Long-term outcomes in treatment of deformational plagiocephaly and brachycephaly using helmet therapy and repositioning: a longitudinal cohort study

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Received: 12 January 2015 / Accepted: 25 May 2015 © Springer-Verlag Berlin Heidelberg 2015

Abstract
Objectives Deformational plagiocephaly and/or brachycephaly (DPB) is a misshapen head presenting at birth or shortly thereafter, caused by extrinsic forces on an infant’s malleable cranium. There are two treatment methods available for DPB: helmeting and repositioning. Little is known about the long-term outcomes of these two treatment options. The purpose of this study was to examine children who received helmeting or repositioning therapy for DPB as infants and compare the long-term head shape outcomes of the two groups.

Methods A longitudinal cohort study design was used to evaluate change in head shape of the two groups. One hundred children (50 helmeted, 50 repositioned) were initially evaluated at 6 months or younger for DPB. Anthropometric skull measurements taken as infants before treatment were compared with measurements taken for this study. Inclusion criteria included initial clinic visit at age 6 months or younger, evaluation by the same practitioner, and current age 2–10 years. Cephalic index and cranial vault asymmetry were calculated based on caliper measurements.

Results Data from 100 children were evaluated for this study. Significant differences between the treatment groups in the mean change in cephalic index (p=0.003) and cranial vault asymmetry (p<0.001) were found; the children that used helmet therapy demonstrated greater improvement.

Conclusions This is one of the larger published long-term outcome studies comparing children that used helmets and repositioning to treat their DPB as infants. The data suggest that infants will have more improvement in head shape with a helmet than with repositioning.

Keywords Deformational plagiocephaly · Brachycephaly · Positional plagiocephaly · Non-synostotic plagiocephaly · Long-term outcomes · Plagiocephaly treatment

Introduction

The Safe to Sleep campaign, formerly known as the Back to Sleep campaign, was commenced in 1994 by the American Academy of Pediatrics [1]. The campaign recommended that infants sleep in the supine position in an effort to decrease the incidence of sudden infant death syndrome (SIDS) [1]. Since the recommendation of supine positioning, the prevalence of SIDS has decreased by approximately 50 % [1–4]. However, the occurrence of deformational plagiocephaly and/or brachycephaly (DPB) has increased to as high as 48 % of infants [5–12, 11, 13–15]. DPB is diagnosed at birth or shortly thereafter in children with an abnormal head shape caused by extrinsic forces on an infant’s malleable cranium [16, 17]. DPB presents with varying degrees of unilateral or bilateral occipital flattening and often ventral displacement of the ear, forehead, and cheek on the affected side [11, 18–20]. In addition to sleep position, there are many other risk factors that may contribute to the development of DPB. These include multiple births, primagravidity, restricted intrauterine environment,
assisted delivery, male gender, positional head preference, torticollis, developmental delays, or prematurity [15, 21–24].

There are two treatment options for DPB: helmenting or repositioning [9, 19, 25, 26]. For the purpose of this study, the following definitions were used. Helmenting consists of a custom-made, FDA-approved orthosis that fits over prominent areas of the head and redirects growth to flatter areas. Helmets are worn for a duration of 3 to 6 months and 22–23 h per day. Repositioning works by keeping the infant off of the flat side of the head and positioning on the opposite side. Parents are advised to decrease time in car seats, rockers, bouncers, and swings and increasing supervised tummy time. Parents receive detailed education on ways this can be achieved.

There are disagreements among pediatric health care providers as to whether head shape will normalize on its own over time and whether molding helmet treatment is even indicated [7, 11, 27]. In studies comparing helmet versus repositioning treatment for DPB, primarily short-term outcomes have been addressed [13, 19, 25, 28, 29]. With limited published data on the long-term outcomes of helmeting versus repositioning for the treatment of DPB, health care providers have little evidence-based research to guide parents in treatment decision making for DPB. There is a need to examine the differences in long-term symmetry of the skull among infants who have received cranial molding helmets versus repositioning for treatment of DPB. This research aims to fill the gap in the literature. These outcomes will provide guidance to health care providers as to advise their patients about DPB treatment.

