Orthotic (helmet) therapy in the treatment of plagiocephaly

JO LING GOH, B.A.,1 DAVID F. BAUER, M.D.,2 SUSAN R. DURHAM, M.D.,2 AND MITCHELL A. STOTLAND, M.D.3

1Geisel School of Medicine, Hanover; and Departments of 2Neurosurgery and 3Plastic Surgery, Dartmouth-Hitchcock Medical Center, Lebanon, New Hampshire

Object. The goal of this study was to review the current literature on orthotic (helmet) therapy use in the treatment of deformational plagiocephaly.

Methods. PubMed was used to search English articles using the medical subject headings “deformational plagiocephaly” and “orthosis,” and “deformational plagiocephaly” and “helmet.”

Results. Forty-two articles were found. There were no Class I studies, 7 Class II studies, 1 Class III study, and 13 Class IV studies. Cranial orthoses have been shown to be effective in treating deformational plagiocephaly. It continues to be debated as to whether the statistical significance of treatment with cranial orthoses compared with conservative therapies is clinically significant. Children older than 12 months of age with deformational plagiocephaly may still benefit from orthotic therapy. The long-term effects of orthotic therapy are controversial.

Conclusions. There is a lack of Class I literature evidence supporting the use of helmet therapy in deformational plagiocephaly. There are controversies surrounding the use of orthotic therapy such as appropriate use, cost, use in older children, and long-term outcomes. Clinical indications for orthotic therapy need to be better defined with further research studies.

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Key Words • deformational plagiocephaly • cranial orthoses • helmet therapy

In 1992, the American Academy of Pediatrics Task Force recommended that infants be placed on their backs during sleep to reduce the risk of sudden infant death syndrome. Following this “Back to Sleep” recommendation, a significant drop in sudden infant death syndrome and an associated increase in the incidence of deformational plagiocephaly was noted,1,2,21,28 and the use of cranial orthoses have been commonplace for the treatment of deformational plagiocephaly.

Brief History of Orthotic Therapy

A cranial orthotic device is also referred to as a cranial helmet, cranial orthosis, or cranial band. These devices were first described in the scientific literature by Clarren et al. in 1979.4 However, the idea of using artificial cranial deformation was conceived at least 30,000 years ago in ancient Peru,2 where infant skulls were artificially shaped using external compression with fixed boards and pads2 or ritual head wrapping.25

Modern-day cranial orthotic devices use that same principle. They are usually custom fit and molded to allow for growth in certain regions of the cranium and concomitant growth restriction in others. Most helmets apply passive restriction rather than active compression forces,5,9,12,13 encouraging the infant’s malleable and rapidly expanding skull to grow into a desired configuration. There are helmets that reportedly apply active molding forces to aid in the corrections, such as the Dynamic Orthotic Cranioplasty Band (Cranial Technologies, Inc.) and the pneumatic orthotic helmet described by Lee et al.16 Some researchers argue that there is no true distinction between passive and active devices because the application of constant active pressure would easily exceed the ischemic tolerance of the overlying skin and lead to pressure ulceration.36

In the US, many cranial orthotic devices have been FDA regulated. There are currently 37 FDA-approved cranial orthoses listed on the FDA website (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm; Table 1). Of note, there has been some controversy surrounding the regulation of cranial orthoses. Many argue that FDA regulation helped standardize the industry,19 while others argue that it has caused an increase in treatment-associated costs due to centralized production of the orthoses by larger companies.32

Methods of Anthropometric Assessment

Cranial measurements have traditionally been ob-
TABLE 1: List of FDA-approved cranial orthotic devices*

