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EVIDENCE TABLE: HEAD DEFORMITIES IN PRETERM INFANTS – PREVALENCE, PREVENTION, AND TREATMENTS

Abbreviation List:
BGA: birth gestational age
CA: corrected age
CI: Cranial Index
CPAP: Continuous positive airway pressure
CVAI: Cranial Vault Asymmetry Index
DP: deformational plagiocephaly
ELBW: extremely low birth weight
NICU: neonatal intensive care unit
PMA: post-menstrual age
SCN: special care nursery
TEA: term equivalent age

Prevalence of Head Deformities in Preterm Infants

Title/ Author/ Year	Study Details
Prevalence of head deformities in preterm infants at term equivalent age[1] **Ifflaender et al., 2013**	**Study Design:** Cross-sectional / Prevalence Study **Study Aim:** The purpose of the study was to determine the prevalence of asymmetrical and symmetrical head deformities at TEA and identify risk factors for these deformities. **Subjects:** 195 infants who were discharged from a tertiary neonatal clinic in Dresden, German, between April 2011 and January 2013. All infants who were discharged from the unit during this time period were included, unless they met the following criteria: peripheral IV at the scalp, supplemental oxygen requirement. The cohort was categorized based on gestational age at birth into 3 groups: 1) Very preterm (<32 weeks gestation), 2) Late preterm (32 to 36+6 weeks), and 3) Term (37 to 40 weeks). There were 55 very preterm infants, 85 late preterm infants, and 55 term infants. **Tests/Measures:** Cranial measurements were conducted for each infant, using the STARScanner, a non-invasive laser shaper digitizer, which can be used to measure head shape. Scans were used to determine CI [biparietal diameter / fronto-occipital diameter × 100] and CVAI [(diagonal A – diagonal B) / diagonal A × 100, where diagonal A > diagonal B]. CI

	and CVAI measurements were used to determine whether patients had symmetrical head deformities, such as brachycephaly and dolichocephaly, and asymmetrical head deformities, such as plagiocephaly. **Interventions:** This study was observational in nature. Thus, there was no intervention that was used in the study. **Results:** *Asymmetrical Head Deformities*: Very preterm infants had a higher risk of moderate to severe plagiocephaly (OR 3.75, 95% Confidence Interval 1.48-9.46, p=0.005, compared to term infants. Additionally, very preterm infants had significantly higher CVAI (4.1% IQR 1.9-5.6%), compared to late preterm infants (2.7%, IQR 1.1-4.6%) and term infants (2.4%, IQR 0.7-4.0%). Risk factors for asymmetrical head deformities included intracranial hemorrhage grade II-IV, higher median duration of invasive mechanical ventilation (IMV) and higher duration of CPAP therapy. *Symmetrical Head Deformities*: Very preterm (OR 21.78, 95% CI 7.74-61.61, p<0.0001) and late preterm infants (OR 3.21, 95% CI 1.22-8.48, p=0.02) had a significant risk of moderate to severe dolichocephaly compared to term infants. CI was also significantly lower at TEA for very preterm infants (71.4%, IQR 68.7-74.6%), compared to late preterm infants (77.2%, IQR 73.2–80.7%) and term infants (80.0%, IQR 75.5–83.3%). Lower TEA indicates dolichocephalic molding. Risk factors for dolichocephaly included female sex and Cesarean section delivery. Dolichocephaly was associated with higher median duration of total respiratory support, longer duration of CPAP, and longer duration of IMV. **Limitations:** One limitation of this study is there is not a consistent method by which CVAI is measured and calculated in the literature. Therefore, it is difficult to make comparisons between different studies. Additionally, this study had a small sample size, which was obtained via convenience sampling. Therefore, the generalizability of the results is limited. **Conclusion & Clinical Implications:** There is a high prevalence of symmetrical and asymmetrical positional head deformities in preterm infants at TEA. These deformities are associated with necessary medical interventions provided in the NICU, especially respiratory support.
Prevalence and predictors of idiopathic asymmetry in infants born preterm[2] **Nuysink et al. 2012**	**Study Design:** Cross-Sectional/ Prevalence Study **Study Aim:** The purpose of this study was to ascertain the prevalence of positional preferences and plagiocephaly preterm infants at TEA and 6 months CA, evaluate the predictors of positional preference and plagiocephaly at TEA, and determine differences in gross motor function at 6 months CA in infants with and without positional preferences and deformational plagiocephaly (DP). **Subjects:** All infants included in the study were born at ≤ 32 weeks gestational age, discharged from a level III NICU and visited a neonatal follow-up clinic. Several infants were excluded due to their family choosing not to participate in the study, or infants being diagnosed with the following conditions: central nervous system disorder, congenital formation, sensory system disorder, developmental dysplasia of the hip, and obstetric brachial plexus lesion. A total of 192 infants

