CRITICALLY APPRAISED TOPIC

FOCUSED CLINICAL QUESTION

Is there a noted difference in infant head shape when a regimented positional protocol is implemented compared to standard positional precautions in premature infants born <32 weeks' gestation?

AUTHOR

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CLINICAL SCENARIO

This clinical question was sparked by a noted recent increase in cranial molding deformities in the Neonatal Intensive Care Unit (NICU). Premature infants, those born less than 32 weeks' postmenstrual age (PMA), typically spend longer durations in the hospital and are subjected to an increased risk for developing cranial molding deformities, including both dolichocephaly and plagiocephaly[1-4]. At a particular hospital, preterm infants do not receive a standardized positional protocol, but rather receive positional change at the choice of the medical team, which often leads to lapses in documented positional changes. Infants in the NICU are also currently being placed on standard mattresses. NICU therapists are trained to be experts in positional placements to improve motor development and decrease contracture or undesired cranial molding. Physical therapists are trained to place infants in optimal positions to help promote growth, environmental interaction, decrease extension bias, promote draw to midline, and help decreased further adverse motor outcomes post discharge. Physical therapist in the NICU want to know how positional change can impact both cranial molding and motor outcomes for preterm infants born at less than 32 weeks.

SUMMARY OF SEARCH

[Best evidence appraised and key findings]

McCarty et al, 2017: A retrospective review[1]

This article directly targets how dolichocephaly develops and is impacted by positional change. Authors describe that direct positional change intervention is needed to decrease the prevalence of dolichocephaly in very premature infants. Authors describe how supine is the best position to limit the development of dolichocephaly; however, note that this position is not ideal for developmental care and many secondary conditions these infants often present with.

Schultz et al, 2008: A single-blind randomized control trial[2]

While this article more specifically assesses a positional device on head shape, it acknowledges that a regimented positional protocol further reduces head molding and is needed for preterm infants. This article targets the exact population (under 32 weeks of birth gestational age) and demonstrates long-term impacts of head shape such as asymmetric motor performance.

CLINICAL BOTTOM LINE

The current available literature indicates that preterm infant positioning in the NICU can directly impact cranial molding and may cause adverse motor outcomes[1-2,9,10]. However, further research is needed to indicate the feasibility and direct impact of a positional protocol on head shape and correlation to infant motor outcomes. Research with comparable outcome measures is needed to establish best practice to decrease infant cranial molding and improve motor outcomes post hospital discharge.

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

Terms used to guide the search strategy			
Patient/Client Group	**I**ntervention (or Assessment)	**C**omparison	**O**utcome(s)
Neonatal ICU Premature infants Premature birth Preterm infants	Positional Change Positional intervention Turning protocol	Standard positional precautions	Cranial index Plagiocephaly Dolichocephaly

Final search strategy (history):

1. Premature
2. premature birth
3. NICU
4. Neonatal ICU
5. Positional change
6. positioning
7. turning protocol
8. Cranial index
9. Plagiocephaly
10. Dolichocephaly
11. Cranial moulding
12. Supine
13. Prone
14. **(1 OR 2 OR 3 OR 4) AND (5 OR 6 OR 7) AND (8 OR 9 OR 10 OR 12 OR 13)**

Databases and Sites Searched	Number of results	Limits applied, revised number of results (if applicable)
CINAHL	**180**	**Academic journals and publication date of 2000-current: 140 results**
PubMed	**202**	**Publication date of 2000-current: 136 results**
Web of Science	**107**	**N/A**

INCLUSION and EXCLUSION CRITERIA

Inclusion Criteria
Systematic Reviews, RCT, meta-analyses, retrospective reviews, prospective studies, cohort studies: • Born prematurely (< 32 weeks) • Evaluation of positional change and head shape • Dolichocephaly or plagiocephaly • Study describes training of evaluating physical therapy • Care provided in NICU setting • English language
Exclusion Criteria
• Poster presentations • Not published in English • Case studies or case reports • Studies published prior to 2000

RESULTS OF SEARCH

Summary of articles retrieved that met inclusion and exclusion criteria

Author (Year)	Risk of bias (quality score)	Level of Evidence	Relevance	Study design
McCarty (2017)[1]	**Downs and Black (21/29)**	**Level 2**	**High**	**Retrospective review**
Madlinger-Lewis[3] (2014)	**PEDro (8/11)**	**Level 1**	**Moderate**	**Single-blind RCT**
DeGrazia (2014)[4]	**PEDro (7/11)**	**Level 1**	**Moderate**	**Single-blind RCT**
Cakici (2020)[6]	**PEDro (7/11)**	**Level 1**	**Low**	**Randomized crossover**
McCarty (2018)[5]	**Downs and Black (22/29)**	**Level 2**	**High**	**Nonrandomized prospective study**
Schultz (2006)[2]	**PEDro (7/11)**	**Level 1**	**High**	**Single-blind RCT**
Di Chiara (2019)[7]	**Downs and Black (17/29)**	**Level 2**	**Low**	**Individual cohort study**
Knorr (2019)[8]	**Downs and Black (23/29)**	**Level 2**	**High**	**Prospective, descriptive, phase 1 clinical trial**

