Evaluating the effectiveness of gel pillows for reducing bilateral head flattening in preterm infants: a randomized controlled pilot study

Alyce A. Schultz, RN, PhD, FAAN, Patricia A. Goodwin, RNC, Cynthia Jesseman, RN, NNP, Heidi G. Toews, RN, BSN, Megan Lane, RN, FNP-C, Christine Smith, RN, BSN

Abstract

This study evaluated the effectiveness of gel pillows for reducing bilateral head molding (plagiocephaly) in preterm infants, as determined by the cephalic index (CI). Eighty-one infants weighing <1,500 g were randomly assigned at birth to usual care on a standard mattress (n = 40) or to placement on a gel pillow (n = 41). The CI was measured with a digimatic caliper upon entry and weekly thereafter, until infants had been transferred or discharged. Repeated measures analysis of variance revealed no statistically significant differences in the CI between subjects upon entry, at 5 weeks postintervention, or at 10 weeks postintervention. The trend was toward less molding over time for smaller infants on gel pillows who were hospitalized longer; however, the sample size was too small to detect statistical significance.

1. Introduction

Survival rates for very low birth weight (VLBW) infants, defined as infants weighing <1,500 g at birth, continue to rise (Kenner, Lott, & Flandermeyer, 1997). In the 1990s, an alarming rise in the number of premature infants presenting with plagiocephaly without synostosis (i.e., head flattening without fusion of normally separate bones, due in part to head molding) has been reported by several craniofacial centers (Argenta, 2004; Najarian, 1999). This increasing incidence has been linked to the American Academy of Pediatrics’ (1996) recommendation regarding sleep positions (supine and side lying) to prevent sudden infant death syndrome and to the increase in the survival of VLBW infants (Argenta, 2004; Huang, Cheng, Lin, Liou, & Chen, 1995; Huang, Mouradian, Cohen, & Gruss, 1998; Moss, 1997). Although deformational bilateral head molding, which is generally caused by prenatal and postnatal positioning constraints, is less concerning developmentally than the more serious cranial molding with synostosis, it is noted more frequently in VLBW infants due to the disproportional weight of the head and weaker neck muscles (Baum & Searles, 1971a, 1971b). Although this outcome has been minimized with some success by repositioning, in very tiny infants with delayed motor development, the head may retain the abnormal shape for a much longer period, even into adulthood (Baum & Searles, 1971b; Shin & Pershing, 2003). Head molding has been identified as a contributor to the negative perception of the cuteness of infants by nonparents, parents, and caregivers (Alley, 1981; Budreau, 1989; Kelly, Vannostrand, Shiflett, & Chan, 1996), suggesting that these premature infants may be at greater risk for the negative physical and psychosocial effects of a dissociated bonding process and lack of caregiver attachment (Crowder & Hunter, 2004; Langlois, Ritter, Casey, & Sawin, 1995). Nurses in the neonatal intensive care unit (NICU) of a 606-bed tertiary care center perceived head molding in preterm infants as an undesirable outcome that might be reduced by a relatively simple intervention—the use of a gel pillow.
2. Literature review

Various craniocephalic measurements, including anteri-or–posterior (AP) diameter, biparietal (BP) diameter, occipitofrontal circumference (OFC), height of skull, posterior length of skull, distance between auditory meatus and nasal point, distance between auditory meatus and upper gum, and bizygomatic facial breadth, have been used to assess changes in skull formation during the first weeks of life (Cartlidge & Rutter, 1988; Chan, Kelley, & Khan, 1993; Hemingway & Oliver, 1991, 2000a, 2000b; Huang et al., 1995; Marsden, 1980; Schwirian, Eesley, & Cuellar, 1986). The most commonly reported measurement for comparison across studies is the cephalic index (CI), which is derived by dividing the AP diameter by the BP diameter (AP:BP). Greater bilateral head flattening is indicated by larger CIs, with ratios of $>1.40$ considered indicative of undesirable bilateral head molding (Chan, Kelly, & Khan, 1995).