	were included in the study population. They were observed at two appointments, the first at TEA, and the second at 6 months CA. **Tests/Measures:** During neonatal follow-up clinics, infants were observed by a pediatric physical therapist who made note of any positional preferences or DP. Positional reference was defined as restriction in turning head towards the opposite side or difficulty maintaining head in rotated position towards opposite side. DP was observed from a cranial and posterior view and defined as a unilateral occipital flattening of the skull and/or ear deviation (homolateral ear is typically displaced anteriorly with respect to the other ear). Objective measurements were not used to identify positional preference or DP. Additionally, the general movements observation technique was used to determine each patient's motor behavior at TEA. Movements were classified as normal, mildly abnormal (lack of fluency, poor repertoire) or definitely abnormal (cramped-synchronized). At 6 months CA, the Alberta Infant Motor Scale (AIMS) was used to determine gross motor maturation. **Interventions:** This study was observational in nature. Thus, there was no intervention that was used in the study. **Results:** At TEA, the prevalence of a positional preference was 44.8%. Of these patients, 91% had a preference to the right side. The prevalence of DP was 10.4%. At 6 months CA, none of the infants displayed a positional preference. The prevalence of DP was 13%, with 10 infants who showed DP at TEA showing resolution by 6 months CA, and 8 infants who showed no asymmetry at TEA demonstrating a new DP at 6 months CA. There were also 4 infants who had corrective helmets to treat this deformity at the 6-month CA follow-up appointment. Predictors of positional preference and DP were evaluated. At TEA, positional preference was associated with periventricular leukomalacia Grade I and intraventricular hemorrhage grade II, but this association was not significant. At TEA, positional preference with DP was significantly associated (p=0.03) with chronic lung disease (OR 4.4 95% CI 1.66-11.61). At 6 months CA, significant predictors of DP were male gender (p=0.03, OR 3.2, 95% CI 1.14-9.15) and multiple births (p=0.02, OR 3.1, 95% CI 1.28-7.31). Furthermore, positional preference was a predictor for DP (p=0.02, OR 3.0 95% CI 1.23-7.39). At TEA, the general movements of 145 infants were observed, with 1/145 demonstrating abnormal general movements and 27/145 (19%) demonstrating mildly abnormal general movements. There was not a significant association found between mildly abnormal general movements and positional preference and DP. AIMS scoring at 6 months CA was compared to norms for (Dutch) infants born preterm. There was a significant difference in gross motor maturation identified between infants with and without idiopathic asymmetry at TEA (p=0.01). There were no differences in gross motor maturation between infants with and without DP at 6 months CA.

	Limitations: There were no objective measurements used to evaluate positional preference or DP, which could result in some cases being missed, or either condition being incorrectly identified. The severity of positional preferences and DP were also not identified. Additionally, this study was a retrospective design, with a small sample size. **Conclusion & Clinical Implications:** There was a higher prevalence of positional preference in preterm infants than what is usually seen in term infants. However, there was a reduction in prevalence of plagiocephaly by 6 months CA, which demonstrates that cranial molding improves over time.
Dolichocephaly in Preterm Infants: Prevalence, Risk Factors, and Early Motor Outcomes[3] **McCarty et al. 2017**	**Study Design:** Retrospective Prevalence Study **Study Aim:** The purpose of this study was to evaluate the development of dolichocephaly in preterm infants, determine risk factors for dolichocephaly, and assess motor outcomes at follow-up. **Subjects:** A total of 143 infants included in the study were patients in the intensive care nursery at Duke University Medical Center from September 2013 through January 2015. Inclusion criteria were birthweight of ≤1500 g and/or BGA ≤32 weeks, stable on room air, nasal cannula, or CPAP at initial PT evaluation, and at least two of three CI measures (initial evaluation, re-evaluation, or discharge) recorded during study period. Exclusion criteria included if the patient was diagnosed with a genetic abnormality, neuromuscular disorder, craniofacial abnormality, congenital or posthemorrhagic hydrocephalus, or other diagnoses determined to impact generalizability of results. **Tests/Measures:** CI was measured using Ballert orthopedic cranial calipers, by 4 PTs who were trained, based on the Ballert user guide instructions. CI was calculated using biparietal diameter (BFD) (widest transverse diameter of the head) and occipitofrontal diameter (OFD) (diameter of the head from the most prominent midline point of the frontal bone, glabella, to the occipital protuberance), as CI = (BFD/OFD) x100). Dolichocephaly was defined as CI <76%. CI was measured at the time of initial evaluation (approximately 2 weeks chronological age), at reevaluation (approximately 32-34 weeks PMA), and within 1-2 weeks prior to hospital discharge. CI was measured again at the time of outpatient follow-up. Additionally, adverse motor outcomes were recorded by a PT, including asymmetry, extension bias, decreased head control, decreased midline control, or decreased prone skills. **Interventions:** All participants received standard care in the hospital, which included the use of various positional aids, in order to improve head shaping and maintain optimal body positioning. Positioning aids included moldable pillows and mattresses and bean bags. **Results:** A total of 35 (54%) of infants developed dolichocephaly during their hospital stay. There were 43 infants who had CI measurements at initial evaluation, and 4 (9%) had dolichocephaly. When CI was measured at 32-34 weeks PMA (re-evaluation), 25/65 (39%) had dolichocephaly. At the time of discharge, 19/57 (33%) infants measured had dolichocephaly. At the post-discharge follow-up, 6/50 (12%) infants had dolichocephaly.