BEST EVIDENCE

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

- McCarty DB, Peat JR, Malcolm WF, Smith PB, Fisher K, Goldstein RF. Dolichocephaly in preterm infants: prevalence, risk factors, and early motor outcomes. *Am J Perinatol*. 2017;34(4):372-378. doi:10.1055/s-0036-1592128
- Schultz AA, Goodwin PA, Jesseman C, Toews HG, Lane M, Smith C. Evaluating the effectiveness of gel pillows for reducing bilateral head flattening in preterm infants: a randomized controlled pilot study. *Appl Nurs Res*. 2008;21(4):191-198. doi:10.1016/j.apnr.2006.11.003

SUMMARY OF BEST EVIDENCE

(1) Description and appraisal of Dolichocephaly in preterm infants: prevalence, risk factors, and early motor outcomes by McCarty et al, 2017

Aim/Objective of the Study/Systematic Review:
The purpose of this study was to determine when dolichocephaly develops in preterm infants, establish the various factors and situations that contribute to its development, and to assess for the association between dolichocephaly and adverse motor outcomes[1].
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.
This study was a retrospective review where outcomes were assessed at three different time points: approximately 2 weeks chronological age, approximately 32 to 34 weeks postmenstrual age (PMA), and within 1 to 2 weeks before hospital discharge[1]. Descriptive statistics were used to characterize the demographics of the study cohort, hospital course, and clinical outcomes that included growth and prevalence of dolichocephaly. Wilcoxon rank sum and Fisher exact tests were used to compare characteristics and outcomes of infants exhibiting dolichocephaly. Logistical regression was used to determine associations between dolichocephaly and neonatal morbidities at discharge, and between dolichocephaly and motor outcomes at follow-up. STATA was used for complete analysis and a $p<0.05$ was considered statistically significant[1].
Setting [e.g., locations such as hospital, community; rural; metropolitan; country]
The study took place in the intensive care nursery (ICN) of an urban research hospital. Follow-up measurements were taken at an outpatient physical therapy clinic that was in conjunction with the hospital[1].
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.

A total of 143 infants were enrolled in the original study. Of these, 65 infants met inclusion criteria for the present study. These infants had a birth weight of <1,500g and/or PMA of <32 weeks, were stable on room air, nasal cannula, or continuous positive airway pressure (CPAP) at the initial PT evaluation. Further, no infant presented with a genetic abnormality, neuromuscular disorder, craniofacial abnormality, congenital or posthemorrhagic hydrocephalus, or other diagnosis determined to impact generalizability of results[1].

Key demographics demonstrated that the average gestational age was 27 weeks (ranging from 23 to 32), the average birth weight was 900 grams (ranging from 475 to 1,430), that 35% of the infants were born to mothers who had experienced multiple births, and that 47% of the participants were male. 2% of the participants had a grade III or IV intraventricular haemorrhage (IVH), 31% had bronchopulmonary dysplasia (BPD), and 60% had gastroesophageal reflux (GERD)[1].

Intervention Investigated

[Provide details of methods, who provided treatment, when and where, how many hours of treatment provided]

Experimental

A retrospective review documenting the frequency of dolichocephaly and evaluation of associated demographics and neonatal risk factors was completed for all infants in the ICN who were <32 weeks PMA and/or <1,500g in the medical center over an eighteen month period[1].

The Ballert orthopedic cranial caliper was used to measure cranial index (CI). CI was defined as the ratio of head width to head length and was noted as a percentage. Four physical therapists were trained to use the Ballert caliper following the user guide instructions. Interrater reliability was established between the therapists until an agreement to the lead physical therapist was within 0.25cm for head width and length measurements[1].

Physical therapists would use these values to monitor head shape changes overtime to educate caregivers about optimal positioning. The PMA of infants at the initial evaluation varied from 26 to 32 weeks based on the infant's physiologic stability. A physical therapy revaluation was the conducted at 32 to 34 week's PMA. If the infant's PMA was 32 to 34 weeks' at initial evaluation, only two CI measurements instead of three were recorded. Two infants were measured later than 34 weeks (at 35 and 38 weeks' PMA) due to medical instability during the revaluation period. Due to the nature of this study, data was excluded if only one CI measurement was recorded or if the infant was transferred to another facility[1].

During each infant's hospitalization, various positioning aids were employed as a standard of care to improve head shape and optimal body positioning. This was conducted at the discretion of ICN nursing staff and was not controlled by study investigators. The physical therapist would then provide additional positioning consultation for infants that demonstrated difficulty maintaining midline of the head or extremities. Positioning aids utilized included moldable pillows, moldable mattresses, bean bags, and foam bumpers[1].

