

Nonsurgical Treatment of Deformational Plagiocephaly

A Systematic Review

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Objective: To evaluate and summarize the evidence comparing nonsurgical therapies in the treatment of infants with deformational plagiocephaly.

Data Sources: Scientific articles and abstracts published in English between January 1978 and August 2007 were searched from 5 online literature databases, along with a manual search of conference proceedings.

Study Selection: Studies were selected and appraised for methodological quality by 2 reviewers independently using a Critical Appraisal Skills Programme form (cohort criteria).

Interventions: Molding helmet therapy vs head repositioning therapy.

Main Outcome Measure: Success rate of the treatment.

Results: A total of 3793 references were retrieved. There were no randomized controlled trials. Only 7 cohort stud-

ies met the inclusion criteria. Five of the 7 studies presented evidence that molding therapy is more effective than repositioning, even with the biases favoring the repositioning groups. In the molding groups, the asymmetry was more severe and the infants were older. The infants who failed to respond to repositioning therapy were also switched to molding therapy. The treatment outcomes from the other 2 studies were difficult to assess because of flaws in their study design. Finally, the relative improvement of using molding therapy was calculated from one study. It was about 1.3 times greater than with repositioning therapy.

Conclusion: The studies showed considerable evidence that molding therapy may reduce skull asymmetry more effectively than repositioning therapy. However, definitive conclusions on the relative effectiveness of these treatments were tempered by potential biases in these studies. Further research is warranted.

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THE AMERICAN ACADEMY OF Pediatrics in 1992 recommended that infants be placed on their back to sleep to reduce the risk of sudden infant death syndrome.¹ Since that time, while the incidence of sudden infant death syndrome has decreased, there has been a concomitant increase in the incidence of deformational plagiocephaly.²⁻⁸ Prior to 1992, the incidence of the deformity was estimated at 1 in 300 infants.⁹ Current estimates are as high as 16% to 48% of typical healthy infants younger than 1 year, depending on the sensitivity of the criteria used to make the diagnosis.^{2,10,11}

Plagiocephaly is a general term used for patients with cranial asymmetry. Deformational plagiocephaly occurs in infants subject to intrauterine constraint and is perpetuated by postnatal positioning.^{2,4} There are 2 main types of deformational plagiocephaly: posterior deformational plagio-

cephaly and deformational brachycephaly.^{3,8} The current treatment modalities for deformational plagiocephaly include observation and head repositioning,^{9,12} helmet therapy,^{3,5,13-15} surgery, or any combination. Head repositioning therapy is usually performed by the parents. The purpose of head repositioning therapy is to position the infant's head on the nonflattened side. It also involves increased tummy time and physiotherapy if torticollis is involved. Molding helmet therapy, sometimes referred to as molding therapy or helmet therapy, uses a soft-shell helmet to reshape the deformed skull to a normal shape without restricting the cranial growth.¹⁶ Helmets made by different companies have the same principle and similar design. Finally, surgery is almost never warranted for deformational plagiocephaly, except in a very rare instance when the deformities are severe and resistant to nonsurgical treatment.^{5,10} At present, controversy persists regarding the ap-

appropriate indications for head repositioning vs molding therapy in the treatment of infants with deformational plagiocephaly.

The 1997 Skull Molding Symposium¹⁷ was called to develop a consensus regarding the management of deformational plagiocephaly. Unfortunately, a consensus was not reached because of a lack of information regarding the natural history of plagiocephaly and the evidence regarding the effectiveness of various treatments. The argument has continued unresolved over the last decade. Therefore, the purpose of this systematic review is to address this issue: Which is the more effective non-surgical therapy (repositioning or molding helmet therapy) in the treatment of infants with deformational plagiocephaly, taking into consideration the severity of plagiocephaly and the age on entering treatment?

METHODS

The protocol for this systematic review was prospectively designed to define study objectives, search strategy, study selection criteria, and methods for determining study eligibility based on patient populations of interest and outcomes of interest, methods for assessment of study quality, data to be abstracted, and methods for abstraction.

SEARCH STRATEGY

The search strategy was designed to follow the guidelines of the Cochrane Handbook for Systemic Review of Intervention.¹⁸ The term *deformational plagiocephaly* has not always been consistent. This is especially true in the studies published prior to 1997. *Craniosynostosis* was sometimes also referred to as deformational plagiocephaly. Because of the inconsistencies and changes in terms, we searched for articles using the following text words in their titles, abstracts, or keyword lists: plagiocephaly, lambdoid, synostosis, craniosynostosis, cranial suture, positional molding, skull molding, flat head syndrome, and deformational skull deformity.