Methods

Participants for this study were children evaluated for DPB at St. Louis Children’s Hospital in the Pediatric Plastic Surgery DPB Clinic between 2002 and 2010. All baseline and follow-up anthropometric head measurements were obtained by the same highly experienced provider. Inclusion criteria for this study were (1) child between 2 and 10 years of age and (2) baseline assessment performed in the St. Louis Children’s Hospital DPB clinic at 6 months of age or younger. Exclusions were the presence of any other craniofacial deformities, anomalies, syndromes, and initial diagnosis after age 6 months. The minimum age of 2 years was chosen because skull growth is approximately 85% complete at 2 years of age [30, 31].

After obtaining IRB approval from the Washington University Human Research Protection Office, a letter explaining this study was mailed to all potential participants (n=1660) meeting inclusion criteria. This letter invited parents to bring their child into the DPB clinic for additional anthropometric skull measurements. Parents who were interested in participating called in and scheduled a one time study visit (n=63). The remaining participants were randomly recruited by follow-up phone calls (n=37). The study recruiter was blinded to child’s intake measurement and only knew their treatment category. All parents/guardians signed an informed consent before having their child’s head measured. Recruitment was closed when 100 participants (50 helmeted and 50 repositioned) were enrolled. Parents were given a verbal and/or written copy of the results of the anthropometric measurements. In recognition of the participant’s time and transportation costs, each participant was provided a $25 gift card.

A longitudinal cohort design was used to compare the two study groups: one group who received helmenting (n=50) and one group that received repositioning (n=50) for the treatment of DPB. One hundred participants were needed to detect a difference (median effect size 0.5, 0.05 significance level, and power 0.8). Anthropometric measurements (cephalic index and cranial vault asymmetry) of the head were obtained and compared to each participant’s baseline measurements. Cephalic index (CI) is head width (side to side) divided by head length (front to back) multiplied by 100 [31]. Cranial vault asymmetry (CVA), the difference between diagonal measurements over the cranial vault or top of the head, was also used to assess head shape [32]. This was achieved by measuring from the frontozygomaticus (fz) (superoïtal orbital rim) to a point that is approximately 30° from the opisthocranion (op) on the opposite side (Fig. 1). For this study, normal parameters were set at 75–85% for CI and ≤4 mm for CVA.

Independent t tests were conducted to examine the differences in head shape between the two groups. Differences in baseline anthropometric measurements and long-term post-

![Fig 1 Anthropometric skull measurements (vertex view, nose up) anterior](https://www.researchgate.net/publication/277600400_Long-term_outcomes_in_treatment_of_deformational_plagiocephaly_and_brachycephaly_using_hello...
treatment measurements were examined. Analysis of covariance was used to assess longitudinal changes in CI and CVA at follow-up taking into account the severity of initial deformity. Statistical analysis was performed using SPSS version 20 (Armonk, NY. IBM Corp.).

Patients with torticollis were included in the overall analysis. In addition to the repositioning or helmet therapy to directly address DPB, all patients with torticollis were also given recommendations specifically to address their torticollis including neck range of motion exercises and referral to physical therapy.

Results

A total of 100 children were measured in the DPB clinic for this study. The same practitioner evaluated all 100 of these children in the DPB clinic at both the initial visit and at follow-up using high precision spreading GPM Swiss Made calipers (Zurich, Switzerland). Mean age at intake was 4.42 months for repositioned and 4.87 months for helmeted infants. Mean age at follow-up was also very similar in both groups, 4.43 years for repositioned and 4.66 years for helmeted. The average length of time in the helmet was 94 days (range 23 to 176). Gender was also equally distributed between the two groups. Twenty percent (n=20) of participants had torticollis. There was no missing data (Table 1).

Cephalic index

Differences in the two groups’ mean CI at baseline and follow-up were compared. Only participants that had measurements outside of the normal CI range of 75 to 85 % were included in the analysis (n=36 repositioned and n=37 helmeted) [30].