The final aspect of the study assessed for adverse motor outcomes at follow-up outpatient physical therapy appointments following hospital discharge (hospital-based outpatient clinic). Corrected age at the outpatient follow-up visit as well as CI was recorded. Initial follow-up physical therapy evaluations were performed at 1 to 6 moths corrected age depending on gestational age at birth, age at hospital discharge, and risk of developmental delay. Adverse motor outcomes documented by the physical therapist at the follow-up visit included the presence of asymmetry, extension bias, upper extremity retraction and decreased head control, decreased prone skills, and decreased midline orientation[1].

Time intervals for treatment or measurement were not provided in the literature due to the retrospective nature of the study[1].

Outcome Measures

[Give details of each measure, maximum possible score and range for each measure, administered by whom, where]

Cranial Index

CI was determined by measuring biparietal diameter (BiPD) to occipitofrontal diameter (OFD). BiPD is defined as the widest transverse diameter of the head and OFD is the diameter of the head from the most prominent midline point of the frontal bone to the occipital protuberance. CI was then calculated as (BiPD/OFD) x 100. Dolichocephaly was defined as CI <76%. Ci was taken by the four trained physical therapist in both the hospital and outpatient setting[1].

Adverse Motor Outcomes

Asymmetry was defined as a rotational head preference, asymmetric upper extremity use, or asymmetric cranial molding affecting motor skills. Extension bias was defined as preference for using extensor muscle groups in the trunk and lower extremities. Upper extremity retraction referred to the dominant posture of scapular retraction, upper extremities splayed to surface at rest in supine, difficulty preforming reaching skills at midline, inappropriate upper extremity weight-bearing in prone, and use of scapular retraction pattern in support sitting to stabilize the head. Decreased head control was noted as the inability to maintain midline orientation of the head in supported sitting, head control score of “fair” or “poor”, and head leg score of “moderate” or “severe”. Decreased prone skills were defined as the inability to clear airway or lift the head, decreased endurance in prone position, or lack of cauda weight shift. Decreased midline orientation was defined as the inability to sustain midline orientation of the head at rest without visual stimulation. It was also noted whether the infant was currently receiving or being referred for further outpatient services at the time of follow-up for one or more of these early motor abnormalities. All motor outcomes were considered on an age-related basis. Adverse motor outcomes were assessed and documented by one of the four trained physical therapists[1].

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. You may summarize results in a table but you must explain the results with some narrative.]

Development of Dolichocephaly

Overall, 35 infants (54%) developed dolichocephaly at some point during their hospital stint. A total of 43 infants (66%) received an initial physical therapy evaluation when they were < 32 weeks' PMA, and of these, 4 (9%) had dolichocephaly. Of the 65 infants measured during the 32 to 34 weeks' PMA period, 25 (39%) had dolichocephaly. Out of the 65 total number of participants, 57 infants were measured at hospital discharge and 19 (33%) had dolichocephaly. At the follow-up visit, 6 out of 50 (12%) had dolichocephaly[1].

With univariable analysis, CI at discharge was predictive of CI at outpatient follow-up, with a p value of p=0.005. Younger gestational age at birth (p=0.03) and chronological age at outpatient follow-up (p=0.05) was associated with lower CI measurement. Birth weight, gender, and neonatal morbidities (BPD, GERD, and severe IVH) were not associated with dolichocephaly[1].

With multivariable analysis, infants were more likely to have dolichocephaly at outpatient follow-up if they had dolichocephaly between 32 and 34 weeks' PMA (OR=6.7, 95% CI=1.1, 39.1 and p=0.04) or at discharge (OR-11.3, 95% CI=1.2, 107.0 and p=0.004)[1].

Patient Demographic Data (page 376)[1]

Factor	At discharge		At follow-up	
	OR (95% CI)	*p* Value	OR (95% CI)	*p* Value
Gestational age (wk)	1.0 (0.8, 1.2)	0.9	0.9 (0.7, 1.3)	0.6
Birth weight (g)	1.0 (0.997, 1.002)	0.7	1.0 (0.99, 1.004)	0.5
Multiple births	1.6 (0.5, 4.9)	0.4	0.2 (0.0, 2.0)	0.2
Male	0.7 (0.2, 2.2)	0.6	3.0 (0.6, 17.3)	0.2
BPD	0.9 (0.3, 3.0)	0.8	0.3 (0.0, 3.0)	0.3
GERD	0.5 (0.2, 1.4)	0.2	0.6 (0.1, 2.9)	0.5
Dolichocephaly at 32–34 wk PMA[a]	–	–	**6.7 (1.1, 39.1)**	**0.04**
Dolichocephaly at discharge[a]	–	–	**11.3 (1.2, 107.0)**	**0.04**

Assessment of Motor Outcomes

Infants with dolichocephaly at 32 to 34 weeks' PMA were more likely to either be receiving physical therapy services or be referred for physical therapy services at the time of the follow-up appointment (p=0.05); however, no statistically significant associations between prevalence of dolichocephaly and adverse motor outcomes were noted[1].

