to spend a minimum of 12 hours per day on the cranial cup device with position changes performed by the nursing staff every 3-4 hours. Specific details regarding positions utilized were not provided in the article. In actuality, participants spent a median of 12.7 hours per day on the device, with a range of 6.3-18.0 hours. While not utilizing the cranial cup, infants were placed on another modifiable positioner, a gel pillow, a bed mattress, or were held by a caregiver. Infants were involved in the study for a median of 22 days with a range of 7-62 days. |
| **Outcome Measures** (Primary and Secondary) |
| The outcome measures related to head shaping for this study were cranial index and cranial symmetry. Cranial measurements were obtained by licensed orthotists in the hospital locations where the study took place, and interrater reliability was established. A cranial caliper was utilized as the measurement device, along with a measurement procedure that has been standardized through the use of specific anatomical landmarks.  Cranial Index (percentage)   * Cranial index = (cranial width / cranial length) x 100   + Cranial width is the medial-lateral head measurement; cranial length is the anterior-posterior head measurement * Goal = 73% - 85%   + A value outside of this goal range indicates head shaping deformity   Cranial Symmetry (millimeters)   * Difference between right anterior-posterior and left anterior-posterior measurements   + These measurements represent the diagonal lengths of the infant’s head * Cranial asymmetry is defined as a difference of ≥ 8 mm * Goal = 0 mm difference |
| **Main Findings** |
| * At baseline, 19 subjects (86%) demonstrated a measurable head shape deformity. Head shape measurements were not obtained for 1 participant. * Subjects spent a median of 12.7 hours per day on the cranial cup, with a range of 6.3-18.0 hours. * Following the intervention period, 4 subjects (17%) demonstrated a persisting measurable head shape deformity as indicated by abnormal cranial index and/or cranial asymmetry at discharge.   + The median cranial index at discharge was 77.5%, with a range of 69.8%-83.9%.   + Values for cranial index and cranial symmetry at baseline and discharge were only reported for the 4 infants who demonstrated cranial abnormalities following the intervention period. * There was no association between ventilator use and cranial shape (p = 0.12) or CPAP use and cranial shape (p = 0.28), indicating that the use of these devices did not have an effect on cranial shaping outcomes. * Effect sizes were not presented in the article and could not be calculated for these data due to median values being reported rather than mean values. Cranial measurement outcomes were reported as the number of infants who demonstrated abnormalities rather than the actual values for cranial index and cranial symmetry for all participants. |
| **Original Authors’ Conclusions** |
| Based on the results of this study, the authors concluded that the cranial cup device can be utilized safely and effectively to correct the head shape of premature infants with deformational plagiocephaly in the hospital setting. |
| **Critical Appraisal** |
| **Validity** |
| In order to assess the methodological quality of this study, I used the Downs and Black checklist since it is appropriate for non-randomized trials. The article scored 18/29 points and demonstrated weaknesses in a variety of areas including reporting, internal validity, and power as follows:  Reporting:   * A specific protocol was not developed for position changes on the cranial cup, duration of device use, or other head shaping strategies used when not on the device. In addition, the authors did not report details of these variables for each infant. Therefore, there is no indication of which protocol might be most successful for improving head shape. * Baseline and discharge measurements for cranial index and cranial symmetry, along with their probability values, were not reported for all participants. * An additional limitation was a lack of follow up after hospital discharge, which eliminates the ability to determine if head shaping outcomes were maintained over time.   Internal Validity:   * There was no blinding of subjects or assessors due to the nature of the intervention and study design. * Since subjects were recruited between May of 2012 and June of 2013 and utilized the cranial cup during their hospital stay, they did not receive treatment over the same period of time. * There was no randomization of subjects and no opportunity for concealed allocation due to a single intervention being utilized. * Since there was no control group in this study, it is difficult to know if the cranial cup caused greater improvements in head shaping than would have occurred without the device.   Power:   * There was no power analysis reported in this study. * The sample size was small (n = 23), and there was no justification for how and why the sample sizes were selected.   Overall, the strengths of this study were that compliance with use of the cranial cup was recorded through a daily log, a standardized procedure was utilized for the primary outcome measures (cranial index and cranial symmetry measurements), and adverse events were reported with potential confounding from ventilator and CPAP use taken into account. |
| **Interpretation of Results** |