Six studies (Table 1) that examined the effectiveness of various surfaces, pillows, or turning protocols designed to reduce bilateral head molding in preterm infants, as measured by the CI, were found (Cartlidge & Rutter, 1988; Chan et al., 1993; Hemingway & Oliver, 1991, 2000b; Marsden, 1980; Schwirian et al., 1986). Two studies published in the 1980s reported that water pillows were effective for reducing head molding in preterm infants (Marsden, 1980; Schwirian et al., 1986). Marsden reported that the use of a water pillow for 36 days was more effective than the use of a standard mattress for reducing head molding in preterm nonidentical female twins, with a CI of $1.39$ for the infant placed on the water pillow as compared to a CI of $1.49$ for the infant placed on the standard mattress. Cross-sectional examination of head measurements verified significant head flattening for the twin on the standard mattress. Although the turning schedule was not reported, the investigator attributed the difference in head molding to the use of the water pillow. The water pillow was also effective for reducing head molding in a small quasiexperimental study of 21 preterm infants of < 36 weeks’ gestation (Schwirian et al., 1986). Infants placed on water

Table 1
Comparison of interventions to standard mattresses

<table>
<thead>
<tr>
<th>Citation</th>
<th>Study design</th>
<th>Sample size</th>
<th>Length of study</th>
<th>Mean CI*</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water pillows</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Marsden (1980)</td>
<td>Randomized</td>
<td>One pair of nonidentical preterm twins</td>
<td>36 days</td>
<td>WP, 1.39; SM, 1.49</td>
<td>Turning not reported; Only two subjects; essentially a case–control study</td>
</tr>
<tr>
<td>Schwirian et al. (1986)</td>
<td>Quasiexperimental</td>
<td>21 Preterm infants aged $&lt;36$ weeks</td>
<td>Experiment: $M = 25.2$ days; control: $M = 23.2$ days</td>
<td>WP, 1.33; SM, 1.40</td>
<td>($p &lt; .0005$) Turning every 2 hours with experimental group 1 hour supine every 6 hours Data collector blinded to group Equivalent groups</td>
</tr>
<tr>
<td>Air-filled mattress</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cartlidge and Rutter (1988)</td>
<td>Quasiexperimental</td>
<td>34 Preterm infants aged 32 weeks</td>
<td>21 days</td>
<td>AFM, 1.40; SM, 1.47</td>
<td>($p &lt; .001$) No turning schedule reported Findings verified by pictures Equivalent groups</td>
</tr>
<tr>
<td>Water beds</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hemingway and Oliver (1991)</td>
<td>Experimental</td>
<td>84 Preterm infants aged $&lt;32$ weeks</td>
<td>Compared at 4 and 8 weeks</td>
<td>4 weeks: both groups $&gt;1.5$, ns; 8 weeks: both groups $&gt;1.4$, ns</td>
<td>Turned every 2 hours Data collectors blinded to group Terminated due to attrition Five infants at 11 weeks Equivalent groups</td>
</tr>
<tr>
<td>Foam pressure-relief mattress</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chan et al. (1993)</td>
<td>Experimental</td>
<td>144 Preterm infants aged $&lt;36$ weeks and weighing $&lt;1,500$ g</td>
<td>Compared at 2 and 7 weeks</td>
<td>2 weeks: both groups $&gt;1.40$, ns; 7 weeks: FPRM, 1.51; SM, 1.49, ns</td>
<td>Turned every 3–4 hours Attrition with only 63 infants on Week 7 Equivalent groups</td>
</tr>
<tr>
<td>Positioning protocol</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hemingway and Oliver (2000b)</td>
<td>Quasiexperimental</td>
<td>146 Preterm infants pre–post design</td>
<td>9 weeks: Phase 1: turned every 3 hours; Phase 2: turned every 3 hours to six positions, never repeating during the 8-hour period</td>
<td>PP, 1.30; SP, 1.42</td>
<td>($p = .05$) Attrition not reported Equivalency not reported</td>
</tr>
</tbody>
</table>

*NS = Not statistically significant.

