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RESEARCH

Prevention of Deformational Plagiocephaly in Hospitalized Infants Using a New Orthotic Device

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ABSTRACT

Objective: To measure the feasibility, safety, and efficacy of the cranial cup device in a sample of hospitalized infants at risk for deformational plagiocephaly (DP).

Design: A multisite, stratified, and randomized single-blinded study.

Setting: Neonatal intensive care units (NICU) from three urban and one suburban hospital participated.

Participants: Subjects included 62 infants with lengths of stay ≥ 14 days.

Methods: Nurses caring for infants in study group 1 used the moldable positioner. In study group 2, nurses rotated the moldable positioner and cranial cup devices using the cranial cup for a target goal of 12 hours/day. Both study groups received routine position changes. Outcome measures included hours of device use (feasibility), cardiorespiratory and emesis events (safety), and cranial measurements obtained at discharge (efficacy) by one of four, licensed orthotists who were blinded to the study.

Results: A total of 35 infants were randomized to study group 1 (moldable positioner) and 27 infants to study group 2 (moldable positioner and cranial cup). The median hours per day on the cranial cup was 10.7 (range 4.5 – 15.3). Emesis and cardiorespiratory events were equally distributed for the moldable positioner and cranial cup devices in study group 2. At discharge, more infants in study group 1 (46%, $n = 16$) exhibited abnormal cranial measurements than those in study group 2 (19%, $n = 5$) ($p = .03$).

Conclusion: Rotating the cranial cup with the moldable positioner provides a feasible, safe, and potentially efficacious therapy for prevention of DP.

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Sick or premature infants spend more time in bed than healthy term newborns. The prolonged exposure of the hospitalized infant's head to the flat and often firm bed mattress can lead to deformational plagiocephaly (DP). This condition is characterized by a flattening of the head that results in an asymmetrical, elongated, narrowed, or widened head shape and may be accompanied by ear misalignment, frontal bossing, and facial asymmetry (Hummel & Fortado, 2005; Littlefield, 2003). Numerous researchers have described problems of parent/infant attachment and social isolation for infants with positional head shape deformities or DP (Alley, 1981; Badr Zahr & Abdallah, 2001; Hemingway & Oliver, 2000a; Ritter, Casey, & Langlois, 1991). Also concerning are reports linking DP to deficits in neurodevelopment (Constantin, Waters, Morielli, & Brouillette, 1999; Hunter & Malloy, 2002; Hutchison, 2009; Hutchison, Stewart, de Chalain, & Mitchell, 2010; Miller, Johnson, Duggan, & Behm, 2011; Robertson, 2011; Speltz et al., 2010).

Neonatal health care providers have implemented various interventions, including waterbed therapy, water-filled pillows, gel pillows, air-filled mattresses, foam mattresses, and repositioning procedures aimed at prevention of DP. However investigators have shown these interventions are not consistently successful in preventing DP (Cartlidge & Rutter, 1988; Chan, Kelley, & Khan, 1993; Hemingway & Oliver, 1991, 2000b; Hutchison et al., 2010; Marsden, 1980; Schultz et al., 2008; Schwirian, Eesley, & Cuellar, 1986).

The cranial cup is a sleep surface specifically designed to prevent or correct DP by supporting the infant's head and entire body in the supine and

semiside lying positions. In 2008, researchers in a nonrandomized prospective clinical trial found that an older and customized version of the cranial cup successfully corrected early positional head shape deformities in infants younger than age 4 months (Rogers, Miller, & Mulliken, 2008). Subsequently, the custom cranial cup was revised into a standardized device that can accommodate infants of various weights and lengths. In addition, a special scaled-down version has been developed specifically for use in the NICU. This newest model accommodates infants weighing between 1 and 2.5 kg.

Previous success in correcting mild positional head shape deformities in healthy infants with the cranial cup and the newly revised standardized cranial cup models supported testing in the NICU population (Seruya, Oh, Sauerhammer, Taylor, & Rogers, 2013). In this multisite, stratified, randomized, single-blinded study, we measured the feasibility, safety, and efficacy of the cranial cup device in a sample of hospitalized infants at risk for DP. The specific aims of this study were as follow:

1. Describe the feasibility of using the cranial cup for 12 hours per day on a sample of NICU infants.
2. Determine the safety of the cranial cup by comparing the incidence of cardiorespiratory (apnea, bradycardia, and oxygen desaturation) and emesis events for the subset of NICU infants rotating between the cranial cup and a traditional moldable positioner.
3. Compare the efficacy of rotating the cranial cup and moldable positioner device versus the moldable positioner alone on head shapes as measured by cranial index and cranial symmetry on a sample of NICU infants at hospital discharge.

Literature Review

Commonly observed forms of DP include brachycephaly, plagiocephaly, scaphocephaly, and dolichocephaly. Head shape deformities are further characterized as being unilateral or bilateral and are sometimes accompanied by ear misalignment, frontal bossing, and asymmetrical or distorted facies (Littlefield, 2003; Pollack, Losken, & Fasick, 1997). Risk factors for DP include restricted uterine environment, birth trauma, prematurity, lack of full bone mineralization, neurological deficits, torticollis or preferential head position when lying down, sedation, paralysis, multiple-birth infants, limited prone positioning, and the application of continuous positive airway pressure devices (Hemingway & Oliver, 1991; Hutchison, Thompson, & Mitchell, 2003; Ifflaender, Rudiger, Konstantelos, Wahls, & Burkhardt, 2013; Littlefield, Kelly, Pomatto, & Beals, 1999; van Vlimmeren et al., 2007). Hospitalized infants spend more time in their beds and have positioning restrictions due to their medical needs; therefore they are more vulnerable to developing DP.

Sick infants are more vulnerable to developing deformational plagiocephaly from spending more time in their beds and illness-associated positioning restrictions.

Deformational plagiocephaly has social and neurodevelopmental implications (Bialoskurski, Cox, & Hayes, 1999; Collett, Breiger, King, Cunningham, & Speltz, 2005; Miller & Clarren, 2000) and may interfere with parent/infant attachment due to the atypical appearance of the infant with DP. Most full-term healthy infants have round symmetrical head shapes. In contrast, many premature and sick term infants develop DP. Infants with DP exhibit asymmetrical, narrowed, or widened head shapes, sometimes accompanied by ear misalignment and distorted facial features. Due to these features, premature and sick infants do not look like full-term healthy infants and thus do not conform to parental expectations (Bialoskurski et al., 1999). Kelly, Vannostrand, Shiftlett, and Chan (1996) demonstrated this by asking mothers of preterm and term infants to rate pictures of premature infants with DP, premature infants without DP, and full-term infants. These investigators found that premature infants with DP were perceived to be less attractive than premature infants without DP and full-term infants (Kelley et al., 1996).

Even more concerning are the proposed neurodevelopmental implications of DP. In one retrospective study of 287 infants with DP, 36% of parents reported that their children had one or more developmental delays (Hutchison, 2009). However that study had significant limitations due to unknown birth data and medical histories of participants. In another study, researchers compared toddlers with and without positional head shape deformities, and toddlers with deformities scored lower than similar but unaffected peers using the Bayley Scales of Infant Development III (Collett et al., 2011). In 2002, Balan et al. demonstrated that depressed cortical sound processing was indicative of auditory processing dysfunction in

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