| Though the results of this study suggest that the cranial cup is effective for normalizing head shape measurements in hospitalized premature infants, my interpretation is that there is no way to know whether use of the device can account for the improvements in head shaping due to the lack of control group for comparison. There were also other positioning devices used while the infants were not on the cranial cup, such as gel pillows, bed mattresses, and modifiable positioners. Therefore, the effects cannot be isolated to the orthotic device alone. In addition, there were several factors that introduced bias into the study including the inability to utilize blinding or randomization, as well as the lack of a specific intervention protocol. This indicates that each infant did not undergo the same procedure while on or off the cranial cup, which makes the intervention more difficult to replicate and limits the ability to identify which factors contributed to head shaping improvements. Lastly, the range of hours per day of device utilization was very wide, as was the range of treatment duration overall, which decreases the clinical meaningfulness of the data due to high variability.  From my reading and review of the study, the findings suggest to me that the cranial cup device may be effective for improving head shape in hospitalized premature infants in the convalescent phase of care with deformational plagiocephaly. I do feel fairly confident stating that the orthotic device is safe for use in the NICU and special care nursery settings with this patient population since no significant adverse events were associated with use of the device; however, consideration of additional studies with larger sample sizes would be beneficial for strengthening this assertion. |

**(3) Description and appraisal of *Prevention of Deformational Plagiocephaly in Hospitalized Infants Using a New Orthotic Device* by DeGrazia M, Giambanco D, Hamn G, Ditzel A, Tucker L, and Gauvreau K (2015).**

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| **Aim/Objective of the Study/Systematic Review:** |
| The purpose of this study was to determine the effectiveness of utilizing the cranial cup orthotic device along with a moldable positioner for the prevention of deformational plagiocephaly in hospitalized infants at risk for head shaping deformity, as well as to assess the feasibility and safety of using the cranial cup. |
| **Study Design** |
| This study was a stratified, randomized, single-blinded design. Subjects were stratified by study site and weight prior to being randomized into study groups due to weight requirements of the cranial cup device. Allocation was concealed as randomization cards were computer-generated and prepared by individuals not associated with the study. Head shaping outcomes were measured at baseline and discharge, and the four orthotists who took cranial measurements were blinded to intervention groups. Follow up sessions were not conducted beyond the time of final evaluation at hospital discharge. |
| **Setting** |
| This study was conducted at four different hospital locations: one suburban and three urban neonatal intensive care units (NICUs). The primary site was an urban Level IV NICU, and the secondary sites were three Level III NICUs. |
| **Participants** |
| Infants (N = 88 total) were recruited from the four participating study locations between April of 2010 and July of 2012 if they were born at 22 weeks gestational age or later and were expected to remain in the hospital for at least 2 weeks. All infants were in the critically ill phase of hospitalization. There were no additional details provided with respect to recruitment procedure, though it appears that convenience sampling was used. Groups were similar at baseline for important characteristics including gender, gestational age at birth, and birth weight.  Experimental Group:   * N = 42 total, 27 analyzed * Male = 18, Female = 9 * Gestational age at birth: median of 30 weeks; range of 23-39 weeks * Birth weight: median of 1495 grams; range of 510-3370 grams   Control Group:   * N = 41 total, 35 analyzed * Male = 22, Female = 13 * Gestational age at birth: median of 31 weeks; range of 24-39 weeks * Birth weight: median of 1575 grams; range of 455-3710 grams   Twenty-six infants were not included in the final analysis due to various reasons as follows:   * Discharged or transferred prior to study completion 🡪 n = 14 * Withdrawn from study by parents due to perceiving the device was uncomfortable 🡪 n = 5 * Died from medical illness 🡪 n = 3 * Used cranial cup following closure of the study 🡪 n = 4   However, there were no statistically significant differences in gender, age at NICU admission, gestational age, birth weight, or primary clinical diagnosis between those who were included in final analysis and those who were not. |
| **Intervention Investigated** |
| *Control* |
| The control group for this study utilized a moldable positioner and regular position changes performed by nurses every 3-4 hours for the prevention of deformational plagiocephaly. The positioner is a pillow-shaped, fluidized, moldable device that supports the infant’s head, neck, and shoulders while in the supine, side-lying, or prone position. Specific details regarding positions utilized were not provided in the article. Participants spent a median of 18.1 hours per day on the positioner with a range of 9.7-21.8 hours, and the total length of treatment was not reported. |
| *Experimental* |