	CI at discharge was found to be predictive of CI at outpatient follow-up (p=0.005). Additionally, younger BGA (0.03) and chronological age at outpatient follow-up (p=0.05) were associated with lower CI measurement, which can indicate dolichocephaly if <76%. Additionally, at outpatient follow-up, participants were more likely to have dolichocephaly, if they had dolichocephaly at 32-34 weeks PMA (OR=6.7, 95% CI 1.1-39.1; p=0.04) or at discharge (OR=11.3, 95% CI 1.2-107.0; p=0.04). Participants with dolichocephaly at 32-43 weeks PMA were more likely to be receiving PT services or be referred to PT services during the follow-up appointment (p=0.05), when controlling for gestational age. There were no associations found between dolichocephaly and individual adverse motor outcomes at follow-up. **Limitations:** This study was a retrospective study, so CI measurements were not available for all 3 time points for all infants in the study. Additionally, the study had a small sample size. **Conclusion & Clinical Implications:** There is a high prevalence of dolichocephaly in preterm infants at 32-34 PMA. Additionally, dolichocephaly is associated with increased referrals to outpatient PT, indicating a possible association with early motor abnormalities. This demonstrates the importance of prevention of cranial molding deformities and early treatment once they have developed.
Cranial shapes of Japanese preterm infants at one month of age using a three-dimensional scanner[4] **Miyabiyashi et al. 2022**	**Study Design:** Retrospective Cohort Study **Study Aim:** The purpose of this study was to compare the head shapes of preterm and full term infants at 1 month of age, examine risk factors for dolichocephaly, and determine cranial characteristics of Japanese preterm infants. **Subjects:** There were 149 preterm infants and 165 term infants included in this study. Preterm infants included in the study were born at <37 weeks BGA and required NICU care in 4 Japanese centers between April 2020 and March 2022. Infants were also seen at an outpatient clinic for a 1-month follow-up. Exclusion criteria were congenital diseases, severe interventricular hemorrhage, and periventricular leukomalacia. The control group consisted of full term infants, whose data was collected during a previous study. **Tests/Measures:** The Artex Eva 3D scanner was used to scan the head of each preterm infant. An elastic wig cap was used, in order to prevent a child's hair from affecting the measurement. During each measurement, heart rate and saturation of percutaneous oxygen saturation was measured. Head measurements were used to calculate CI and CVAI. DP was defined as CVAI >5%, based on criteria for Japanese infants that were established in a previous study. Dolichocephaly was defined as CI ≤79.1, mesocephaly was defined as CI 79.2-93.8, and brachycephaly was defined as CI ≥93.9, based on classification for the Japanese population. **Interventions:** N/A

	Results: There was no significant difference in the age of measurement and sex ratio, between the term and preterm infant groups. Mean BGA for the preterm group was 33.8 weeks. There were significantly higher Cesarean section births and multiple births in the preterm group, compared to the term group. There was a significantly higher incidence of dolichocephaly seen in the preterm group versus the term group (54.3% vs. 12.3%, p<0.001). There was not a significant difference in incidence of DP. Additionally, there was a higher incidence of dolichocephaly among female infants (p=0.012). *Risk Factors for Dolichocephaly:* Female sex (OR 3.32), Cesarean section (OR 4.07), and use of mechanical ventilation (OR 4.66) were found be significant risk factors for dolichocephaly. **Limitations:** One of the limitations of this study was that head scans were only taken at one time point, 1-month chronological age. This excluded most extremely premature infants from the study, as they were not medically stable at one month of age. Additionally, this study did not include neurodevelopmental outcome measures. **Conclusion & Clinical Implications:** This study concluded that Japanese preterm infants demonstrate similar dolichocephalic head shapes as preterm infants in Western countries. Risk factors for dolichocephaly, including female sex, Cesarean section, and use of mechanical ventilation are important for predicting which infants are more likely to develop dolichocephaly.
Clinical Course of Asymmetric Motor Performance and Deformational Plagiocephaly in Very Preterm Infants **Nuysink et al. 2013[5]**	**Study Design:** Prospective Prevalence Study **Study Aim:** The purpose of this study was to evaluate the clinical course of positional preference and DP in preterm infants born at BGA <30 weeks or birth weight <1000g, up to 6 months CA, and examine factors which can be predictive of the persistence of these conditions. **Subjects:** A total of 120 infants were included in the study, all of which were born in or referred to a level III NICU within a 1 week of birth, from January 2009 – October 2010. Inclusion criteria included BGA <30 weeks or birth weight <1000g and visits to the neonatal follow-up clinic at TEA. Exclusion criteria was diagnosis with a disease or diagnosis which could lead to asymptomatic asymmetry, such as a central nervous system disorder or congenital malformation. **Tests/Measures:** Each participant in the study was examined 3 times, within 6 months. The first and third visit took place at the neonatal follow-up clinic at TEA (Time 1 [T1]) and 6 months CA (Time 3 [T3]). The second visit was conducted by a physical therapist within the participant's home at 3 months CA (Time 2 [T2]). Visits at the neonatal follow-up clinic consisted of a 20-minute session with a neonatologist and a pediatric physical therapist. The home visit involved a 30-minute assessment.