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Company</th>
<th>Approval Date</th>
<th>FDA 510(K) No.</th>
</tr>
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<tr>
<td>Dynamic Orthotic Cranioplasty Band; Doc Band</td>
<td>Cranial Technologies, Inc.</td>
<td>5/29/1998</td>
<td>K964992</td>
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<td>Opi Band</td>
<td>Orthomerica Products, Inc.</td>
<td>7/7/2000</td>
<td>K001167</td>
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<tr>
<td>CranioCap</td>
<td>Gillette Children's Specialty Healthcare</td>
<td>10/30/2000</td>
<td>K000861</td>
</tr>
<tr>
<td>Hanger Cranial Band</td>
<td>Hanger Orthopedic Group, Inc.</td>
<td>12/8/2000</td>
<td>K001669</td>
</tr>
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<td>Cranial Molding Orthosis</td>
<td>Orthotic Solutions, Inc.</td>
<td>4/25/2001</td>
<td>K010273</td>
</tr>
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<td>Danmar Products Michigan Cranial Helmet</td>
<td>Danmar Products, Inc.</td>
<td>5/29/2001</td>
<td>K003630</td>
</tr>
<tr>
<td>Clarenne Helmet</td>
<td>Children's Hospital &amp; Medical Center</td>
<td>6/6/2001</td>
<td>K003035</td>
</tr>
<tr>
<td>Ballert Cranial Molding Helmet</td>
<td>Gema, Inc.</td>
<td>6/12/2001</td>
<td>K011433</td>
</tr>
<tr>
<td>RHS Helmet</td>
<td>Restorative Health Svs, Inc.</td>
<td>9/19/2001</td>
<td>K012007</td>
</tr>
<tr>
<td>Cranial Helmet</td>
<td>Children's Hospital</td>
<td>10/29/2001</td>
<td>K013458</td>
</tr>
<tr>
<td>Lerman &amp; Son Cranial Orthosis Helmet</td>
<td>Lerman &amp; Son</td>
<td>11/20/2001</td>
<td>K012830</td>
</tr>
<tr>
<td>Molded Cranial Helmet</td>
<td>Fairview Orthopedic Laboratory</td>
<td>11/28/2001</td>
<td>K012920</td>
</tr>
<tr>
<td>Plagiocephalic Applied Pressure Orthosis; P.A.P. Orthosis</td>
<td>Scott E Allen CP</td>
<td>1/17/2002</td>
<td>K012804</td>
</tr>
<tr>
<td>Orthosis Helmet Molding</td>
<td>Precision Prosthetics &amp; Orthotics, Inc.</td>
<td>2/5/2002</td>
<td>K013700</td>
</tr>
<tr>
<td>Becker Band Cranial Remolding Orthosis</td>
<td>Becker Orthopedic Appliance Co.</td>
<td>2/5/2002</td>
<td>K013719</td>
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<tr>
<td>Static Cranioplasty Orthosis</td>
<td>Eastern Cranial Affiliates</td>
<td>4/12/2002</td>
<td>K020448</td>
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<td>O&amp;P Cranial Molding Helmet</td>
<td>Orthotic &amp; Prosthetic Lab, Inc.</td>
<td>7/1/2002</td>
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<td>Cranial Symmetry System</td>
<td>Beverly Hills Prosthetics Orthotics, Inc.</td>
<td>9/9/2002</td>
<td>K022273</td>
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<td>Loma Linda University Medical Center (LIUMC) Cranial Remolding Helmet</td>
<td>Rehabilitation Institute Loma Linda University</td>
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<td>Providence Molding Helmet</td>
<td>Northeast Orthotics and Prosthetics, Inc.</td>
<td>7/18/2003</td>
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<td>Danmar Products Cranial Adjustive Prosthesis</td>
<td>Danmar Products, Inc.</td>
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<td>COPC Band</td>
<td>Center for Orthotic and Prosthetic Care, LLC</td>
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<td>Cranial Helmet</td>
<td>Otto Bock Health Care, LP</td>
<td>9/9/2004</td>
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<td>Doc Band-Postop</td>
<td>Cranial Technologies, Inc.</td>
<td>12/17/2004</td>
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<td>O&amp;P Bivalve Cranial Molding Helmet</td>
<td>Orthotic &amp; Prosthetic Lab, Inc.</td>
<td>12/22/2006</td>
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<tr>
<td>Cranial Solution Orthosis</td>
<td>Cranial Solutions</td>
<td>7/2/2007</td>
<td>K063133</td>
</tr>
<tr>
<td>CCRO (Craniocephalic Custom Remolding Orthosis)</td>
<td>Mike Miner</td>
<td>9/10/2007</td>
<td>K070694</td>
</tr>
<tr>
<td>Hanger Cranial Band</td>
<td>Hanger Prosthetics &amp; Orthotics, Inc.</td>
<td>1/9/2008</td>
<td>K072566</td>
</tr>
<tr>
<td>Boston-Band Cranial Remodling Orthosis</td>
<td>Boston Brace Intl., Inc.</td>
<td>1/22/2008</td>
<td>K072862</td>
</tr>
<tr>
<td>Starlight</td>
<td>Orthomerica Products, Inc.</td>
<td>9/12/2008</td>
<td>K081994</td>
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<td>Starlight</td>
<td>Orthomerica Products, Inc.</td>
<td>10/31/2008</td>
<td>K082945</td>
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<tr>
<td>Starband</td>
<td>Orthomerica Products, Inc.</td>
<td>12/5/2008</td>
<td>K082950</td>
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<tr>
<td>Camlab Cranial Orthosis Helmet</td>
<td>Biosculptor Corporation</td>
<td>1/27/2009</td>
<td>K081787</td>
</tr>
<tr>
<td>Michigan Cranial Reshaping Orthosis</td>
<td>Danmar Products, Inc.</td>
<td>1/6/2010</td>
<td>K090341</td>
</tr>
<tr>
<td>AOI Cranial Helmet</td>
<td>Advanced Orthopro, Inc.</td>
<td>4/18/2011</td>
<td>K103362</td>
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<td>Cranial Remolding Orthosis</td>
<td>Orthotic Care Services LLP</td>
<td>8/15/2011</td>
<td>K111247</td>
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<td>Boston Band</td>
<td>Boston Brace Intl., Inc.</td>
<td>8/22/2011</td>
<td>K111609</td>
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* All information taken directly from FDA website (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm).