Outpatient Motor Outcomes (page 377)[1]

Factor	At 32–34 wk PMA		At discharge	
	OR (95% CI)	*p*	OR (95% CI)	*p*
Asymmetry	1.1 (1.0, 1.3)	0.1	0.1 (0.9, 1.1)	0.9
Extension bias	1.0 (0.9, 1.2)	0.9	1.0 (0.8, 1.2)	0.7
Decreased head control	1.1 (1.0, 1.3)	0.2	1.0 (0.9, 1.2)	0.9
Decreased prone skills	1.1 (1.0, 1.3)	0.3	1.0 (0.8, 1.1)	0.8
Difficulty maintaining midline	1.4 (0.9, 2.2)	0.1	0.8 (0.6, 1.2)	0.4
Scapular retraction	1.1 (1.0, 1.3)	0.1	1.1 (1.0, 1.3)	0.2
PT services at follow-up[a]	**1.8 (1.0, 1.4)[a]**	**0.05[a]**	1.0 (0.8, 1.1)	0.8

Original Authors' Conclusions

[Paraphrase as required. If providing a direct quote, add page number]

The authors' concluded that dolichocephaly is frequently observed in premature infants by 32 to 34 weeks' PMA. Dolichocephaly is a cranial molding deformity that appears to be associated with early motor abnormalities which may prompt infants to be referred to outpatient physical therapy services in the early phases of infancy (defined as 1 to 6 months of age). In prevention of adverse cranial molding due to hospitalization and attempt to improve early motor outcomes, these findings support developmental intervention in the hospital before 32 weeks' PMA. Future studies are warranted to determine the adverse motor outcomes directly linked to dolichocephaly and to assess for any long-term effects on neurodevelopmental outcomes. There is a need for direct methods to prevent or treat dolichocephaly, Further, the impact of the supine sleep position on the development of dolichocephaly in preterm infants after discharge should be further investigated[1].

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.]

This article received a 21 out of 29 on the Downs and Black risk of bias and quality score. Given that the study is a retrospective review, it qualifies as a level 2 quality of evidence. The study design could also have impacted the internal validity of the study because CI measurements were not available for all time points for all infants. Furthermore, the smaller sample size could have prevented an adequate analysis of the importance of demographic variables, neonatal morbidities, and the development of specific early motor abnormalities. Other confounding variables include the idea that positioning regimens and props used were not regulated throughout the study. A wide variety of nursing staff worked with the participants and utilized a variety of positioning devices and systems. In this study, infant demographics (age, birth weight, gender) and neonatal morbidity (BPD, GERD, severe IVH) were not associated with the development of dolichocephaly; however, this is in stark contrast to previous literature that cites gestational age, birth weight, length of time on respiratory support, and male gender are all indicative of the development of dolichocephaly[5]. While the small sample size could have contributed to this finding, it could also be in correlation to the variance in nursing practice. On the other hand, the study design contributes to strong external validity of the study because the data was collected without strict parameters and following "real world" protocols. The study describes the natural course of care each participant who met the inclusion criteria would have received[1].

Weaknesses of this study are rooted in the small sample size and lack of complete data collection. Due to the design, some participants were missing various data points throughout the course of the study. Another key weakness is rooted in the lack of control for confounding variables and lack of control versus experimental group. A variety of positioning practices were implemented, making it difficult to know for sure what contributed to the prevalence of dolichocephaly. On the other hand, strengths of this study indicated the timeline of dolichocephaly, demonstrating that regardless of intervention, dolichocephaly is most commonly present during 32 to 34 weeks' PMA and is most likely to warrant outpatient follow-up if present during this period or at hospital discharge[1].

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.]

This study suggests that the development of dolichocephaly is a factor that needs to be highly considered in preterm infants, with 54% of participants developing dolichocephaly at some point throughout their hospital course. This prevalence is strongest during the 32 to 34 week PMA mark, and if an infant had dolichocephaly at this point or at hospital discharge, they were also more likely to have dolichocephaly at an outpatient follow-up. This concept suggests that without proper intervention, dolichocephaly may be difficult to reverse in the first 6 months post discharge. This study also provides a correlation between dolichocephaly at 32 to 34 weeks' PMA and the need for outpatient physical therapy in early infancy. This highlights the need for prevention and treatment of cranial molding, especially during the period of birth to 34 weeks' PMA, as this is a critical period for cervical muscle development[5,11]. While no statistically significant results were noted for the prevalence of adverse motor outcomes at follow-up, study results did indicate the infants with dolichocephaly are more likely to demonstrate a combination of adverse motor outcomes that may contribute to early motor delays, resulting in an increased need for outpatient physical therapy services.

This study indicates an association between preterm birth and the development of dolichocephaly. It provides a strong timeline for when patients are most likely to develop the condition and the further implications of this cranial molding deformity. It also indicates the need for further research on exact protocols and positioning devices to be implemented to prevent or treat cranial molding deformities. While literature indicates that supine is the best position to limit the prevalence of dolichocephaly, this position is often contraindicated due to other comorbidities and complications associated with very preterm birth[5,9]. This study notes the need for a regimented positional protocol and warrants further research being conducted in this area[1].