	Positional preference was defined based on observation of the infant maintaining their head persistently in one direction for 75% of the assessment while in supine, as well as restricted active motion in the opposite direction and difficulty maintaining passive rotation. Deformational plagiocephaly was defined as unilateral occipital flattening of the skull and/or homolateral anterior ear displacement. The Argenta classification system was used to evaluate the degree of plagiocephaly. Argenta grade I involved one-sided posterior flattening only, grade II also includes forward ear placement, and grades III and IV includes additional involvement of the frontal skull and face. For this study, DP was defined as ≥ Grade II. The authors developed an asymmetry scale to determine whether asymmetrical movement patterns were persistent at T3, which included head and trunk control, arm movements, leg movements, and asymmetry in range of motion of the cervical spine or hips and in bidirectional skills. The max score was 6 points; asymmetrical motor performance was defined as a score of ≥2 points. Motor performance was also assessed at each time point. At T1 and T2, general movements were observed. This was classified as normal, subnormal, mildly abnormal, or definitely abnormal, based on fluency, complexity, and variability. The TIMP Screening Instrument (TIMSPI) was done at T1, and the Test of Infant Motor Performance (TIMP) was done at T2. The Alberta Infant Motor Scale (AIMS) was done at T2 and T3. **Interventions:** N/A **Results:** *Asymmetry in Motor Performance:* At T1, the prevalence of positional preference of the head was 65.8% and at T2, the prevalence was 36.7%. At T3, 15.8% of participants were found to have asymmetrical motor performance (score of ≥2 on asymmetry clinical scale). *Deformational Plagiocephaly:* At T3, 23.3% of participants had DP and ear deviation (Argenta ≥II). Plagiocephaly graded as Argenta ≥I was seen at T1 in 30% of participants, at T2 in 50% of participants, and at T3 in 36.7% of participants. The majority of participants demonstrated some level of plagiocephaly at one of the three timepoints; only 18% had no observable deformity at any point. *Association of Asymmetry in Motor Performance with Deformational Plagiocephaly:* There was a strong association of concurrent positional preference and DP at T1 (OR, 31.8; 95% CI, 4.17-243.08; P = 0.001) and at T2 (OR, 15.5; 95% CI, 5.76-41.98; P = 0.001). The association was still significant at T3, but not as strong (OR, 3.9; 95% CI, 1.39-10.88; P = .010). DP at T1 was associated with positional preference at T2. Infants with DP at T2 were more likely to have asymmetrical motor performance at T3 (OR, 3.3; 95% CI, 1.12-9.99; P = .030). Positional preference at T1 was significantly associated with DP at T2 only. Additionally, positional preference at T2 was predictive of persistent DP at T3 (OR, 21.6; 95% CI, 6.71-69.50). *Predictors of Asymmetry in Motor Performance*

	At T2, male sex and a lower TIMP z-score was associated with asymmetric motor performance at T3 ($p \leq 0.10$). Sleeping primarily in the supine position was also associated with asymmetric motor performance at T3, but this association was not significant ($p \geq 0.05$). *Predictors of Deformational Plagiocephaly* There were significant associations between persistent DP at T3 and lower birthweight, small for gestational age (SGA) status, longer duration of hospitalization and mechanical ventilation, and diagnosis of chronic lung disease grade II. Additionally, mildly abnormal general movements, low TIMP score, or low AIMS score were associated with increased likelihood of persistence of DP ay T3. At T3, DP was highly correlated with birthweight and SGA status (r= 0.77), moderately to highly correlated with duration of hospitalization, duration of intubation, and diagnosis of chronic lung disease (r= 0.55-0.76). **Limitations:** One of the main limitations of this study is that there is not a standardized assessment tool used to measure asymmetrical motor performance, which is consistently used in the literature. Additionally, it is not possible to control for other factors in daily clinical practice which could affect outcomes, such as positioning protocols in the hospital, education provided to parents, and variations in physical therapy interventions. **Conclusion & Clinical Implications:** There is a high prevalence of deformational plagiocephaly among preterm infants. Plagiocephaly appears to improve around 3-6 months CA. Additionally, preterm infants demonstrate asymmetric movement patterns, including positional preference of the head at TEA.

Interventions to Prevent/Treat Head Deformities

Title/ Author/ Year	Study Details
Evaluating the effectiveness of gel pillows for reducing bilateral head flattening in preterm infants: a randomized controlled pilot study **Schultz et al. 2008[6]**	**Study Design:** Quasi-experimental study **Study Aim:** The purpose of the study was to evaluate the effectiveness of gel pillows in reducing bilateral head molding (plagiocephaly) in preterm infants. **Subjects:** There were a total of 81 preterm infants included in the study. The criteria for inclusion were gestational age ≤34 weeks and weight ≤1500 g. Exclusion criteria included hydrocephaly, microcephaly, cranial deformities, and central nervous system abnormalities. Infants were randomized to a control group, which received usual care on a standard mattress or an experimental group, which had placement of the head on a gel pillow. **Tests/Measures:** CI was assessed using a 6-inch digimatic caliper. The anterior-posterior (AP) measurement was taken by placing the calipers on the widest point of the head, from the glabella to the occipital prominence. The biparietal (BP) measurement was taken by placing the calipers on the widest part of each side of the head. The occipitofrontal