Current Research on Helmet Therapy

The rise in prevalence of deformational plagiocephaly secondary to the “Back to Sleep” campaign has fueled a significant amount of research regarding the use of cranial orthotic devices as a means of correcting infantile cranial deformity. This paper focuses on the role of orthotic therapy in treating deformational plagiocephaly.

Methods

PubMed was used to search English articles with the following medical subject heading terms “deformational plagiocephaly” and “orthosis,” and “deformational plagiocephaly” and “helmet.” To judge the quality of the studies, the following classifications were used: Class I,
There were 7 Class II studies, 10,11,13,17,25,31,36 12 were reviews,7,8,22–24,29,30,32,34,38,40,42 2 were letters,3,18 and study,33

Treatments

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comparison group.

evidence from a prospective trial that compared more than 2 treatments in a nonrandomized manner; Class III,
evidence from a prospective or retrospective case series
with historical controls; and Class IV, evidence from a
prospective or retrospective case series with no control or
comparison group.

Results

Forty-two articles were found using the search terms
detailed above. Six articles were excluded because they
were not directly related to cranial orthoses therapy in
deformational plagiocephaly (n = 5), or involved nonhu-
man subjects (n = 1). Of the remaining 36 papers, 21 were
primary research literature articles,5,6,9–17,20,26,35–37,39,41
12 were reviews,7,8,22–24,29,30,32,34,38,40,42 2 were letters,3,18 and
1 described the methodology of an ongoing randomized
controlled trial.43 Of the 21 primary research articles,
there were 7 Class II studies,10,11,13,17,25,31,36 1 Class III
study,33 and 13 Class IV studies.5,6,9,12,14–16,20,26,35,37,39,41

Discussion

This review article focuses on the controversies that
exist in the use of orthotic therapy in deformational pla-
giocephaly.

Helmet Therapy in Comparison With Conservative
Treatments

There is a lack of Class I evidence surrounding the
use of helmet therapy in deformational plagiocephaly,
as has been noted in previous review articles.7,22,32 Never-
theless, the general consensus is that cranial orthoses
are indeed as efficacious, if not more efficacious, in treat-
ing deformational plagiocephaly as compared with other
more conservative treatments.22,23,32

Studies of helmet therapy often target patients who
have already undergone unsuccessful osteopathy and/or
physiotherapy as conservative measures.8 This experi-
ence consequently introduces a selection bias whereby

patients who have more severe deformational plagioce-
phaly are selected to take part in orthotic trials. It is uncer-
tain whether orthotic therapy is warranted to treat infants
with mild to moderate deformational plagiocephaly.6 Moss
prescribed only neck-stretching exercises, position-
ing changes, and parental training to 66 infants with de-
formational plagiocephaly of mild to moderate severity,
and found that the outcomes were comparable to infants
who were treated by headbands in a previous study.27

However, because the rate of correction is faster if infants
start using the helmets earlier,13,36 parents and providers
alike may feel the pressure to begin infants with mild to
moderate cases of deformational plagiocephaly on helmet
therapy to prevent long-term cosmetic issues.