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.]

McCarty et al demonstrates the need for intervention to prevent adverse outcomes associated with infant cranial molding. This study cites the perceived developmental timeline of dolichocephaly and how the prevalence of cranial molding can lead to adverse motor outcomes following hospital discharge. While this study does not directly provide a protocol to decrease the likelihood of developing dolichocephaly or other cranial molding abnormalities, it exhibits the need for regimented and documented care in very premature infants of low birth weight. It also highlights the concept that medical providers need to be increasingly aware of the development of dolichocephaly during the 32 to 34 weeks' PMA period and take extra caution during this timeframe to prevent adverse cranial molding. Further, this study directly answers the second part of the clinical scenario by addressing the correlation between dolichocephaly and adverse motor outcomes. While no statistically significant results were found, study results did indicate that infants with dolichocephaly at both the 32 to 34 week PMA and discharge mark are more likely to demonstrate a sequence of adverse motor outcomes that an contribute to early motor delays[1].

Providing treatment to prevent or decrease the impact of preterm infant cranial molding is something that is both practical and feasible. While this study does not apply a direct experimental treatment or protocol, its retrospective design demonstrates the idea that intervention is needed. The findings of this study support early developmental intervention at less than 32 weeks' PMA to hopefully prevent or treat cranial molding deformities and potentially, improve early motor outcomes. Due to physical therapists' current presence in the NICU and expertise in positioning, researchers suggest that due to the findings of this study, physical therapists can implement and educate other members on the medical team on positioning protocols to decreased the presence of cranial molding deformities[1].

(2) Description and appraisal of Evaluating the effectiveness of gel pillows for reducing bilateral head flattening in preterm infants: a randomized controlled pilot study by Schultz et al, 2008

Aim/Objective of the Study/Systematic Review:
The primary objective was to evaluate the effectiveness of gel pillows for reducing bilateral head molding in preterm infants (>32 weeks PMA), as determined by cephalic index[2].
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.
This study was conducted using a quasiexperimental design. Infants were randomly assigned to a control group (usual care on the standard mattress) or to an experimental group (placement of the head on a gel mattress). Study researchers, using computerized random number listing, prepared sealed packets that included the study identification number and the results of randomization for that study number. The study investigator who obtained the informed consent opened the sealed packets in numerical order. On top of this, a green card was placed on top of the incubator of infants in the study other medical personal would be aware to not interfere. Informed consent was obtained by one of the study investigators from the infants' legal guardians at least 72 hours prior to life. Two graduate students were trained to use the digital calipers and established and interrater reliability of 0.811 prior to the start of the study and was reassessed approximately halfway through the study[2]. Infants in the experimental group were placed on the gel pillow no later than 72 hours of life and initial head measurements were taken. From there, head measurements were taken every seven days from the day of admission to the day of discharge or transfer. At the time of each measurement, data collectors did not have access to previous measurements or if the infant was in the control or experimental group as to not bias measurement results. All infants were repositioned at least every three hours following the schedule of: supine, side, prone, side. The infant's nurse was responsible for documenting each position change. In the event that an infant could not maintain a particular position, this was documented, but the infant was allowed to remain in the study. All data was assessed using repeated measures analysis of variance (RMANOVA). Tests for homogeneity of variance and Mauchly sphericity for RMANOVA were also performed, and gestational age and birth weight were added as covariates to the RMANOVA model to assess for further statistical significance[2].

Setting [e.g., locations such as hospital, community; rural; metropolitan; country]
The study took place at a tertiary level III NICU at Barbara Bush Children's Hospital at Maine Medical Center in Portland, ME. This hospital averages more than 600 NICU admissions annually[2].
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.
Infants were eligible for the study if they were less then 32 weeks of age, weighed less than 1,500g, and did not have hydrocephaly, microcephaly, cranial deformities, and/or central nervous system abnormalities. Informed consent was obtained for 87 infants; however, 36 males and 45 females were randomized to the experimental group (with an n of 41) and control group (with an n of 40). Seventy-seven percent of the subjects (62) were delivered via caesarean birth with a mean gestation age of 28.3 weeks. The average weight of the study participants was 1,024g, with 50% of the infants weighing <1,000g upon entry[2].
Intervention Investigated [Provide details of methods, who provided treatment, when and where, how many hours of treatment provided]
Control
Infants in the control groups were placed on the standard foam core mattress, which is 2.5 cm thick. Infants in this group also achieved proper spinal curvature, neck flexion, and airway clearance[2]. Infants were repositioned at least every three hours based on the studies repositioning design schedule (supine, side, prone, side). Nurses were responsible for recording positioning change. If an infant could not maintain or achieve a particular position due to instability, this was documented, but the infant was able to remain in the study[2].
Experimental
The Gel-E Donut is 3/8 inch thick and 7 inches and diameter. It is designed to simultaneously reduce pressure while providing support. The pillow was placed under the sheet of the mattress and infants had their torsos elevated to the level

of the pillow to provide proper spinal curvature, neck flexion, and airway obstruction[2].