	circumference was measured by placing a tape measure around the largest circumference of the head, from the occipital protuberance to the frontal bosses. CI was calculated as the ratio AP to BP measurements. A CI of >1.40 was considered undesirable or abnormal head molding. Baseline measurements were completed within the first 72 hours of life. Repeated head measures were done every 7 days, until the infant was discharged or transferred out of the hospital. **Interventions:** The experimental group was placed on a gel pillow once consent was received, within the first 72 hours of life. The pillow used a was Gel-E Donut, which is 3/8 inch thick and 7 inches in diameter. The pillow is designed to reduce pressure on the head and provide support. Pillows were placed under the mattress sheet, and extra linens were provided to maintain optimal spine and neck positioning. The control group was placed on a standard foam core mattress which is 2.5 cm thick. All infants, in both the control and experimental group, were repositioned every 3 hours, as part of standard care. Position changes were documented by nurses. **Results:** The control and experimental groups did not have any statistically significant differences in type of delivery, birth weight, gestational age, gender, therapeutic care interventions (days with eye shields during phototherapy, days on CPAP, days on a ventilator, and days meeting repositioning protocol). The use of the gel pillow did not result in significant reduction in bilateral head molding, based on CI measurements. By week 5, there were only 52 subjects remaining, and by week 10, only 21 subjects remained, as infants were either discharged or transferred. There was a trend towards reduced head molding in the experimental group, but this difference was not statistically significant. However, by week 10, there was a significant difference in CI between the experimental and control groups (gel pillows: mean CI = 1.388, SD = 0.061; standard mattress: mean CI = 1.468, SD = 0.084; t = -2.456, df = 19, P = .024). Additionally, in the gel pillow group, 40% of subjects had a CI >1.40, while in the control group, 91% had a CI >1.40. **Limitations:** The main limitation of this study was a small sample size. There was a high attrition rate, due to discharges and transfers, resulting in a reduction in the sample size by Week 5. This reduced the statistical power of the study. Additionally, the data collectors were not blinded, as the gel pillows were often present at the time of measurements. This may have resulted in some biases during measurements. **Conclusion & Clinical Implications:** Although there was not a significant reduction in head molding in the experimental group, the use of gel pillows did result in a significant difference in CI between the two groups. There were fewer subjects with abnormal head molding in the experimental group, compared to the control group, indicating the efficacy of the gel pillows in maintaining normal cranial molding in preterm infants.

Use of the Cranial Cup to Correct Positional Head Shape Deformities in Hospitalized Premature Infants[7] **Knorr et al. 2016**	**Study Design:** Prospective Description Research Design **Study Aim:** The purpose of the study was to evaluate the safety, feasibility, and effectiveness of the cranial cup infants in the NICU or SCN as a treatment for visible head shape deformities. **Subjects:** Subjects were selected using a convenience sample. The sample consisted of 23 infants born preterm, who were admitted to a Level 4 NICU or Level 2 SCN between May 2012 and June 2013 and had a positional head shape deformity. Inclusion criteria were BGA <35 weeks, weight >1000 g at enrollment, clearance from medical team, estimated minimum length of stay >14 days, and visible dolichocephalic head shape deformity. Subjects were also required to be in convalescent phase of hospitalization, and no longer critically ill. Exclusion criteria included inability to maintain airway patency in supine or side-lying, craniofacial anomaly, implanted scalp devices, drains or shunts, or severe parturitional head shape deformity. **Tests/Measures:** Calipers and a tape measure were used to measure anterior-posterior (A-P) length, medial-lateral width, diagonal measures, and head circumference. Additionally, an iPhone was used to take photos of each infant's head. CI was calculated using the A-P length and medial-lateral width. Normal CI was defined as 73-85%. Plagiocephaly was diagnosed using the right and left diagonal measures and defined as a >8-mm difference in the right and left measurements. Cardiorespiratory events, defined as apnea, bradycardia, or desaturation and emesis events were recorded by nursing staff. **Interventions:** The cranial cup is an adjustable orthotic device, which can be used to support the patient's head and body in both supine and semi-side-lying positions. It consists of a plastic base and 4 layers of cross-linked polyethylene foam, which are removable based on the infant's size. Straps are used to maintain the position of the infant on the device. All staff involved in the use of the orthotic device, including physicians, nurses, and orthotists were educated on the use of the cranial cup. Infants were positioned on the cranial cup device for a (goal) minimum of 12 hours per day. They were also repositioned as part of routine care every 3-4 hours. If the cranial cup was not in use, infants were positioned on either a gel pillow or mattress or held by a caregiver. **Results:** *Length of Device Use:* The 23 infants enrolled in the study had visible cranial molding deformities. Of these participants, 86% also had abnormal cranial measurements, which corresponded to the visible deformity. Participants spent a median of 288 total hours on the cranial cup with a median of 12.7 hours per day on the cranial cup and a median of 7.8 hours on a different positioning aid or being held. *Safety and Feasibility:*