The Cochrane Library was initially searched to determine whether a systematic review on the treatment of deformational plagiocephaly had been recently completed. There was none. The MEDLINE databases were then searched from January 1978 through August 2007 using the earlier-mentioned searching text words. The Medical Subject Headings (MeSH) term *plagiocephaly, nonsynostotic* (introduced in 2005) was also used. Moreover, the following databases were also searched electronically: ISI Web of Science, ScienceDirect, and Journals@Ovid. Finally, a manual search of the conference proceedings for nonsurgical treatment for deformational plagiocephaly was also conducted. The proceedings included conferences of the American Cleft Palate–Craniofacial Association, craniofacial surgery, neurosurgery, and prosthetics and orthotics.

SELECTION CRITERIA

Randomized controlled trials (RCTs) are considered the gold standard for addressing questions regarding therapeutic efficacy. Unfortunately, there were no RCT studies on the treatment of deformational plagiocephaly. Therefore, inclusion was limited to cohort studies. The following selection criteria were used:

1. The infants had deformational plagiocephaly with or without torticollis.

2. The infants were otherwise healthy without underlying conditions that may alter the natural course of deformational plagiocephaly. These conditions include craniosynostosis; congenital craniofacial deformities, such as Treacher Collins syndrome; and genetic conditions, such as Down syndrome.

3. The infants were never treated prior to the study enrollment.

4. The studies were designed to compare the effectiveness of 2 nonsurgical treatments: molding therapy and head repositioning.

METHODS FOR APPRAISAL AND GRADING METHODS

Included studies were selected and appraised for methodological quality by 2 reviewers (J.J.X. and J.F.T.) independently. A Critical Appraisal Skills Programme (CASP) critical review form (cohort criteria)¹⁹ was used to assess each selected study. The critical review for each study was divided into 3 major questions: Are the results of the study valid? What are the results? Will the results help me locally? Finally, the magnitude of benefit was assessed. The magnitude of effect in individual studies was given by a point estimate surrounded by a confidence interval.

RESULTS

SELECTION OF THE STUDIES

Total retrieval was 3793 references. Among these, 11 cohort studies, including 9 full-length journal articles^{5,6,13,20-25} and 2 conference abstracts,^{26,27} met the selection criteria based on relevance. After initial review, one article was excluded because it did not provide enough information on how the cohort was assembled for repositioning or molding therapy.⁶ The authors only noted that 51 patients were included in the study, with older ones receiving molding and younger ones receiving repositioning, but did not give the number of infants for each group. Two articles^{22,25} in different journals in the same year with the same author, institution, patient sample, and treatment period appeared to be very similar. Therefore, only the more recent one²² was included. One conference abstract²⁷ was excluded because it was published later as a full-length journal article.²⁰ The other conference abstract²⁶ was excluded because it did not provide enough information on how the cohort was assembled and how the measurements were performed. Therefore, a total of 7 full-length studies^{5,13,20-24} were included for critical review (**Table 1**). The results of the studies are summarized in **Table 2**.

QUALITY OF EVIDENCE

Based on the CASP form,¹⁹ the overall quality of evidence for each of the 7 studies was initially assessed. As mentioned earlier, there was no RCT. All selected studies used a cohort study design to compare the effectiveness between molding therapy and repositioning therapy. Although this is a more robust study design than case series, considerable biases still exist. All selected studies were interpreted with caution using CASP criteria for cohort studies.