The actual clinical significance of a change of a few
millimeters when using orthotic therapy compared with
repositioning therapy is also another issue of contention.
For example, Graham et al. compared repositioning with
orthotic therapy and showed that orthotic therapy resulted
in a 61% decrease in the reduction of diagonal differ-
cence compared with 52% in the repositioning group.10 While a
difference of 9% was statistically significant, the absolute
change was actually only 0.16 cm (or 1.6 mm). Similarly,
Lipira et al. showed in his 2010 prospective cohort study
that orthotic helmets yielded statistically superior redu-
ction in overall head asymmetry compared with active re-
positioning via a novel 3D surface scanning technique.17

However, this study also questioned the actual clinical
significance of these statistically significant values in
terms of quality of life, long-term outcomes, and parental
satisfaction. Interestingly, another study that was aimed
toward determining the optimal time to begin helmet
therapy noted that some parents requested to withdraw
prior to study aims being met, as they believed that the
asymmetry was already corrected.26

Two studies have attempted to address the issue of
clinical significance compared with statistical signifi-
cance by also incorporating measurements of parental
satisfaction into their research study. Both studies showed
that subjective assessments are often discordant with ob-
jective measurements.12,24 Katzel et al. measured both

TABLE 2: Methods of anthropometric assessment

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Definition</th>
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</thead>
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<tr>
<td>cranial width/breadth</td>
<td>greatest transverse diameter (maximum biparietal diameter) of the head, on a horizontal plane</td>
</tr>
<tr>
<td>cranial length</td>
<td>measured from the glabella (most prominent midpoint between eyebrows) to the opisthocranion (most prominent point on the occiput)</td>
</tr>
<tr>
<td>cephalic index/cephalic index</td>
<td>(cranial width / cranial length) × 100</td>
</tr>
<tr>
<td>occipital-frontal transcranial diameter</td>
<td>transverse cranial diameters measured obliquely from supraorbital rim directly above pupil, orbitale superius, to the occipital landmark directly posterior to the orbitale superius on the contralateral side</td>
</tr>
<tr>
<td>transdiagonal difference/transcranial diagonal difference</td>
<td>difference between the 2 occipital-frontal transcranial diameters</td>
</tr>
<tr>
<td>cranial vault asymmetry</td>
<td>distance between lt frontozygomatic point &amp; rt euryon point – distance between rt frontozygomatic point &amp; lt euryon point</td>
</tr>
<tr>
<td>cranial vault asymmetry index</td>
<td>(cranial vault asymmetry / shorter frontozygomatic-euryon distance) × 100; 0% = perfect symmetry, score &gt;3.5% = significant asymmetry</td>
</tr>
<tr>
<td>cranial base asymmetry</td>
<td>inion point to rt tragus point – inion point to lt tragus point</td>
</tr>
<tr>
<td>orbitotragal depth asymmetry</td>
<td>rt exocanthion point to rt tragus point – lt exocanthion point to lt tragus point</td>
</tr>
</tbody>
</table>

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head asymmetry and improvement in ear position following helmet therapy. They also asked parents to subjectively rate the improvements in both head asymmetry and ear position before and after therapy. Interestingly, the parents’ perceived improvement in ear position were particularly apparent when observed from the vantage point of the parent from above. In their study, 40% of babies with deformational plagiocephaly without initial ear shift showed subsequent increased ear shift after being treated with cranial orthoses. However, they found that subjective impressions of the babies’ ear positions as measured by ratings of medical doctors had a low concordance rate when compared with objective measures of ear shift.

The issue of clinical significance correlating with statistical significance is not a trivial one, as this could potentially affect the prevalence of use of cranial orthoses in deformational plagiocephaly. Ultimately, it is a cost-benefit analysis. These cranial orthotic devices cost anywhere from $1000 to $3500. Part of the high cost is secondary to the fact that the companies that make most devices pride themselves on custom-making the orthosis for the baby. However, Thompson et al. reported positive results in 2009 while using a generic-sized soft foam helmet that was fitted to patients by applying extra foam padding. In the current atmosphere of burgeoning health care costs, this may potentially be more cost-effective for the health care system as a whole.