	There was no difference in the number of cardiorespiratory events or emesis events when infants were placed on the cranial cup versus other positioning. Additionally, there were no adverse events related to the cranial cup. *Effectiveness:* At the time of discharge, 19 (83%) of participants had normal cranial measurements with no observable cranial molding deformities, and a median CI at discharge was 77.5%. The remaining 4 participants had abnormal cranial indices, which indicated dolichocephaly. Additionally, 2 of the remaining participants had abnormal cranial symmetry. There was no significant association identified between mechanical ventilation or CPAP and head shape. **Limitations:** This study had a small sample size, which was obtained through convenience sampling, which reduces the generalizability of the study. Additionally, this study did not include any follow-up measurements after discharge, which would have demonstrated any recurrences of positional deformities. **Conclusion & Clinical Implications:** This study demonstrates the safety, feasibility, and efficacy of the cranial cup orthotic device in treating existing cranial molding deformities, in preterm infants with dolichocephaly. Typically, helmet therapy is used to treat positional deformities, and requires that the infant wears the helmet for 22 hours per day. The cranial cup may be a viable option for treating these deformities earlier on, with less time required in the orthotic device.
Feasibility and Safety of the Preemie Orthotic Device to Manage Deformational Plagiocephaly in Extremely Low Birth Weight Infants **Knorr et al. 2019[8]**	**Study Design:** Prospective, descriptive clinical trial (pilot study) **Study Aim:** The purpose of this study was to determine if a preemie orthotic device (POD), previously tested in preterm infants weighting >1 kg, was feasible for use in ELBW infants (weight <1 kg). Additionally, the study aimed to determine if the POD was rated as easy to use by bedside nurses and to determine if the POD was safe to use in ELBW infants. **Subjects:** The study was conducted at 3 NICUs in the Northeastern United States (Site A: Level IV referral center, Site B: Level III urban NICU with birth center, site C: Level III suburban NICU with birth center). Convenience sampling was used, and 10 patients were included in the study. Inclusion criteria were weight <1 kg, BGA ≥22 weeks, medical clearance for study participation, and an estimated minimum hospital stay of 14 days or greater. Infants were excluded if they required prone positions for airway patency, required a medical device such as a continuous ventricular drain or subgaleal shunt which could impede proper position of the POD, or if they had a craniofacial anomaly, craniosynostosis, cervical anomaly, critical airway, cutis aplasia, or other significant breakdown of the scalp. **Tests/Measures:** A daily log was used to keep track of how long the POD was used, and whether the foam inserts of the POD were in place. An Ease of Use questionnaire was used to assess feasibility. The questionnaire had 7 items and used a 6-point Likert Scale. The face validity of the questionnaire was assessed by 2 bedside NICU nurses, a research manager, and a research coordinator. Also, an Adverse Event Data collection tool was used to track adverse events that occurred during POD use, including skin irritation, accidental extubation, or dislodged lines or tubes. The Cranial Measurement form was used to assess cranial measurements, head shape, and shift in ear alignment. Calipers were used to take cranial

	measurements at study enrollment and completion. CI, cranial symmetry, and head circumference were measured by 6 measurers. **Interventions:** The POD was designed to be used immediately after birth for ELBW preterm infants, in order to prevent DP. The POD has a concave-shaped foam, which helps to maintain the head and neck in an appropriate position and prevent forces on the infant's skull. There were several sizes foam inserts to be used with the POD to accommodate infants with weight 0.5-1.7 kg. Inserts could be exchanged as the infant grew, allowing for better fit. Infants could be positioned in supine, sidelying or prone while in the POD. The POD was recommended to be used for 24 hours per day, with the foam insert in place for 12 hours, while the infant was in supine or sidelying. The insert was removed in the patient was in prone position. Infants were repositioned at a minimum of 3-4 hours and skin assessments were performed during repositioning. Patients were discharged from the study when they reached 1.7 kg, thus outgrowing the POD. **Results:** *Feasibility:* On the Ease of Use Questionnaire, approximately 72-82% of nurses reported that the POD device was easy to fit and position the infant and did not interference with other medical devices and procedures. The POD was used for a median of 21.2 hours per day. The foam insert was in place for a median of 11.1 hours per day. *Safety:* There were no adverse events associated with the POD device that were reported during the study. All of the 10 participants had normal cranial symmetry at study enrollment and completion. At enrollment, 9 of the 10 participants had an abnormal CI. At study completion, 5 of the 10 participants had an abnormal CI. Of these 5, 2 were intubated and 2 were on traditional CPAP during the study. Additionally, 4 of the 5 had complex clinical courses, including pneumonia, necrotizing enterocolitis, renal failure, and other issues. **Limitations:** This study had a small sample size of 10 and used convenience sampling. Additionally, the amount of time that infants were held was not captured during this study, and therefore, the effects of being held could not be factored into the results. It was also noted by nurses that many of the infants outgrew the POD device before they were weaned from respiratory support, which limited the amount of time that the POD could be used. Because respiratory support is often associated with abnormal cranial molding, it would be beneficial for an orthotic device to be available until respiratory support is weaned. **Conclusion & Clinical Implications:** The POD device was found to be safe and feasible for use with ELBW preterm infants being treated in the NICU. The POD was also effective in maintaining a symmetrical head shape. There were also more infants with normal CI at the study completion, compared to study enrollment, indicating some effectiveness in