* SM = standard mattress; WP = water pillow; AFM = air-filled mattress; FPRM = foam pressure relief mattress; PP = positioning protocol; SP = standard protocol.
pillows (mean CI = 1.33) experienced significantly less head molding ($P < .0005$) than infants placed on standard mattresses (mean CI = 1.40). In addition to a 2-hour turning protocol, infants on water pillows were also placed supine for 1 hour every 6 hours, with folded blankets used to align their torsos when placed on the pillows. One rater completed all head measurements and was blinded to the treatment group; all infants were placed on standard mattresses during data collection. Although a larger study of 40 subjects had been planned, the study was stopped at 21 subjects due to the visual and statistical success of the water pillow treatment.

Contrasting results were reported for three studies comparing the effectiveness of standard incubator mattresses to the effectiveness of other types of mattresses for reducing bilateral head molding (Cartlidge & Rutter, 1988; Chan et al., 1993; Hemingway & Oliver, 1991). In a small quasiexperimental study of 34 infants (< 32 weeks’ gestation), infants were alternately assigned to an air-filled mattress or to a standard mattress. At 3 weeks of age, infants on the air-filled mattress had significantly ($P < .001$) less bilateral head molding (mean CI = 1.40) than infants on the standard mattress (mean CI = 1.47); statistical findings were verified visually through an analysis of pictures. The investigators concluded that treatment with a safe, cheap, and simple air-filled mattress was effective for reducing head molding in preterm infants (Cartlidge & Rutter, 1988).

In a larger study, 84 preterm infants of < 32 weeks’ gestation were randomized to water beds or standard mattresses (Hemingway & Oliver, 1991). Cranial measurements remained statistically equivalent at 4 weeks for 71 infants (CI > 1.50) and at 8 weeks for 20 infants (CI < 1.40). An a priori power analysis supported a sample size of 100 infants to find a 20% difference between the groups. Based on interim analysis and substantial attrition of subjects by 8 weeks of treatment, the study was terminated with a sample of 84 infants; only 5 infants remained in the study at 11 weeks. The investigators concluded that the use of standard mattresses was equivalent to water bed therapy in the prevention of bilateral head molding.

In a later clinical trial, 144 preterm infants of < 36 weeks’ gestation and weighing <1,500 g were randomly assigned to placement on a foam pressure-relief mattress or to placement on a standard mattress (Chan et al., 1993). Head measurements remained equivalent from the start of the study to 7 weeks of treatment. By Week 2, the mean CI was > 1.40 for infants in both groups; by Week 7 of the study, only 66 infants remained in the study, with a mean CI of 1.51 for infants on the pressure-relief mattress and with a mean CI of 1.49 for infants on the standard mattress. Infants were lost to the study due to discharge, transfer, or a weight gain of 2,000 g. The researchers concluded that the pressure-relief mattress was not effective for reducing bilateral head molding. They suggested that more research was needed to test interventions effective for reducing head molding in preterm infants.

More recently, the effectiveness of a positioning protocol for reducing head molding was evaluated in 146 preterm infants in a multisite quasiexperimental study (Hemingway & Oliver, 2000b). In Phase 1, 73 infants were turned every 3 hours according to standard care; in Phase 2, 73 infants were placed in six positions and were never placed in the same position during an 8-hour period. At 9 weeks, there was a statistically significant difference in bilateral head measurements ($P = .05$), with a mean CI of 1.30 (range, 1.24–1.35) for infants receiving the positioning protocol and with a mean CI of 1.42 (range, 1.31–1.55) for infants receiving standard turning care. The researchers suggested that adherence to a positioning protocol reduces head molding in preterm infants.

