Orthotic (helmet) therapy in the treatment of plagiocephaly

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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,^{1,21,28} 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*

Product Name	Company	Approval Date	FDA 510(K) No.
Dynamic Orthotic Cranioplasty Band; Doc Band	Cranial Technologies, Inc.	5/29/1998	K964992
Opi Band	Orthomerica Products, Inc.	7/7/2000	K001167
Craniocap	Gillette Children's Specialty Healthcare	10/30/2000	K000861
Hanger Cranial Band	Hanger Orthopedic Group, Inc.	12/8/2000	K001669
Cranial Molding Orthosis	Orthotic Solutions, Inc.	4/25/2001	K010273
Danmar Products Michigan Cranial Helmet	Danmar Products, Inc.	5/29/2001	K003630
Clarren Helmet	Children's Hospital & Medical Center	6/6/2001	K003035
Ballert Cranial Molding Helmet	Gema, Inc.	6/12/2001	K011433
RHS Helmet	Restorative Health Svs, Inc.	9/19/2001	K012007
Cranial Helmet	Children's Hospital	10/29/2001	K013458
Lerman & Son Cranial Orthosis Helmet	Lerman & Son	11/20/2001	K012830
Molded Cranial Helmet	Fairview Orthopedic Laboratory	11/28/2001	K012920
Plagiocephalic Applied Pressure Orthosis; P.A.P. Orthosis	Scott E Allen CP	1/17/2002	K012804
Orthosis Helmet Molding	Precision Prosthetics & Orthotics, Inc.	2/5/2002	K013700
Becker Band Cranial Remolding Orthosis	Becker Orthopedic Appliance Co.	2/5/2002	K013719
Static Cranioplasty Orthosis	Eastern Cranial Affiliates	4/12/2002	K020448
O&P Cranial Molding Helmet	Orthotic & Prosthetic Lab, Inc.	7/1/2002	K021221
Cranial Symmetry System	Beverly Hills Prosthetics Orthotics, Inc.	9/9/2002	K022273
Loma Linda University Medical Center (LIUMC) Cranial Remolding Helmet	Rehabilitation Institute Loma Linda University Med	1/13/2003	K023572
Providence Molding Helmet	Northeast Orthotics and Prothetics, Inc.	7/18/2003	K030669
Danmar Products Cranial Adjustive Prosthesis	Danmar Products, Inc.	10/31/2003	K013452
COPC Band	Center for Orthotic and Prosthetic Care, LLC	11/13/2003	K021594
Cranial Helmet	Otto Bock Health Care, LP	9/9/2004	K041215
Doc Band-Postop	Cranial Technologies, Inc.	12/17/2004	K042385
O&P Bivalve Cranial Molding Helmet	Orthotic & Prosthetic Lab, Inc.	12/22/2006	K063395
Cranial Solution Orthosis	Cranial Solutions	7/2/2007	K063133
CCRO (Craniocephalic Custom Remolding Orthosis)	Mike Miner	9/10/2007	K070694
Hanger Cranial Band	Hanger Prosthetics & Orthotics, Inc.	1/9/2008	K072566
Boston-Band Cranial Remodling Orthosis	Boston Brace Intl., Inc.	1/22/2008	K072862
Starlight	Orthomerica Products, Inc.	9/12/2008	K081994
Starlight	Orthomerica Products, Inc.	10/31/2008	K082945
Starband	Orthomerica Products, Inc.	12/5/2008	K082950
Camlab Cranial Orthosis Helmet	Biosculptor Corporation	1/27/2009	K081787
Michigan Cranial Reshaping Orthosis	Danmar Products, Inc.	1/6/2010	K090341
AOI Cranial Helmet	Advanced Orthopro, Inc.	4/18/2011	K103362
Cranial Remolding Orthosis	Orthotic Care Services LLP	8/15/2011	K111247
Boston Band	Boston Brace Intl., Inc.	8/22/2011	K111609

* All information taken directly from FDA website (<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>).

tained using anthropometric calipers. Recent technological advances such as photogrammetry^{25,35} or 3D surface scanning with a laser^{31,41} allow clinicians and researchers to use more accurate and efficient measurement.⁴¹ The common anthropometric measurements used are explained in Table 2.

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,

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TABLE 2: Methods of anthropometric assessment

Measurement	Definition
cranial width/breadth	greatest transverse diameter (maximum biparietal diameter) of the head, on a horizontal plane
cranial length	measured from the glabella (most prominent midpoint btwn eyebrows) to the opisthocranium (most prominent point on the occiput)
cephalic index/cranial index	(cranial width / cranial length) × 100
occipital-frontal transcranial diameter	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
transdiagonal difference/transcranial diagonal difference	difference btwn the 2 occipital-frontal transcranial diameters
cranial vault asymmetry	distance btwn lt frontozygomatic point & rt euryon point – distance btwn rt frontozygomatic point & lt euryon point
cranial vault asymmetry index	(cranial vault asymmetry / shorter frontozygomatic-euryon distance) × 100; 0% = perfect symmetry, score >3.5% = significant asymmetry
cranial base asymmetry	inion point to rt tragus point – inion point to lt tragus point
orbitotragal depth asymmetry	rt exocanthion point to rt tragus point – lt exocanthion point to lt tragus point

evidence from a randomized controlled trial; Class II, 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 nonhuman subjects (n = 1). Of the remaining 36 papers, 21 were primary research literature articles,^{5,6,9–17,20,25,26,31,33,35–37,39,41} 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 plagiocephaly.

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} Nevertheless, the general consensus is that cranial orthoses are indeed as efficacious, if not more efficacious, in treating 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.⁵ This experience consequently introduces a selection bias whereby

patients who have more severe deformational plagiocephaly are selected to take part in orthotic trials. It is uncertain whether orthotic therapy is warranted to treat infants with mild to moderate deformational plagiocephaly.²⁷ Moss prescribed only neck-stretching exercises, positioning changes, and parental training to 66 infants with deformational 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 difference 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 reduction in overall head asymmetry compared with active repositioning 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.³⁶

Two studies have attempted to address the issue of clinical significance compared with statistical significance by also incorporating measurements of parental satisfaction into their research study. Both studies showed that subjective assessments are often discordant with objective measurements.^{12,14} Katzel et al. measured both

head asymmetry and improvement in ear position following helmet therapy.¹² He 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 similar in magnitude to the changes in head shape, despite less impressive changes in actual ear offset.

The issue of ear position was made even more interesting in a study by Kluba et al.¹⁴ They observed that parents often noted ear shifts because they often have infants in their laps, and ear displacements 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 \$3500.²³ 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.⁴¹ 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.¹³ 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.²⁰

More recently, in 2013 Seruya et al. investigated the correction rate of plagiocephaly with helmet therapy in groups of infants stratified by age.³⁶ 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.^{15,39} 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.¹⁵

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.⁹ Steinbok et al.³⁹ 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.^{7,22,32} 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.⁴³ 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.

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