	improving CI. Additional studies with a larger sample size, and additional sizes of the POD are necessary to determine if the device is truly effective in preventing DP.
Effects of continued positioning pillow use until a corrected age of six months on cranial deformation and neurodevelopment in preterm infants: A prospective case-control study[9] **Uchio et al. 2020**	**Study Design:** Prospective case-control study **Study Aim:** The purpose of this study was to examine the effect of the continued of a specialized foam pillow until 6 months CA on DP and neurodevelopmental delay in preterm infants. **Subjects:** Infants recruited into the study were admitted to the NICU at Tokyo Women's Medical University Hospital between November 2018 and August 2019. Inclusion criteria was birth weight < 1800g, gestational age <37 weeks, and informed consent from the parent or legal guardian of the infant. Exclusion criteria were diagnosed chromosomal abnormalities, malformation syndromes, neurological disorders, diagnosed cerebral palsy, and the presence of cranial magnetic resonance imaging (MRI) abnormalities confirmed by a radiologist and neurological abnormalities diagnosed by a clinician. **Tests/Measures:** Cranial deformities were assessed at 2 time points: discharge and 6 months CA. Lateral plagiocephaly deformities were rated based on the Argenta scale, with a score of 1 to 5 (higher score indicated more severe deformity). Asymmetries in the occipital, temporal, frontal, and parietal regions and the facial bones were recorded. CI was also measured, using digital Vernier calipers. CI was calculated as anteroposterior diameter of the skull divided by biparietal diameter. At 6 months CA, neurodevelopment was assessed using the Bayley Scales of Infant Development III (BSID-III) and asymmetric motor performance was assessed using the asymmetric clinical scale (ACS). **Interventions:** The use of the Little Tree Memory Foam Baby pillow was first introduced for home use in April 2019. Therefore, the patients were divided into a non-pillow group (NP) (born between November 2019 and March 2019) and a pillow group (P) (born between April 2019 and August 2019). The pillow is made from cotton with a concave section in the center; the infant's head was placed with the external occipital protuberance in the concavity. Parents of the infants were instructed on proper use of the pillow at home for at least 8 hours overnight, until 6 months CA. In the event of increased vomiting or persistent crying, the parents were instructed to discontinue pillow use. **Results:** There were 25 infants identified who met the inclusion criteria. Of these, five were excluded due to chromosomal abnormalities, and one was excluded because informed consent was not received. Therefore, a total of 19 participants were included in the final analysis. There were 11 subjects in the P-group and 8 subjects in the NP-group. At the time of discharge, there were no differences in lateral plagiocephaly deformities and CI. At 6 months CA, the P-group had significantly lower classifications of lateral plagiocephaly deformities, compared to the NP-group (p=0.001).

	Additionally, the P-group had significantly higher BSID-III cognitive composite scores (p=0.02) and significantly higher fine motor scores (p=0.02), compared to the NP-group. The P-group also had significantly lower ACS scores than the NP-group (p=0.01), indicating decreased asymmetrical motor performance. **Limitations:** One major limitation of the study was the small sample size. Additionally, this study only evaluated cognitive, language, and motor developed at 6 months of age and does not capture long-term development. **Conclusion & Clinical Implications:** This study showed that the use of a pillow in preterm infants until 6 months CA was associated with prevention of DP, improved cognitive and fine motor scores on the BSID-III, and decreased asymmetrical motor performance. Typically, gel pillows and other devices are only used during hospitalization, as a method of preventing or reducing head deformities. This study demonstrates the efficacy of continued use of these devices after discharge.
Use of a Midliner Positioning System for Prevention of Dolichocephaly in Preterm Infants[10] **McCarty et al. 2018**	**Study Design:** Non-randomized prospective study **Study Aim:** The purpose of this study was to evaluate the effectiveness of the Tortle Midliner, a midliner positioning system (MPS) in preventing dolichocephaly. **Subjects:** This study cohort included 30 preterm infants who used the MPS. This study cohort (SC) was compared to 65 preterm infants from a previous retrospective study cohort (RSC), who were provided with positioning aids, such as moldable pillows at the discretion of nursing staff. Both cohorts received PT interventions 1-2 times per week and caregivers were educated regarding cranial molding, as part of standard care. Inclusion criteria was a birth weight of less than 1500g, a BGA less than 31 weeks (≤30 weeks 6 days), less than 3 weeks chronological at time of enrollment into the study, and stability on CPAP, nasal cannula, or room air. The exclusion criteria were genetic/chromosomal abnormality, congenital neuromuscular disorder, craniofacial abnormalities, congenital or posthemorrhagic hydrocephalus, and other diagnoses which might affect generalizability of the results. **Tests/Measures:** Ballert Orthopedic Cranial Calipers were used by 2 trained therapists to measure the CI of each infant's head. CI was calculated based on the ratio of biparietal diameter (BiPD) over occipitofrontal diameter (OFD). Dolichocephaly was defined as CI <76%. The normative change for CI is 76-85%. CI measures for the retrospective cohort were conducted at one time point between 32- and 34-weeks PMA. For the study cohort, CI measures collected at the beginning of the study period, and then weekly until the infant was 34 weeks PMA (the end of the study period). Additionally, demographic and comorbidity information was collected via retrospective chart review. The amount of time spent in supine positioning was recorded by nurses in a position log. Additionally, nursing staff completed a 10-question survey regarding the feasibility of the MPS in daily care.