**Are Cranial Orthoses Suitable for Children Older Than 1 Year of Age?**

Currently, most experts agree that starting cranial orthoses at 4 to 6 months of age is appropriate once more conservative measures have failed to correct the plagiocephaly. Kluba et al. in 2011 showed that patients who began helmet therapy prior to 6 months of age showed better relative and absolute reduction in head asymmetry when compared with patients who started after 6 months. They found that patients older than 6 months on average continued to have an abnormal cranial vault index at 4.5% at last follow-up. This suggests that a later starting age for helmet therapy may result in incomplete resolution of the asymmetry compared with beginning helmet therapy earlier. However, there have been published case reports in which infants older than 12 months of age were treated with dynamic orthotic cranioplasty with a reduction in cranial asymmetry.

More recently, in 2013 Seruya et al. investigated the correction rate of plagiocephaly with helmet therapy in groups of infants stratified by age. They showed that the correction rate decreases with increasing infant age and that the correction rate reached the plateau rate of change (transcranial difference rate of 0.42 mm/week) once the infants were older than 32 weeks (approximately 8 months). As such, it appears that cranial orthotic therapy continues to be warranted for older infants, but the rate of correction is slower and cranial asymmetry may not be absolutely corrected. In addition, many researchers have mentioned the logistical difficulty parents have in keeping their now more-active infant in a helmet for long periods of time per day, which may contribute toward the relatively slower rate of change documented in the literature.

**What Are the Long-Term Outcomes of Deformational Plagiocephaly Treated With Helmet Therapy?**

Two studies investigating the long-term follow-up of infants treated with helmet therapy were reviewed. It appears that in terms of the cranial asymmetry itself, infants treated with helmet therapy show relatively stable anthropometric measurements after discontinuation of helmet therapy. Lee et al. showed that 5 years after helmet therapy was discontinued, very little change happened in terms of cranial vault asymmetry values and orbitotragial depth asymmetry.

Another study reviewed quality of life and parental satisfaction in long-term follow-up after treatment of plagiocephaly and found that there was no difference in quality of life between a healthy control group and infants treated with helmet therapy at 2 years after their initial clinic visit. Steinbok et al. investigated patient quality of life and parental satisfaction in school-aged children who were treated early in life with helmet therapy. Residual asymmetry was noted by parents in 58% of respondents, with 21% expressing some concern, and only 7% of parents stating they were very concerned about the asymmetry. The children were less aware of their head asymmetry, with only 8% of children noting any asymmetry. In terms of social impact, only 5% of children reported having been teased about their head asymmetry.

**Promising Future Studies**

Many review papers have acknowledged the lack of randomized control trials in the deformational plagiocephaly study. However, van Wijk et al. are trying to correct this void in the literature with their current pragmatic randomized controlled trial nested in a cohort study. Participants are recruited at 2–4 months of age when first diagnosed with deformational plagiocephaly. At 5 months of age, they will be reassessed; if the plagiocephaly persists, parents are offered the opportunity to participate in a randomized controlled trial for helmet therapy compared with conservative treatment. Parents who decline to participate will then be part of a nonrandomized controlled trial and allowed to choose helmet or nonhelmet therapy. Participants will be followed at set intervals until 24 months of age. Their outcome measures will include anthropometric measures and assessments of satisfaction in parents. Final results of this trial are expected in 2013.

**Conclusions**

In this study we demonstrate a lack of Class I literature evidence supporting the use of helmet therapy in deformational plagiocephaly and address the issues of appropriate use, cost, use in older children, and long-term
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outcomes. Hopefully, as new research studies address these issues, the clinical indications for helmet therapy in deformational plagiocephaly will be better defined.

Disclosure

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

Author contributions to the study and manuscript preparation include the following. Conception and design: Bauer, Goh. Acquisition of data: Goh. Analysis and interpretation of data: Goh. Drafting the article: Goh. Critically revising the article: Goh, Durham. Approved the final version of the manuscript on behalf of all authors: Bauer. Administrative/technical/material support: Bauer, Durham.

References