Infants were repositioned at least every three hours based on the studies repositioning design schedule (supine, side, prone, side). Nurses were responsible for recording positioning change. If an infant could not maintain or achieve a particular position due to instability, this was documented, but the infant was able to remain in the study[2].

Outcome Measures

[Give details of each measure, maximum possible score and range for each measure, administered by whom, where]

A mean difference of 0.06 in cranial index was deemed to represent clinically significant results based off of previous literature after five weeks of the intervention[10]. With power analysis, a sample size of 29 participants in each group would have 80% power to detect statistically significant results ($P < 0.05$), assuming a standard deviation of 0.08. A cranial index of > 1.40 was used to signify undesirable head molding or plagiocephaly[2].

The degree of head flattening was expressed as the AP:BP ratio (cranial index). The AP diameter was measured from the glabella to the occipital prominence (the widest point on the midline of the head). The BP measurement was obtained using the widest points on the lateral aspects of the head[2].

Baseline measurements were taken no later than 72 hours into life. Then, head measurements were taken every 7 days from the day of admission to discharge. Data collectors did not have access to previous head measurements to reduce the natural tendency to attain measurements similar to previous days[2].

Demographic information of gestational age, birth weight, gender, type of delivery, days on a ventilator, and general health was collected from patient charts. The repositioning standard was defined as “met” if repositioning was documented 6 times throughout the day with less than 3 hours between positioning changes[2].

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.]

Infants in both the control and experimental group were equivalent for demographics and there were no statistically significant difference in gender between the two groups. Infants in the two groups were also equivalent for therapeutic care interventions (days with eye shields, days on CPAP, days on a ventilator, and days adhering to positioning protocol). CI upon entry into the study ranged from 1.12 to 1.52, with a mean CI of 1.313 and a SD of 0.085. 9 or 11% of the participants had an entry CI of >1.40, demonstrating that some head molding was already present at birth[2].

The use of gel pillows did not significantly reduce the degree of bilateral head molding, as measured by the CI. By the fifth week of the study (which was the expected time frame to note statistically significant results), on 52 infants remained in the study (29 were either discharged, transferred to a hospital closer to their homes, or inadvertently dropped from the measuring protocol). Of the 51 subjects remaining in the study, the mean birth weight was 950g. Using repeated measures analysis of variance (RMANOVA), there was no noted statistically significant difference in CI (p=0.348) or OFC (p=0.867) between the two groups. The average CI for subjects in the control group was 1.41 (SD= 0.085) and the mean CI for the experimental group was 1.40 (SD = 0.066)[2].

At 10 weeks into the study, only 21 infants remained on the measurement schedule. At this 10 week postintervention mark, the mean weight of infants remaining was 1,887g (SD = 324g and range of 1,250-2,680g). At this mark, the trend was towards less head molding in the experimental group; however, the difference in CI was not statistically significant (p = 0.119). At week 7, the degree of head molding for the infants on the gel pillows began a downward trend and at week 10, the CI for the infants in the experimental group was 1.39 (SD = 0.061), as compared to the 1.47 (SD = 0.085) for participants in the control group. A T-Test for the singular time interval revealed a statistically significant difference in CI with a p value of 0.024, mean difference between CI measurements of -0.080, and 95% confidence interval = -0.148, -0.012. 40% of the infants in the experimental group had a CI greater than 1.40, as compared to the 91% of the subjects with a CI greater then 1.40 in the control group[2].

When birth weight and gestational age were added as covariates into the RMANOVA model, birth weight was a statistically significant covariate (p = 0.05) in the CI between the two groups. The difference in the CI between the two groups remained nonsignificant overtime with a p value of 0.209. As expected with typical growth and development, head circumference gradually increased overtime in both groups, with no statistically significant difference over time between the two groups[2].

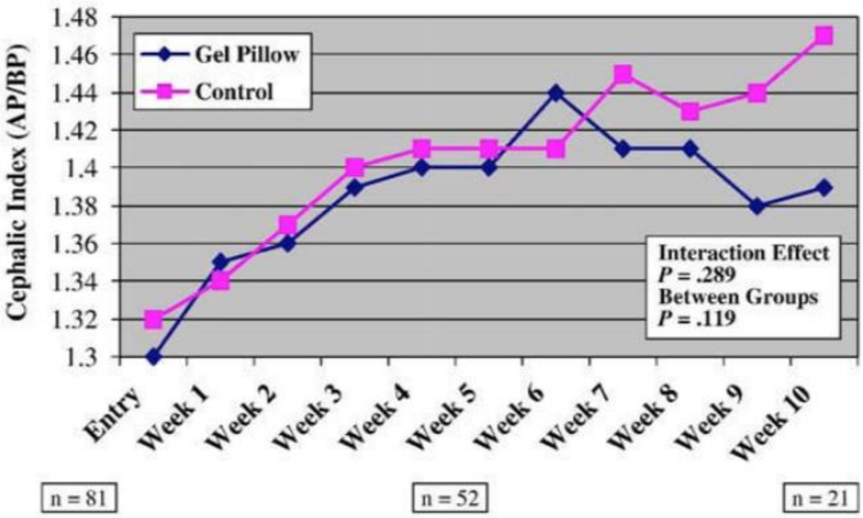

Fig. 4. Comparison of cephalic measurements over time.