Early studies suggest that water pillows and air-filled mattresses are effective for preventing undesirable bilateral head molding in preterm infants; however, no studies measuring the effectiveness of gel pillows, a newer product on the market, for reducing bilateral head molding have been found. The specific aim of this study was to evaluate the effectiveness of gel pillows for reducing bilateral head molding in preterm infants, as determined by the CI (AP:BP...
The hypothesis was that infants in the experimental group (on gel pillows) would demonstrate significantly less head molding over time than those in the control group (on standard mattresses) by 5 weeks postbirth. The 5-week period for finding statistically significant differences was based on the previous work and recommendation of Chan et al. (1993, 1995).

3. Framework of the study

The framework for determining the variables of interest for the study was developed based on the expertise of nurses in the NICU and based on literature review. The framework was divided into three factors: uncontrollable factors in utero (around the birth experience), therapeutic or care factors, and dependent or outcome variable. In utero factors included oligohydramnios and multiple births/in utero crowding (Dias & Klein, 1996; Moss, 1997). Birthing experience factors included type of delivery, birth weight, and gestational age (Baum & Searles, 1971b; Najarian, 1999). Therapeutic or care factors included repositioning, attention to restricting devices (i.e., ventilator, continuous positive airway pressure [CPAP], and eye shields during phototherapy), and type of mattress surface or pillow (Moss, 1997; Najarian, 1999; Pollack, Loseken, & Fasick, 1997). The dependent variable was defined as bilateral head molding ( plagiocephaly), as measured by the CI (Hemingway & Oliver, 2000a).

4. Methods

The study was conducted using a quasiexperimental design (Fig. 1). Approval by the Institutional Review Board included informed consent for randomization and head measurements until infants were discharged or until infants weighed 2,000 g. 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 pillow). The study was conducted in a tertiary level III NICU that averages more than 600 admissions annually.

4.1. Sample

Infants were potentially eligible for the study if they were ≤ 34 weeks of age and weighed ≤ 1,500 g. Exclusion criteria included hydrocephaly, microcephaly, cranial deformities, or central nervous system abnormalities. Informed consent was obtained for 87 infants; entry measurements were missed for 3 infants, and 3 infants died before entry. Thirty-six male infants and 45 female infants were ultimately randomized into the experimental group (gel pillows; n = 41) and the control group (standard mattress; n = 40). Seventy-seven percent of the subjects (62 of 81) were delivered by cesarean birth, with a mean gestational age of 28.3 weeks (standard deviation [SD] = 2.6; range, 22–34 weeks). The mean weight of the subjects was 1,024 g (SD = 293; range, 470–1,490 g). Fifty percent of infants weighted < 1,000 g upon entry into the study.

Based on findings and definitions from a previous study (Chan et al., 1993), a mean difference of 0.06 in the CI would represent a clinically significant difference; this difference would be evident after 5 weeks of the intervention. Using power analysis, a sample size of 29 in each group would have 80% power to detect a statistically significant (P < .05) mean difference of 0.06 in the CI between the groups, assuming a common SD of 0.08. For example, a difference in the CI between a Group 1 mean of 1.45 and a Group 2 mean of 1.39 would be statistically significant if CI results were normally distributed. A CI of > 1.40 would suggest undesirable head molding.

4.2. Procedure

All registered nurses in the NICU received education on the rights of subjects participating in research studies and information on the inclusion criteria to assist in identifying potential infants for the study. Information on the study protocol, documentation needed for the study, and data collection procedures was also covered.

Information about this study was introduced to the infants’ parents or legal guardians at the time of admission to the unit. Informed consent was obtained by one of the study investigators from the infants’ parents or legal guardians prior to 72 hours of life. Following informed consent, infants were randomly assigned to placement on the gel pillow (experimental group) or placement on the standard mattress. The nurse researcher, using a 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 had obtained the informed consent opened the sealed packets in numerical order. A green card was placed on the incubator to indicate that the infant was enrolled in the study. Parents and legal guardians were assured that all other care procedures for the infant, including repositioning, would not be altered during the study.
Two graduate nursing students were trained in the use of digital calipers to measure the infants’ heads. To establish interrater reliability (IRR), the two students simultaneously measured the heads of 10 premature infants. Using Spearman’s correlation, an IRR of 0.811 was obtained by the graduate students prior to the start of the study and was reestablished approximately halfway through the study. One additional graduate student, an experienced NICU nurse, also collected data for a portion of the subjects after she had attained an IRR of > 0.80 with other graduate assistants.