The head shapes of the helmeted group were slightly more brachycephalic at intake than the repositioned group, although there was no statistically significant difference in CI (p=0.122). Overall, improvements in CI were positively correlated with baseline CI (r=0.657, p<0.001). The improvement in CI due to the treatment was statistically significant (p=0.003, 95 % confidence interval for group difference=[0.7 %, 3.4 %]), accounting for the fact that the helmeted group started with slightly higher mean CI (Table 2).

Cranial vault asymmetry

Participants with baseline asymmetry of 5 mm or more were used in the analysis of CVA (n=41 repositioned and n=37 helmeted). There was a significant difference in CVA between the groups at intake. Overall improvement in CVA and CVA at intake were strongly correlated (r=0.748, p=0.001). The mean change in CVA was 3.32 mm for the repositioned group and 6.65 mm for the helmeted group. ANCOVA was performed to determine if the improvement in CVA was due to the effect of the treatment taking into account the differences in CVA at intake. The improvement in CVA was statistically significant due to the treatment (p=0.007, 95 % confidence interval for group difference [0.446, 2.674]) (Table 3).

Discussion

Background

Since the recommendation of supine sleeping, there has been a significant increase in the prevalence of DPB [10]. With this has come great debate on the most appropriate method of treatment. Helmeting and repositioning are the only two treatment choices for DPB [9, 19, 25, 26]. The helmet applies slight pressure over the prominent areas, limiting further growth in those areas while redirecting the growth to the flatter areas of the skull [11, 13]. Cranial molding helmets work well during the first year of life because the skull bones are very malleable and the cranium is expanding rapidly [12, 13, 26, 28]. Repositioning, laying the infant on the opposite side of the occipital flattening, is often recommended in infants younger than 4 months of age and as a first line of treatment [25, 33, 34]. Beyond 4 months, infants are often too mobile for this method to be fully effective [33]. The option of repositioning may also include other measures to limit pressure on the back of the head which can be more effective after 4 months of age.

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Characteristics of participants</th>
<th>Repositioned (n=50)</th>
<th>Helmeted (n=50)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age</td>
<td>4.42 (range 2.39 to 6.89) SD=1.12</td>
<td>4.87 (range 2.49 to 6.66) SD=1.06</td>
<td></td>
</tr>
<tr>
<td>Intake (months)</td>
<td>4.43 (range 2.07 to 7.59) SD=1.42</td>
<td>4.66 (range 2.11 to 7.92) SD=1.88</td>
<td></td>
</tr>
<tr>
<td>Follow-up (years)</td>
<td>Gender</td>
<td>Male</td>
<td>34/68 %</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>16/32 %</td>
<td>11/22 %</td>
</tr>
<tr>
<td>Torticollis</td>
<td>7</td>
<td>13</td>
<td></td>
</tr>
</tbody>
</table>
These include increasing supervised prone positioning while awake and decreasing time in infant carriers, swings, and bouncer seats [34].

The concept of using a helmet to treat DPB has been one of debate among pediatric health care providers. Some providers still see the use of cranial molding helmets as controversial, but those that use them state that the outcomes are superior to repositioning alone. This controversy has been well documented in the literature [9, 11]. In a review performed by Saeed et al. [11], it was found that many providers believe that DPB is self-limiting and helmenting is not necessary. Bruner et al. [35] reports that facial asymmetry that results from untreated DPB will persist into adulthood. Such differences of opinion make the decision to use a molding helmet or repositioning to treat DPB difficult for parents and health care providers.

Comparison with other studies

While there are a number of published studies about the treatment of DPB, there are very few publications that examine the long-term outcomes [26, 36, 37]. A review of the literature revealed only four studies that examined the long-term treatment outcomes of children with DPB [26, 36–38]. The first looked only at helmet therapy and found no statistically significant change in the shape of the head during the 5-year post-treatment period [26]. The second compared both groups (helmented and repositioned) and found a greater trend toward more symmetrical heads at age 5 years or older in those children who used cranial molding helmet therapy [37]. These first two studies had very small numbers of participants, \( n = 28 \) and \( n = 27 \) [26, 37]. The third study evaluated 129 children at 3 to 4 years of age that used repositioning therapy to treat their DPB. Of the 129 children evaluated, 39% had anthropometric skull measurements that were classified as abnormal [36]. In addition, the parameters used to define normal head measurements in this study had a much wider range than those used by most researchers making evaluation of the study results difficult.

