Helmet Treatment of Deformational Plagiocephaly: Systematic Reviews of the Literature and their Findings

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Objectives: *The objectives of this investigation were to review and summarize the currently available research on cranial helmet treatment of plagiocephaly, with special emphasis on systematic reviews of the literature.* ***Methods:*** *An electronic database of all articles published on plagiocephaly has been maintained since 1996. Additional searches of PubMed, Cochrane, and Google Scholar were preformed to identify any missing English language articles. The database was filtered to identify articles specifically reporting on helmet treatment, including literature reviews.* ***Results:*** *A total of 29 cranial helmet studies, and 7 seven systematic reviews of the literature were identified. The 29 helmet studies included 22 single arm case series, and seven cohort studies. While all seven systematic reviews identified the lack of Class 1, RCT trials and recommended that further research is needed, all concluded that helmets are effective and play a critical role in the treatment of plagiocephaly. The studies also concluded that age is an important factor to treatment success; with the younger the infant begins treatment, the better the outcome and the shorter the treatment duration.* ***Conclusions:*** *All seven systematic reviews of the literature concluded that helmets are effective in the treatment of deformational plagiocephaly, and are indicated for moderate-to-severe deformities, or for plagiocephaly that has not responded to conservative intervention.*

Over the past two decades, hundreds of articles have been written on the subject of deformational plagiocephaly. The majority have focused on the differential diagnosis from craniosynostosis, etiology, or identifying the risk factors that may predispose an infant to this condition. A smaller subset focus on various treatment options and recommendations ranging from conservative intervention (repositioning and physical therapy) to surgery in the most severe cases.

The existing literature on cranial orthotic treatment began with the 1979 publication by Sterling Clarren introducing the concept of the 'molding helmet'. Since that time, countless institutions have provided this treatment for their patients and reported their findings in the literature. However, comparing the results from studies of various designs, sample sizes, treatment protocols, and methods for reporting treatment outcomes can be a daunting task.

Fortunately, a number of independent systematic reviews of the literature have been performed which help to distill the key findings of these articles into recommendations based on the quality and methodological soundness of the evidence. Systematic reviews represent the highest caliber of evidence available, considered even more reliable than randomized control trials, due to their objectivity, independence and inclusion of all available research on a given subject. (Figure 1)

The purpose of this investigation was to identify all English language, peer-reviewed articles discussing helmet treatment of deformational plagiocephaly, as well as review and present the conclusions of any systematic reviews that have been performed on this body of evidence.

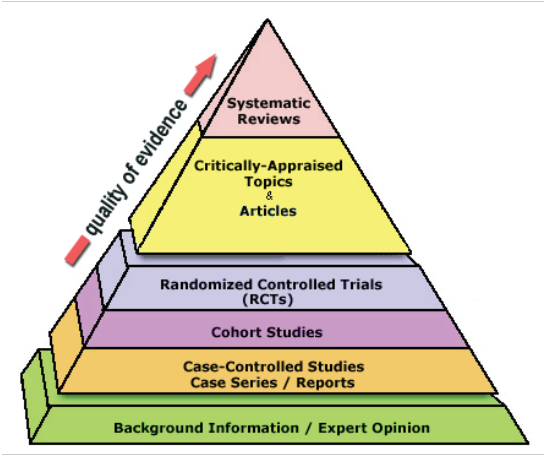

Figure 1: Evidence-Based Pyramid

(From: Sackett DL, Straus SE, Richardson WS, et al. Evidence-based medicine: how to practice and teach EBM. 2nd ed. Edinburgh: Churchill Livingstone, 2000.)

Methods

An electronic library of articles written on the subject of plagiocephaly has been maintained since 1996. In 2000 an ACCESS database was created to allow the identification and filtering of this library by keywords, author, subject, year, and journal. To date, there are 273 original research articles, literature reviews, policy statements, case studies, book chapters, consensus statements, meeting proceedings and editorials in this library. This library does not include items such as unpublished works, abstracts, magazine/newspaper articles, patents, reimbursement, or marketing/promotional materials.

Additional searches were performed for the key words 'cranial helmet, cranial orthosis, plagiocephaly, flat head syndrome, cranial molding, brachycephaly, scaphocephaly, and dolichocephaly' in PubMed, Cochran, and Google Scholar to identify any relevant articles for inclusion to the database. Reference reviews of published articles were also performed. After removing duplicates, thirty-six additional articles were added to the database (n=309).

The database was then filtered to identify all articles reporting on the use of a cranial helmet for treatment of deformational plagiocephaly. These articles had to be original research, but may have been as a case report, single arm study, dual arm study, prospective, retrospective, randomized or non-randomized. Articles which appeared to be either a subset or re-publication of previous data were excluded. Literature reviews were also identified

Results

A total of 29 cranial helmet studies (1979-2013), and 11 literature reviews (1997-2013) were identified. The 29 helmet studies included 22 single arm case series, and seven cohort studies. No randomized control studies were found. The 11 literature reviews included 7 systematic reviews, and four narrative reviews. The narrative reviews were excluded from further consideration.

While all seven systematic reviews performed between 1997 and 2013 identified the lack of Class 1, RCT trials and recommended that further research is needed, all drew nearly the same conclusions from the literature. These include:

1) Both conservative therapy (repositioning & physical therapy), and helmet therapy play a role in the treatment of deformational plagiocephaly.

2) Repositioning and physical therapy should be considered for mild deformities and for infants less than 4-5 months of age.