Infants in the experimental group were placed on the gel pillow as soon as consent had been obtained and at no later than 72 hours of life. The Gel-E Donut manufactured by Children’s Medical Ventures (Wallingford, CT) is 3/8 in. thick and 7 in. in diameter (Fig. 2). The pillow is a nontoxic carboxyvinyl bag filled with a combination of water and antibacterial agent. It is designed to reduce pressure while providing support. The pillow was placed under the mattress sheet at the head of the bed. The infants also had their torsos elevated to the level of the pillows with extra linen to prevent untoward curvature of the spine, neck flexion, and airway obstruction. Infants in the control group were placed on the standard foam core mattress, which is 2.5 cm thick and has a polyvinyl exterior.

All infants were repositioned at least every 3 hours based on the current repositioning standard (supine, side, prone, side), if tolerated. A nurse caregiver was responsible for documenting position changes on the flow sheet. If an infant could not maintain the positioning schedule due to instability, that information was also documented on the infant’s flow sheet, but the infant was allowed to remain in the study.

4.3. Measurements

The degree of head flattening was expressed as the AP:BP ratio or the CI. The AP and BP diameters were measured using a 6-in. digimatic caliper (700-113 MyCal Lite; Fig. 3) manufactured by Mitutoya (Suzhou, PR China; Fig. 4). The sharp tips of the caliper were covered with a flat lightweight aluminum paddle, which was designed and produced by a high school vocational arts student. The caliper setting remained at 0.0, with paddles. This electronic caliper has a range of 0–150 mm, with an accuracy of 0.2 mm. The measurement resolution is 0.1 mm. The OFC was measured in centimeters using a plastic cloth-covered measuring tape.

The AP diameter was measured by placing the caliper tips at the widest point on the midline of the head, from the glabella to the occipital prominence. The BP diameter was measured at the widest point on the sides of the head. The OFC was measured by placing a cloth-covered tape measure around the head at its largest circumference, from the occipital protuberance to the frontal bosses.

Baseline head measurements were taken upon entry into the study, but not later than 72 hours of life. Additional head measurements were taken every 7 days from the day of admission into the study to discharge or transfer. To enhance the credibility of the data, data collectors did not have access to previous head measurements at the time of subsequent head measurements. This technique reduced the natural tendency to attain head measurements similar to previous measurements.

Demographic information on gestational age, birth weight, gender, type of delivery, number of ventilator days, and general health was collected from charts. Repositioning documentation was collected from daily flow sheets. All data collection forms and signed consent forms were kept in a locked box, which was stored in the NICU X-ray room. The code to the box was available to research team members only.

5. Results

Infants in the two groups were equivalent for uncontrollable factors (i.e., type of delivery, birth weight, and gestational age). There was no statistically significant difference in gender between the two groups.

The CI upon entry into the study ranged from 1.12 to 1.52, with a mean CI of 1.313 and an SD of 0.085. Nine (11%) of the subjects had an entry CI of > 1.40, suggesting...
that some undesirable head molding was already present at birth. Two of nine infants were birthed vaginally; four of nine infants weighed >1,000 g. There was no statistically significant difference in the CI between the two groups upon entry into the study (gel pillows: mean CI = 1.30, SD = 0.073; standard mattress: mean CI = 1.32, SD = 0.094; t = –1.202, df = 79, P = .233). There was no statistically significant difference between the CI of infants weighing <1,000 g (CI = 1.31, SD = 0.080) and the CI of infants weighing >1,000 g (CI = 1.32, SD = 0.091) upon entry.