Above graph from page 195[2]

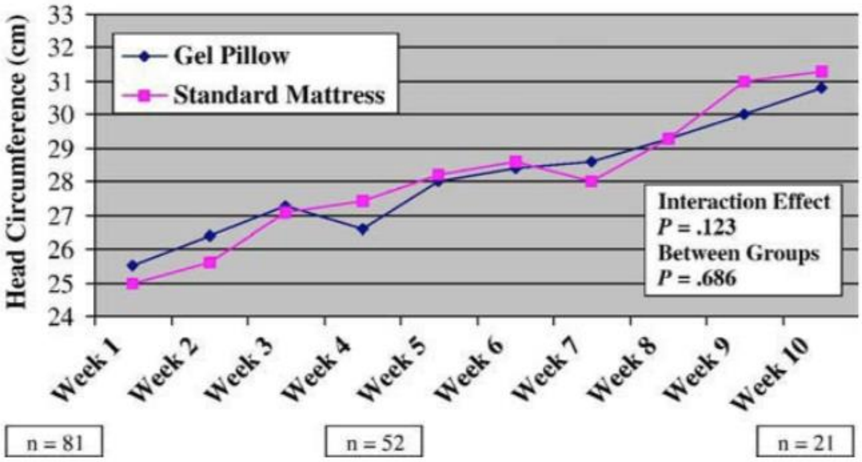

Fig. 5. Head circumference comparisons over time.

Above graph from page 196[2]

Original Authors' Conclusions

[Paraphrase as required. If providing a direct quote, add page number]

The authors concluded that the use of gel pillows in premature infants during the first five weeks of life did not support their hypothesis that gel pillows significantly reduce the degree of bilateral molding as noted by cranial index measures. While not the initial purpose of this study, researchers concluded that these findings may indicate that routine repositioning of preterm infants would significantly reduce head molding by nine weeks of treatment. Any intervention to reduce bilateral head molding needs to be extended past the time frame of five weeks and may be more successful in very small infants weighing less than 1,000g at birth[2].

Visual head shape with Gel Pillow device (page 197)[2]

Visual head shape with standard mattress (page 197)[2]

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.]
To assess for overall quality, this study received a 7 out of 11 on the PEDro assessment. The blinding of research investigators improved both the internal validity and the strength of the study by helping reduce confounding variables. Further, statistical analysis was conducted by an outside researchers not associated with the study to further limit inherent bias. In assessing external validity, the decreasing sample size and low power of the study decreased its external validity. Attrition due to discharge, transfer, and scheduling errors continuously reduced the sample size. This resulted in a power of only 17% for statistical significance between groups and a power of 15% of interaction effect (at the five week mark). At 10 weeks, the power to detect a significant difference in cranial index between the two groups was 34% and the interaction effect was 26%. There were many additional strengths to this study. The results are widely applicable as many hospitals implement either the control standard or the gel pillow already in NICU care. Further, the outcome measures utilized of both cranial index and head circumference are widely implements and considered standard measures. The length of this study is another strength. Previous literature indicates that the large majority of cranial molding studies have not been conducted past seven weeks of measurements[3,4,6-8]. Preterm infants of this size and medical complexity are often hospitalized for extended periods and information is needed regarding the implications of the entire hospital stent. Primary weaknesses of sample size and power analysis are described above; however, further weakness include the obtaining of informed consent being limited to the members of the research team, which potentially restricted potential enrolment to only days and hours these individuals worked. Further, the lack of control for positional regimen limited the applicability and full assessment of the results. The overall quality of evidence was moderate to high considering the study design, randomization of participants, and blinding of investigators; however, throughout the course of the study, the level of evidence decreased as the sample size and power analysis also decreased[2].
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 results of Schultz et al demonstrates the importance of a positional regimen for preterm infants born less than 32 weeks and that a gel pillow may have some effect on decreasing the presence of plagiocephaly. While the study results indicated no statistically significant results for the use of a gel pillow compared to a standard mattress, which contradicts previous literature, previous literature did not implement a strict positional change regimen[3,4,6-8]. This indicates that positional change, at least in the first few weeks following birth, may help decrease bilateral head molding, regardless of support surface. Due to the lack of

effect size and statistically significant results, no formal conclusion can be drawn, but this study does indicate the further need for research in this speciality area. While secondary components such as placement on CPAP or ventilator were controlled for between each group, researchers did not provide data as to how many infants received these services or how these devices may have impacted results[2].