| The experimental group for this study rotated between a cranial cup device and a moldable positioner for the prevention of deformational plagiocephaly. These infants also received position changes at least every 3-4 hours; however, specific details regarding positions utilized were not provided in the article. The cranial cup is an orthotic device made up of a plastic base overlaid with up to four layers of polyethylene foam that can be removed to adjust the fit of the device as the infant grows. It contains a concave portion for the head in order to encourage normal cranial development, and it supports the infant’s body in both supine and semi-side-lying positions. Trained nursing staff performed all position and device changes, and they were instructed that infants should utilize the cranial cup for at least 12 hours per day. In actuality, participants spent a median of 10.7 hours per day on the device with a range of 4.5-15.3 hours, and a median of 9.3 hours per day on the moldable positioner with a range of 0.8-11.7 hours. The total length of treatment was not reported. |
| **Outcome Measures** (Primary and Secondary) |
| The outcome measures related to head shaping for this study were cranial index and cranial symmetry. Cranial measurements were obtained by one of four licensed orthotists in the hospital locations where the study took place. A cranial caliper was utilized as the measurement device, along with a measurement procedure that has been standardized through the use of specific anatomical landmarks.  Cranial Index (percentage)   * Cranial index = (cranial width / cranial length) x 100   + Cranial width is the medial-lateral head measurement; cranial length is the anterior-posterior head measurement * Goal = 73% - 85%   + A value outside of this goal range indicates head shaping deformity   Cranial Symmetry (millimeters)   * Difference between right anterior-posterior and left anterior-posterior measurements   + These measurements represent the diagonal lengths of the infant’s head * Cranial asymmetry is defined as a difference of ≥ 8 mm * Goal = 0 mm difference |
| **Main Findings** |
| * At baseline, groups were similar for the prevalence of head shaping abnormalities as determined by cranial index measures (p = 0.22), though details of these initial measurements were not reported. No infants demonstrated abnormalities of cranial symmetry at baseline. * Following the intervention period, 16 infants in the control group (46%) demonstrated abnormal cranial measurements as determined by cranial index and cranial symmetry.   + Control group subjects spent a median of 18.1 hours per day (range of 9.7-21.8 hours) on the moldable positioner. * Following the intervention period, 5 infants in the treatment group (19%) demonstrated abnormal cranial measurements as determined by cranial index and cranial symmetry.   + Treatment group subjects spent a median of 10.7 hours per day (range of 4.5-15.3 hours) on the cranial cup device and a median of 9.3 hours per day (range of 0.8-11.7 hours) on the moldable positioner. * There was a statistically significant between-group difference in the number and percentage of infants with abnormal cranial measures at discharge (p = 0.03), with more infants experiencing abnormalities in the control group compared to the treatment group. * Effect sizes were not presented in the article and could not be calculated for these data due to median values being reported rather than mean values. Cranial measurement outcomes were reported as the number of infants who demonstrated abnormalities rather than the actual values for cranial index and cranial symmetry. |
| **Original Authors’ Conclusions** |
| Based on the results of this study, the authors concluded that rotating between the cranial cup device and the moldable positioner is a safe and feasible intervention that may be effective for preventing deformational plagiocephaly in infants hospitalized in the neonatal intensive care unit. |
| **Critical Appraisal** |
| **Validity** |
| In order to assess the methodological quality of this study, I used the PEDro Scale since it is appropriate for randomized controlled trials. The article scored 8/11 points and demonstrated weaknesses in a variety of areas including reporting, internal validity, and power as follows:  Reporting:   * A specific protocol was not developed for position changes on the devices or for duration of device use. In addition, the authors did not report details of these variables for each infant. Therefore, there is no indication of which protocol might be most successful for improving head shape. * Baseline and discharge measurements for cranial index and cranial symmetry, along with their probability values, were not reported for all participants. * An additional limitation was a lack of follow up after hospital discharge, which eliminates the ability to determine if head shaping outcomes were maintained over time.   Internal Validity:   * There was no blinding of subjects or providers who administered therapy due to the nature of the intervention. * Since subjects were recruited between April of 2010 and July of 2012 and received the intervention during their hospital stay, they did not undergo treatment during the same period of time. * Due to the number of dropouts for various reasons, outcome measures were not obtained from more than 85% of the subjects initially allocated to groups.   Power:   * Though the investigators conducted a power analysis to determine that a sample size of 160 infants was needed to appropriately power the study with an alpha of 0.05, they went on to select a sample of only 88 participants for which data were analyzed for only 62 infants due to dropouts. Therefore, these numbers suggest that the study did not have a large enough sample size to be adequately powered for a clinically meaningful effect.   Overall, the strengths of this study were that outcome assessors were blinded, subjects were randomized into study groups, compliance with use of the cranial cup and moldable positioner were recorded through use of a daily log, and a standardized procedure was utilized for the primary outcome measures (cranial index and cranial symmetry). Additionally, the similarity of the groups at baseline for important characteristics such as gender, birth weight, gestational age at birth, and cranial abnormalities is another strength of the study. |