	Interventions: The MPS consisted of a knit hat with 2 support rolls which maintained the infant's head in midline while in supine. Velcro attachments were used to maintain positioning of nasal cannula and feeding tubes. The MPS was used 24 hours per day, unless there were signs of skin irritation, discomfort, or instability, or the infant was receiving kangaroo care. If CI was found to be <76% (indicating dolichocephaly), positioning protocols were implemented to allow for cranial reshaping. **Results:** The demographics and comorbidities of the RSC and the SC were found to be similar. The mean values of CI for the RSC group between 32- and 34-weeks PMA and the final CI values between 32 anad 34 weeks CI for the SC group were significantly different (p=0.03), with a larger average CI in the SC. Furthermore, CI values at 32 weeks PMA (p=0.04) and 34 weeks PMA (p=0.03) were significantly greater in the SC group. A lower CI is indicative of more severe dolichocephaly. The SC group was found to have a lower incidence of dolichocephaly than the RSC group. In the RSC group, the mean baseline CI was 80%, while the mean CI at 32-34 weeks PMA was 77%; this was a significant decrease in CI over an average of 5.5 weeks (p<0.0001). Additionally, in the SC group, over an average of 5.7 weeks, the mean baseline CI and mean final CI were both 79%. Based on the results from the questionnaire, which was completed by nursing staff, the MPS was found to be compatible with nasal cannula, easy to adjust, and maintained infant skin integrity. **Limitations:** This study had a small sample size, which limits the generalizability of the results. Additionally, this study did not capture data regarding cranial asymmetry, such as the incidence of plagiocephaly. Therefore, it is unclear how the MPS affects the development or treatment of asymmetrical head deformities. **Conclusion & Clinical Implications:** The MPS was found to result in decreased cranial molding in the SC, compared to a group of infants who did not use the MPS. The MPS was found to be easy to use, and CIs in the SC group remained stable over the course of the study period, indicating the feasibility and efficacy of using such a device as a tool to prevent cranial molding deformities among preterm infants in the NICU.

Measurement of Head Deformities in Preterm Infants

Title/ Author/ Year	Study Details
Measuring for non-synostotic head deformities in preterm infants during NICU management: A pilot study	**Study Design:** Prospective cross-sectional cohort study (pilot study) **Study Aim:** The primary aim of this study was to identify a reliable method of measuring cranial shapes of infants born preterm (<34 weeks PMA), while they are in the NICU or SCN. The secondary aims were to obtain data on CI and CVAI for patients in the NICU or SCN and determine mean head measurement time for bed types and support systems in the hospital.

Willis et al. 2019[11]	**Subjects:** The study cohort included 68 subjects. Infants were recruited from a midwestern regional medical center from April 2017 to August 2018. Patients were eligible for inclusion if they were born <34 weeks. Infants were excluded if they were admitted with a diagnosis of craniofacial abnormalities. The cohort was organized into three groups based on birth PMA: extremely preterm (< 28 weeks); very preterm (28 to<32 weeks); and moderate preterm (32 to 34 weeks). **Tests/Measures:** Weekly head measures were conducted by a physical therapist and registered nurse on medically stable infants. One investigator held the infant in appropriate positioning, while observing that all respiratory supports and lines were in place and monitoring vital signs. A second investigator took the measurement, using an elastic band with pre-marked points and Ballert cranial calipers. A third investigator or bedside nurse recorded the cranial measurements. Head length (AP), head width (SD), and obliques (lines X and Y) were measured for each infant. CI was used to detect brachycephaly and dolichocephaly and calculated as the ratio of head width to length (AP/SD). Brachycephaly was defined as CI>90% and dolichocephaly was defined as CI <76%. CVAI was used to detect plagiocephaly and calculated as the ratio of longest oblique length (LOL) minus shortest oblique length (SOL) divided by LOL×100% ([LOL−SOL] / LOL×100%). Plagiocephaly was defined as a CVAI > 3.5%. Infant characteristics, including position, location, and position of the bed were collected at each measurement. Chart review of demographic and medical factors was also collected retrospectively. **Interventions:** Standard care, including bed location, bed type, positioning, feeding, respiratory support, and physical/occupational therapy were conducted based on the infant's need, at the discretion of the patient's nurses and physicians. There were no other interventions provided during this study. **Results:** *Inter-Rater Reliability:* There was a strong positive correlation between CI measurements (r=0.83) and moderate positive correlation between CVAI measurements (r=0.62). Additionally, there was moderate to good inter-rater reliability for CI and CVAI measurements. *Prevalence of non-synostotic head deformities:* At discharge (PMA = 35.5 ± 2.0 weeks), the prevalence of dolichocephaly and plagiocephaly were 82% and 35%, respectively. The prevalence of dolichocephaly or plagiocephaly was 94% and the prevalence of both dolichocephaly and plagiocephaly was 33%. *Specific Patient Factors:* There were no sex-differences for CI or CVAI at the time of discharge. The amount of time required for measurements was significantly longer for neonates in an isolette with a nasogastric tube (NGT) and mechanical ventilation (MV), compared to other bed types (ex. crib) and respiratory supports (nasal cannula or CPAP).

	There were mild adverse reactions recorded during 2.4% of measurements, including desaturation events and tachycardia. These events were documented as resolving within a few minutes. **Limitations:** This study had a small cohort size. Additionally, interventions (such as respiratory support, PT/OT services, and positioning) were not controlled, as they were provided at the discretion of the medical team, based on each patient's individual needs. Therefore, not every patient received each treatment, further limiting the generalizability of these results. **Conclusion & Clinical Implications:** This study demonstrated the feasibility of conducting head measurements for preterm infants in the NICU using calipers and an elastic band. Regardless of the bed type, presence of an NGT, and respiratory support type, measurements took an average of 1-2 minutes per infant. There was a high prevalence of dolichocephaly and plagiocephaly noted, which is in accordance with other studies.

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