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.]

Schultz et al indicates that a standardized positional protocol may be effective in reducing the effect of undesirable cranial molding often observed in infants less than 32 weeks PMA. Further, this study suggests that in addition to a standardized positional protocol, a gel pillow may aid in reducing bilateral head molding, especially in infants who have been in the NICU for an extended period (as noted by seven weeks in this study). This study is directly correlated to the clinical question as it highlights the importance of a positional protocol. While the clinical questions would have been further supported if researchers implemented a control group to assess the difference between a regimented protocol versus standard positional practice, research in this area is greatly limited and this study highlights the importance of intervention through both positioning and support devices in this patient population. The clinical question is based around physical therapy implementing a positional protocol for preterm infants; however, this study indicates that this is generalizable and feasible for nursing staff as well. While the study did mention how the added time commitment limited the nurses and possibly impacted the scheduling errors the decreased the sample size, a positional protocol or added support device is both practical and feasible for multiple disciplines to implement[2].

SYNTHESIS AND CLINICAL IMPLICATIONS

There is currently a very limited amount of high-quality research that assess the impact of cranial molding deformities and interventions for prevention of adverse head shaping and correlated motor outcomes. It is well documented throughout the literature that infants born prematurely or of very low birth weight are at an increased risk for developing cranial molding deformities[1-8]. If left untreated, cranial molding abnormalities can persist into childhood, and as demonstrated by McCarty et al, may result in neurodevelopmental abnormalities and gross motor asymmetries[1]. The literature is currently heavily limited by interventions studied in combination rather than isolated variables, low-quality study designs, and extremely small sample sizes. While it is known that cranial molding is becoming increasingly prevalent in preterm infants, exact mechanisms for intervention and prevention are still highly debated, as well as the adverse motor outcomes that may follow these cranial molding deformities[1,5].

McCarty et al further establishes the idea that the development of cranial molding deformities is a factor of NICU care that needs to be highly considered with preterm infants, as 54% of the infants in the study developed dolichocephaly at some point throughout their hospital stay[1]. Not only were preterm or very low birth weight infants likely to develop undesired cranial molding, if this head shape was still prevalent at 32 to 34 weeks' PMA or at hospital discharge, the infant was more likely to maintain the head shape deformity at an outpatient follow-up and demonstrate a combination of adverse motor outcomes[1]. These adverse motor outcomes are also believed to contribute to early motor delays, asymmetrical motor performance, and result in an increased need for outpatient physical therapy services[1]. This study was retrospective in design, which did inhibit the complete assessment of the data and limited sample size (due to some data points missing throughout patient charts), the study still conveys the timeline for the development of dolichocephaly and presents the idea cranial molding deformities may lead to adverse motor outcomes[1]. This study further notes the need for a regimented positional protocol and warrants further research being conducted in this highly specialized area[1].

The study by Schultz et al conveys the importance of a positional protocol for preterm infants and infants of very low birth weight[2]. While the impact of the gel pillow is not directly correlated to the clinical question, it highlights another method attempting to decrease positionally-based cranial molding deformities[2]. The primary takeaway from this study in conjunction with the clinical question is how no statistically significant results were obtained whether infants were placed on the gel pillow or standard pillow, but that cranial index measurements remained relatively stable with the both groups implementing a positional protocol[2]. This indicates that positional change, at least in the first few weeks following birth, may aid in decreasing bilateral head molding, regardless of support surface. The exact protocol utilized in this study called for infants to be repositioned at least every three hours, following a schedule of supine, side, prone, and side. While this exact schedule cannot always be followed due to the medical complexities of preterm infants, literature indicates how positional change is vital for cranial molding, sensory integration, motor outcome, symmetrical development, and proper developmental growth[1,5,9,11]. This study was of high quality due to the randomized control trial design that incorporated single-blinded investigators; however, the validity greatly decreased with a continual drop in sample size that largely impacted power analysis and resulted in a lack of formal conclusion due to no statistically significant results[2]. This study does greatly showcase the need for further research this area while alterations in cranial molding were still noted throughout the study.

As mentioned above, there is currently a large need for further high-quality research in the area of cranial molding and the associated motor outcomes. Both studies indicate the correlation between preterm or low birth weight delivery and the development of cranial molding deformities[1,2]. While both studies highlight the prevalence and implications of cranial molding, neither establish nor investigate a regimented positional protocol to prevent and/or treat cranial molding deformities[1,2]. Further research is needed on exact regimens and positioning devices that can be implemented to prevent and treat cranial molding deformities. Further, due to the complex nature many preterm infants present with, further research is indicated that assess the role of positioning in light of the many devices and external support systems these infants are on (such as CPAP and ventilators). Literature indicates that the large majority of infants born less than 32 weeks' PMA or of low birth weight (<1,500g) are in need of these external support devices; however, the associations between these devices, positional changes, and development of cranial molding has yet to be researched or established[1,5].

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