3) Infants with moderate to severe plagiocephaly, and for those whose deformity does not respond to conservative therapy, are best treated with a cranial helmet.

4) When compared as a Cohort, helmets appear to provide a quicker and superior outcome than conservative intervention.

5) Age is an important factor to treatment success; the younger the infant begins helmet treatment, the better and quicker the results will be.

Discussion

The 29 helmet studies included as part of the systematic reviews present a solid body of evidence supporting both the efficacy and medical necessity of treatment with a cranial orthosis. Of great importance is the objective, balanced assessment evident in these reviews. Not a single review suggested that there was a conclusive, 'one-size fits-all' recommendation. Rather, as advocated by the American Academy of Pediatrics (AAP), the appropriate course of treatment depends upon both the age and severity of the deformity. For younger infants, less than 4-5 months of age, conservative intervention including repositioning, physical therapy, and limiting time in devices of convenience should be the first line of defense. However, for infants whose deformity is moderate-to-severe (regardless of age), and for infants who have failed to respond to conservative intervention, a cranial orthosis should be considered.

Some nearly unanimous recommendations were identified in the literature. First is that surgery is rarely, if ever, required for these patients and is reserved for only the most severe cases that have failed all other types of intervention. Second, is the importance of treating congenital muscular torticollis, which historically has been the number one risk factor for plagiocephaly affecting roughly 85%-95% of this population. Although not discussed in detail, 'treatment' is more than just sending the infant to a physical therapist several times a week, but consists of a very regimented home neck exercise program that must be performed at a minimum with every diaper change. Neck exercises do not stop if/when an infant enters treatment with a cranial orthosis. The cranial orthosis works by applying corrective forces, and if torticollis is present, it is working against and minimizing the effectiveness of these devices. Lastly, is that age is a very critical variable in the successful management of this condition – both in terms of early identification and conservative intervention, as well as making a decisive decision to implement helmet therapy if/when the infant is not responding to conservative therapy.

Systematic Review Articles

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3 Xia JJ *et al. Nonsurgical Treatment of Deformational Plagiocephaly: A Systematic Review.* ARCH PEDIATR ADOLESC MED 2008; 162(8): 719-727

4 McGarry A, *et al*. *Head Shape Measurement Standards and Cranial Orthoses in the treatment of infants with deformational plagiocephaly.* DEV MED & CHILD NEURO 2008, 50: 568-576

5 Robinson SR, Proctor M. *Diagnosis and Management of Deformational Plagiocephaly.* J NEUROSURG PEDIATRICS 2009; 3:284-295

6 Flannery AB, Looman WS, Kemper K. *Evidence Based Care of the Child with Deformational Plagiocephaly.* J PED HEALTH CARE 2012, 26(5): 320-331

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3 Pattisapu JV et al. *Use of Helmets for Positional Molding.* CONCEPTS PEDIATR NEUROSURG 1989; 9: 178-184

4 Ripley CE et al. *Treatment of Positional Plagiocephaly with Dynamic Orthotic Cranioplasty.* J CRANIOFAC SURG 1994; 5(3):150-159.

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[14] Teichgraeber JT et al. *Deformational Plagiocephaly: Diagnosis and Treatment..* CLEFT PALATE CRANIOFAC J 2002; 39(6): 582-586

[15] Bruner TW et al. *Objective Outcome Analysis of Soft Shell Helmet Therapy in the Treatment of Deformational Plagiocephaly* J CRANIOFAC SURG 2004; 15(4): 643-650

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Conclusions Quotes (from Systematic Reviews):

"In patients with moderate-to-severe degrees of OP, helmet or band therapy may improve the observed and measureable asymmetry that persists despite mechanical (e.g. repo) intervention. The earlier the helmet or band is applied, the quicker and more complete will be the correction." Pg 29 [1]

"A consistent finding *was that counterpositioning ± physiotherapy or helmet therapy may reduce skull deformity." Pg 563* [2]

"Several metrics (entrance age, severity) biased success towards the repositioning groups, but just the opposite was observed. In helmet groups infants were older and the severity was greater, but still got faster and better results." "The studies showed considerable evidence that molding therapy may reduce skull asymmetry more effectively than repositioning therapy." *Pg 725* [3]

"Clinical studies investigating the use of cranial orthosis in the treatment of infants with deformational plagiocephaly reported beneficial effects in the reduction of facial and cranial asymmetry. These highlight the importance of early identification of deformational plagiocephaly to allow orthotic treatment to begin at 5 to 6 months of age, as the evidence suggests improved results". Pg 573 [4]

"Despite lack of Class I evidence, cranio orthosis are routinely and effectively used to treat persistent severe deformational plagiocephaly." "Mild deformity can be treated with repositioning and physical therapy protocols; and severe deformity is likely to be corrected more quickly and effectively with cranial orthosis than with repositioning and physical therapy." Pg 284 [5]

"There is general consensus that repositioning therapy is preferred over helmet therapy in patients younger than 4 months and in those who have mild or moderate asymmetry; helmet therapy may be appropriate for infants 6 months or older or for infants with severe asymmetry regardless of age." Pg 327 [6]

"The benefits of the orthosis have been under-estimated by several biases in some studies. Yet there seems to be a trend in favor of a greater efficacy of the correction of asymmetry by cranial orthosis than by repositioning programs. This was particularly clear in the case of severe posterior positional plagiocephaly where the orthosis could correct better and faster." Pg 236.[7]

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