The fourth study was the most rigorous. This was a randomized controlled trial in the Netherlands that followed children that used helmenting and repositioning until 24 months of age. A total of 79 children completed the study. The authors found that there was no difference in head shape between the two groups at 24 months of age. However, this study omitted patients that are more likely to benefit from helmet molding therapy, as they excluded children with torticollis and severe DPB [38]. Also of concern with this study is that 73% of parents with infants in the helmenting group reported problems with the fit of the helmet [38]. This would lend the opinion that the lack of improvement in the helmented group may have been due to ill-fitting orthosis.

Findings from the current study, as many others in the literature, show greater improvement in head shape with helmet therapy [6, 13, 25, 39, 40]. This research compares a large cohort \((n = 50\) helmented and \( n = 50\) repositioned\) with an average age at follow-up of approximately 4.5 years. Helmet therapy was found to produce a greater mean improvement in head shape with both CI and CVA.

Limitations

1. All data was collected from one craniofacial center and may not be generalizable to other populations.
2. This research is also limited by 2D caliper measurements of the head. Some research has shown that anthropometric measurements in digital form (i.e., CT scan or 3D photogrammetry) are more accurate than physical measurement [41, 42].

Strengths

The same researcher measured all of the children at both intake and follow-up. The same tool, high precision spreading GPM Swiss made calipers (Zurich, Switzerland), was used for all measurements, thus improving accuracy and reliability. All children that received helmets used the same orthotics company.

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**Table 2** Change in cephalic index\(^a\)

<table>
<thead>
<tr>
<th></th>
<th>Repositioned (( n = 36 ))</th>
<th>Helmeted (( n = 37 ))</th>
<th>( p ) Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean intake CI</td>
<td>90.3 %</td>
<td>92.7 %</td>
<td>0.122</td>
</tr>
<tr>
<td>Mean change in CI</td>
<td>4.9 %</td>
<td>7.8 %</td>
<td>0.001</td>
</tr>
<tr>
<td>Estimated marginal mean change(^*)</td>
<td>5.3 %</td>
<td>7.3 %</td>
<td>0.003</td>
</tr>
</tbody>
</table>

\(^a\) Only those outside of normal range of 75 to 85 %

\(^*\) CI was evaluated at 91.5 % in the (ANCOVA) model

**Table 3** Change in cranial vault asymmetry\(^a\)

<table>
<thead>
<tr>
<th></th>
<th>Repositioned (( n = 41 ))</th>
<th>Helmeted (( n = 37 ))</th>
<th>( p ) Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean CVA at intake(^a)</td>
<td>8.37</td>
<td>10.81</td>
<td>0.001</td>
</tr>
<tr>
<td>Mean change in CVA</td>
<td>3.32</td>
<td>6.65</td>
<td>0.000</td>
</tr>
<tr>
<td>Estimated marginal mean change(^*)</td>
<td>4.18</td>
<td>5.51</td>
<td>0.007</td>
</tr>
</tbody>
</table>

\(^a\) Only participants with 5 mm or more of asymmetry at baseline

\(^*\) CVA was evaluated at 9.53 mm in the (ANCOVA) model
Conclusion

It has been shown that infants have greater normalization in head shape when a helmet is used versus repositioning to treat DDH. This research adds to the body of literature that helmets produce a superior outcome to repositioning alone. Research-based findings and outcome studies are important for providers to make informed treatment recommendations to their patients and their families. The findings of this research will help guide clinical decision making.

Contributors
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Funding
This study was funded by grants from the National Association of Pediatric Nurse Practitioners (NAPNAP) Foundation and St. Louis Children's Hospital Foundation.

Conflict of interest
The authors declare that they have no conflict of interest.

Ethical approval
All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent
Informed consent was obtained from all individual participants included in the study.

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