Infants in the two groups were also equivalent for therapeutic care interventions (i.e., days with eye shields during phototherapy, days on CPAP, days on a ventilator, and days meeting repositioning protocol). Ninety-seven percent of infants were placed under bililights (range, 1–34 days; M = 8.9 days, SD = 5.7). Seventy percent of infants were on CPAP (range, 1–46 days; M = 7.5 days, SD = 10.00, Mdn = 3 days). Seventy-seven of infants were on ventilators (range, 1–70 days; M = 16.6 days, SD = 21.3, Mdn = 4 days). The repositioning standard was defined as “met” if repositioning was documented six times during the day, with ≤3 hours between repositionings. Comparisons were made by the mean number of days per week that the repositioning standard was met. For example, on Week 2, the repositioning protocol for infants on the gel pillow was met for 4.1 days (SD = 1.9), as compared to 4.3 days (SD = 2.0) for infants on the standard mattress. Documentation of compliance with the repositioning protocol was not statistically different between the two groups over time.

The use of gel pillows did not significantly reduce the degree of bilateral head molding, as measured by the CI. By Week 5 of the study, which was the expected time frame for finding statistically significant differences, only 52 subjects remained. One infant was withdrawn from the study because the mother did not like the measuring procedure, and 28 additional subjects were either discharged, transferred to a hospital closer to their homes, or inadvertently dropped from the measurement schedule. There were no statistically significant differences in mean group weights between the subjects remaining in the study at 5 weeks. The mean birth weight of 52 subjects remaining in the study was 950 g (SD = 255; range, 520–1,047 g). Using repeated measures analysis of variance (RMANOVA), there were no statistically significant differences in the CI (P = .348) or OFC (P = .867) between the groups. The mean CI for subjects in the control group was 1.41 (SD = 0.085), as compared to the mean CI of 1.40 for subjects in the experimental group (SD = 0.066). Tests for homogeneity of variance and Mauchly sphericity for RMANOVA were performed.

Head measurements were continuously performed on the subjects who remained in the NICU or in the continuing care nursery longer than 5 weeks. By 10 weeks post-intervention, only 21 subjects remained in the measurement schedule. Nineteen of these infants were of extremely low birth weight (<1,000 g) upon entry into the study. There were no statistically significant differences in weight at birth between subjects in the two groups. At 10 weeks post-intervention, the mean weight of the subjects remaining in the study was 1,887 g (SD = 324 g; range, 1,250–2,680 g). Although the trend at 10 weeks was toward less head molding for subjects on gel pillows, the differences in the CI, as measured by RMANOVA, were not statistically significant (P = .119). As noted in Fig. 4, although not statistically significant, on Week 7, the degree of head molding began a downward trend for those infants placed on gel pillows. On Week 10, the CI for infants in the experimental group was 1.39 (SD = 0.061), as compared to 1.47 (SD = 0.085) for infants in the control group. Student’s t test results for this singular time revealed a statistically significant difference in the CI between the two 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, mean difference = –0.080, 95% confidence interval = –0.148, –0.012). Forty percent of the subjects in the gel-pillow group had a CI of >1.40, which is defined as undesirable bilateral head molding, as compared to 91% of the subjects with a CI of >1.40 in the standard-mattress group. Two infants in the standard-mattress group with CIs of 1.62 and 1.64 at 10 weeks were over the 2,000-g weight level and entered the study with CI >1.40.

When gestational age and birth weight were entered as covariates into the RMANOVA model, birth weight was a statistically significant covariate (P = .005) in the CI between the two groups. The difference in the CI between the two groups over time remained nonsignificant at P = .209. The difference in weight between the infants in the two groups on Week 10 was not significantly different.

As expected with normal growth and development, head circumference measurements gradually increased over time in both groups of infants. There was no statistically significant difference in head circumference over time between subjects in the two groups (Fig. 5).

6. Discussion

The use of gel pillows in premature infants in the first 5 weeks of life did not support the hypothesis that gel pillows significantly reduce the degree of bilateral head
molding, as measured by the CI. The findings do not support previously reported success in reducing bilateral head molding in preterm infants by placing them on air-filled mattresses or on water pillows for approximately 4–5 weeks (Cartlidge & Rutter, 1988; Marsden, 1980; Schwirian et al., 1986). These results are in accord, however, with previous studies where water beds and foam pressure-relief mattresses were used as interventions and no differences were found for their effects on reducing bilateral head molding (Hemingway & Oliver, 1991; Chan et al., 1995).