| **Interpretation of Results** |
| Though the results of this study suggest that rotating between the cranial cup and the modifiable positioner is effective for the prevention of head shaping deformities in hospitalized infants, my interpretation is that the results cannot be fully trusted due to methodological flaws in the study. There were several factors that introduced bias into the study including the inability to blind subjects or providers, as well as the lack of a specific intervention protocol. The range of hours for which each device was utilized was very wide, which decreases the clinical meaningfulness of the data due to high variability. Additionally, the total treatment duration was not reported, which limits the reproducibility of the intervention.  From my reading and review of the study, the findings suggest to me that rotating between the cranial cup device and the modifiable positioner may be more effective than use of a modifiable positioner alone for preventing the development of cranial asymmetry in critically ill, hospitalized infants in the NICU. Also based on the results, I feel relatively confident affirming that both devices are safe for use in the NICU environment since no significant adverse events were associated with use of the devices. |

**EVIDENCE SYNTHESIS AND IMPLICATIONS**

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| **Implications for clinical practice:**  Current best evidence weakly suggests that the cranial cup orthotic device may be effective for correcting head shape in my patient of interest, who is a preterm infant in the neonatal intensive care unit with cranial molding deformity. Although earlier studies have indicated that placing infants in the supine or side-lying positions may lead to an increase in adverse cardiorespiratory and emesis events,11,12 all studies reviewed for this critically appraised topic found that the cranial cup device is not associated with an increase in adverse events, and it is safe to use with infants in both the critically ill and the convalescent phases of hospitalization.2,3,7 In addition, the cranial cup device allows for adjustments to accommodate growth of the infant, which is an important consideration for cost-effectiveness of interventions, especially in pediatrics due to the rapid periods of growth that children experience. Based on current best evidence, it appears that the cranial cup has the potential for effectiveness not only for the management of cranial molding deformity in infants, but the prevention of this condition as well.  Overall, the findings of these studies are not sufficient to answer my clinical question due to the low levels of evidence and inherent methodological flaws that limit trustworthiness of the results. As a clinician, however, I would feel comfortable recommending the cranial cup device for the prevention and treatment of cranial molding deformities in infants, particularly during the first few months of life, as it appears to be a low risk intervention and there is weak evidence to show that this device is more effective than other positioning strategies for normalizing head shape both in the NICU and in the home environment. However, due to the wide range of device use in hours per day as well as the lack of specificity in positioning protocols while on the device, I would be very unsure about what to recommend in terms of intervention procedure. Therefore, in order to treat the patient presented in my clinical scenario based on the evidence reviewed, I would start by aiming for the target duration of device use suggested in the studies by Knorr and DeGrazia, 12 hours per day, with position changes between supine and side-lying every 3 to 4 hours.2,3 While not utilizing the cranial cup device, I would implement alternative head shaping strategies such as a moldable positioner or gel pillow to reduce pressure on the cranium. Since the ideal protocol for use is undetermined, I would take frequent cranial measurements of the infant in order to determine if progress is being made or if changes to the procedure are indicated, including positioning, daily device use, and total treatment duration.  **Future research:**  In future research on this topic of study, more high quality randomized controlled trials and systematic reviews of randomized controlled trials should be conducted in order to increase the level of evidence that exists regarding cranial molding interventions for the hospitalized, preterm infant. Studies with larger sample sizes are also needed in order to decrease the variability of results, provide narrowed confidence intervals, and increase the precision of point estimates. Another implication for further research based on the evidence reviewed is that increased specificity regarding intervention protocols is needed in order to improve the clinical relevance and utility of future studies. In general, current evidence does not allow for precise replication of treatment interventions in the clinical setting due to a lack of specific procedures followed and a lack of detail reported about how interventions were implemented with patients. Lastly, none of the studies reviewed performed follow up assessments of participants after conclusion of the intervention period. Long-term follow up of study participants would certainly be a beneficial component of future research in order to determine the effects of cranial molding interventions over time. |

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