This executive summary provides a review of recent published evidence that clinicians may use when conversing with peers, referral sources, and the families of current and prospective patients about the effectiveness of **remolding helmets**.

Executive Summary

Re: 2014 Dutch Randomized Controlled Trial on management of plagiocephaly

A recent publication in the British Medical Journal (BMJ) reported on the only randomized controlled trial of the management of plagiocepahly with cranial remolding orthoses. The study concluded that the efficacy of remolding helmets was consistent with that observed in children who received no intervention. Further, given the high prevalence of side effects and the costs associated with helmet therapy it was discouraged among infants with moderate to severe skull deformation.[1]

In addition to the publication of this trial within the medical literature, the New York Times, who leveraged the article to portray the sentiment that helmets were ineffective in managing plagiocephaly.

Fortunately, there is an abundance of published literature that contradicts the findings suggested by the BMJ publication and the New York Times article. This paper will summarize some of the more recent supportive literature to provide clinicians with published evidence that can be used in conversations with peers, referral sources, and the families of current and prospective patients.

The Dutch Study

84 infants were enrolled in the study and randomized to a helmet treatment group (n=42) or a non-intervention control group (n=42). Although only 30 of the 42 infants (71%) randomized to the treatment group received helmets, all were included in the collective results of the "helmet" group. Cranial symmetry was evaluated at baseline (5-6 months of age) and at 2 years of age.

The authors reported "full recovery" in 10/39 infants in the "helmet" group (26%) and 9/40 infants in the control group (23%). Of note, 22 of the 30 infants who received helmets reported problems with the fitting (73%), inclusive of the helmet rotating or shifting a few times a week to several times a day. In one case, the parents reported that the helmet came off spontaneously. In addition, 96% of the infants who received a helmet experienced skin irritation.[1]

Alternate Literature

In her 2013 systematic literature review, Paquereau reviewed 11 cohort studies and 6 literature reviews published between 1997 - 2010. The author summarizes her findings as follows: "Many biases have been identified, most of with time, favoring the repositioning groups," (i.e., infants receiving helmets tend to be older with more severe plagiocephaly than those managed with repositioning alone). However, "several different orthotics seem to correct head deformities better and faster than repositioning protocols."[2]

Cohort studies published since 2010 further confirm the efficacy of helmet treatment.

Kluba et al reported upon a cohort of 128 infants, 62 of which received and helmet and 66 of which did not. Treatment was initiated at 6 months of age with follow up at 10 months among the helmet group and an average of 18 months among the control group to allow more time for natural correction of the head shapes. Thus the length of treatment for the non-helmet group was three times longer, on average than that experienced by those in the helmet group. The authors conclude: "All infants showed a significant reduction of their plagiocephaly. Although children with helmet had more severe asymmetry initially, they showed significantly better improvement (68% vs 31%)…Despite concerns against helmet therapy (comfort, finances), it should be the treatment of choice for moderate to severe cases. Only mild cases can be adequately treated by conservative, i.e., non-helmet, management."[3]

In a conference proceeding, Sestokas et al reported upon a cohort of 4,378 patients treated between 2004 and 2010. "Complete correction" was defined as a cephalic index below 0.85 and a diagonal difference (cranial vault asymmetry) of less than 5 mm. Of the 3,381 infants initially treated with repositioning and/or PT, 23% failed management (16% required a helmet and 7% experienced incomplete correction). Of the 1,531 patients who received helmets (997 initially assigned and 534 who failed conservative management), 95% achieved complete correction.[4]

In their trial of 108 cases, Yoo et al reported an average initial cranial vault asymmetry of 16 mm that reduced to an average final cranial vault asymmetry of 4.7 over an average treatment time of 6.5 months. The greatest improvements were observed among those children than began helmet therapy at a younger age and among those presenting with more severe plagiocephaly.[5]

In a smaller trial of 27 subjects, 21 of whom received helmet therapy, Kim et al reported that the average cranial vault asymmetry for the helmet group decreased from 15 mm to 7 mm. By contrast, the average cranial vault asymmetry for the control group (conservative repositioning) decreased from 14 mm to 12 mm. Treatment times for both groups was approximately 4 months.[6]

Summary Conclusions

While the Dutch study is unique as a prospective randomized controlled trial, its findings must be compared against a number of different studies, published within the past 20 years in which the trials were not randomized but the biases present favored conservative management strategies (i.e., repositioning). In these trials, infants receiving helmet treatment were generally older with more severe plagiocephaly and experienced better outcomes than the control cohorts in spite of these biases.

The unique findings of the Dutch trial suggest that, in spite of a rigorously designed study methodology, the prevalent treatment standards, inclusive of frequent skin irritation and poor fittings resulted in a poor outcome for the small cohort of children managed with cranial remolding orthoses.

This summary is intended to educate practicing cranial orthotists with regard to the abundant literature that continues to support the use of cranial remolding orthoses in the management of plagiocephaly.

References

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