The trend toward less head molding in infants treated with gel pillows was suggested by smaller cephalic indices beginning at 7 weeks postintervention. At the time that this study was initiated, there have been no published studies on any intervention to reduce head molding that has continued beyond 8 weeks. In contrast, studies reporting significant reduction in bilateral head molding followed the infants for 3–5 weeks postintervention (Marsden, 1980; Schwirian et al., 1986). The continuous search for published studies testing interventions for reducing positional head molding yielded a reference to an abstract in a systematic review (Hemingway & Oliver, 2000a) suggesting that routine repositioning of preterm infants would significantly reduce head molding by 9 weeks of treatment. Because we had informed permission to continue head measurements until discharge, weekly measurements continued, but the sample size at 9–10 weeks became too small to demonstrate statistical significance. It became evident that an intervention to reduce undesirable bilateral head molding needs to extend past the time frame of 5 weeks, as previously reported in the literature (Marsden, 1980; Schwirian et al., 1986), and may be more successful in very small infants weighing <1,000 g at birth. With the increased survival of VLBW infants, the number of infants who are at risk for bilateral head molding also increases. The similarity in overall head circumference supports the notion that the differences found in CI measurements suggest a difference in the shape of the heads, not in the size of the heads.

6.1. Limitations

Several limitations were identified during the study. Obtaining an informed consent and enrollment into the study were limited to members of the research team. This procedure restricted potential enrollment to days that the study team members were available. Attrition due to discharge, transfer, and scheduling errors continued to reduce the sample size, resulting in a total sample of 52 by Week 5, the expected end date for the study. This resulted in a power of only 17% for statistical significance between groups, and a power of 15% for interaction effects. At 10 weeks, the power to detect a significant difference in the CI between the two groups was 34%, and that for interaction effects was 26%.

The blinding of research assistants to the study group of the subject was another limitation. At the start of the study, efforts were made to remove the subject from the gel pillow prior to the arrival of data collectors. Realistically, this became too cumbersome for nursing staff in the NICU to accommodate. The assistants did remain blinded to prior head measurements during each subsequent measurement, decreasing the tendency of prior measurements to bias subsequent measurements.

7. Implications for practice

This was the second nursing research study to have been conducted in this unit. Although the study was viewed as a very positive experience by the members of the research team, continuously supporting the staff in case finding and in maintaining the continuous use of gel pillows was sometimes challenging. Initiating conversations with parents about the study was also difficult for many of the staff nurses, and case finding became primarily a function of the research team members. There was a strong belief that the gel pillow would reduce the undesirable head molding and that it was not ethical to randomize this treatment. A member of the research team discovered that a few of the staff nurses were filling intravenous bags with liquid and were using them for infants in the control group. This practice was quickly stopped. Initially, the graduate students who were data collectors in the study met some resistance in the unit, but again, with support and education, the resistance diminished, the staff became...
much more helpful, and the study was viewed as a positive endeavor. Today, nurses in this NICU are much more interested in further research and are actively involved in Vermont Oxford quality initiatives.

Although the study was underpowered for statistical significance, based on clinical relevance and on the low cost of gel pillows, they are now used with infants of ≤ 30 weeks’ gestation, weighing <1,000 g, and/or who are unable to have their positions changed frequently. Gel pillows are replaced every 3 weeks, as they lose their buoyancy over time. For safety reasons, infants are never discharged with gel pillows. Parents are carefully counseled about the risk of placing infants in prone position and in the use of any pillow in the home environment.

In many infants, a visual difference in the shape of the head supported the clinical significance of the study (Fig. 6). The infant in the above picture received the gel pillow treatment, and the infant in the bottom picture did not receive the treatment.

Acknowledgment

This work was supported, in part, by Children’s Medical Ventures, which donated the gel pillows.

References