Table 1. Summary of Critical Review

1. Are the Results of the Study Valid?							
Source	Study Design (Cohort)	Did the Study Address a Clearly Focused Issue?	Did the Authors Use an Appropriate Method to Answer Their Question?	Was the Cohort Recruited in an Acceptable Way?	Was the Exposure Accurately Measured to Minimize Potential Selection Bias?	Was the Outcome Accurately Measured to Minimize Bias?	Have the Authors Identified All Important Confounding Factors? List the Ones You Think Might Be Important That the Authors Missed.
Clarren, ¹³ 1981	Prospective	Yes	Yes	Yes. Patients were offered both treatments. Infants older than 18 mo were excluded in the study.	No. Three patients were treated partially because 1 developed dermatitis and the parents of 2 other infants did not like the treatment modality.	Yes. Both objective anthropometric measurements and subjective assessment were used.	Yes, partially. The author identified that age of the infants at the beginning of the treatment was an important confounder. The severity of the plagiocephaly was not identified.
Graham et al, ²⁰ 2005	Retrospective	Yes	Yes	Yes. Physicians offered and parents elected the method of the treatment. For infants older than 6 mo with more severe deformity, molding therapy was recommended. For infants 4 mo or younger, repositioning was recommended. For infants between 4-6 mo of age, both treatments were offered.	No. The deformity in the molding group was more severe than in the repositioning group.	Yes. Only objective anthropometric measurements were used.	Yes. The authors identified both confounders.
Loveday and de Chalais, ²¹ 2001	Prospective	Yes	Yes	Yes. Infants were divided into molding and repositioning groups. However, no detailed information on how treatment was chosen.	No. The deformity in the molding group was slightly more severe than in the repositioning group. Some patients (no detailed numbers were presented) in the molding group were initially managed by repositioning and failed to show improvement.	Yes. Only objective anthropometric measurements were used.	Yes. The authors identified both confounders.
Moss, ²² 1997	Prospective for repositioning group and comparing with historical molding group (Ripley et al, ¹⁵ 1994)	Yes	Yes	No. There were 2 cohorts. A prospective cohort for repositioning therapy was compared with a retrospective cohort for molding therapy.	No. One patient did not show improvement and was subsequently treated with a headband. Six infants with mild to moderate asymmetry were treated with a headband and were excluded.	No. The measurement in the prospective cohort cannot be compared with the measurements in the historical cohort.	Yes, partially. The author identified severity of the deformity as a confounder (cranial vault asymmetry, < 12 mm vs > 12 mm).
Mulliken et al, ⁵ 1999	Prospective	Yes	Yes	No. Physicians offered and parents elected the method of the treatment.	Yes. Although the cohort was assembled based on physician's offer and parent's elected method, the 2 groups were very similar for the important variables, including age and the severity of the deformity.	Yes. Only objective anthropometric measurements were used.	Yes, partially. The authors identified age of the infants at the beginning of the treatment. The severity of the plagiocephaly was not mentioned.
Pollack et al, ²³ 1997	Prospective	Yes	Yes	No. The entire cohort (69 infants) was assembled for repositioning therapy. After 2-3 mo of treatment, the deformity did not improve in 34 infants, who were then given molding therapy.	No. Repositioning therapy failed in the infants in the molding group.	Yes. Only subjective visual assessment by physicians and parents.	Yes, partially. The authors identified age of the infants at the beginning of the treatment (< 6 mo vs > 6 mo). The severity of the plagiocephaly was not mentioned.
Vles et al, ²⁴ 2000	Prospective	Yes	Yes	Yes. Parents were offered both treatment methods.	No. The deformity in the molding group was more severe.	Yes. Only subjective assessment by visual analog scale score (0 = severely abnormal, 10 = normal).	Yes. The authors identified both confounders.

(continued)

Table 1. Summary of Critical Review (cont)

Source	1. Are the Results of the Study Valid?		2. What Are the Results?		3. Will the Results Help Me Locally?	
	Have They Taken Account Confounding Factors in the Design and/or Analysis?	Was Follow-up Sufficiently Long and Complete?	What Are the Results of This Study?	Do You Believe the Results?	Can the Results be Applied to the Location Population?	Do the Results of This Study Fit With Other Available Evidence?
Clarren, ¹³ 1981	No. Infants younger than 5 mo (2 infants) and older than 18 mo (3 infants) were excluded.	Follow-up measurement was completed at the end of the treatment.	See Table 2.	Yes	Yes	Yes
Graham et al, ²⁰ 2005	No. Infants in the repositioning group who showed no improvement at 7.4 mo were switched to molding therapy. Infants in the molding group were divided into subgroups of younger than 8 mo and 8 mo and older.	Follow-up measurement was completed at the end of the treatment.	See Table 2.	Yes	Yes	Yes
Loveday and de Chalain, ²¹ 2001	No. The confounder of severity of deformity was addressed by dividing deformity into plagiocephaly with and without brachycephaly. The age confounder was addressed by dividing infants at the age of 8.3 mo into 2 groups.	Follow-up measurement was completed at the end of the treatment.	See Table 2.	Cannot tell because of very different length between 2 treatments. Follow-up should be completed at the same age.	Yes	Yes
Moss, ²² 1997	No. The cohort included the infants with mild to moderate deformity.	Follow-up measurement was completed at the end of the treatment.	See Table 2.	Cannot tell	Yes	Cannot tell
Mulliken et al, ⁵ 1999	Yes, partially. The average age of the infants at the beginning of the treatment was comparable in both groups.	Follow-up measurement was completed at the end of the treatment. However, only 71% in the molding therapy group and 27% in the repositioning therapy group were followed up, without a reason being given by the authors.	See Table 2.	Yes	Yes	Yes
Pollack et al, ²³ 1997	No. The 5 infants with significant residual deformity were older than 6 mo at the initial repositioning therapy.	Follow-up measurement was completed at the end of the treatment.	See Table 2.	Yes	Yes	Yes
Vles et al, ²⁴ 2000	No. The severity of the deformity was considered for selecting the therapy. The deformity in the molding group was statistically significantly severe (4.2 vs 4.7). In addition, all the treatment was started before age 10 mo.	Follow-up measurement was completed at the end of the treatment.	See Table 2.	Yes	Yes	Yes

Was the Cohort Recruited in an Acceptable Way?

All the cohorts in the 7 studies were assembled with consecutive infants who had deformational plagiocephaly diagnosed. In 6 studies,^{5,20-24} the infants were treated with either molding therapy or repositioning therapy with or without physiotherapy or neck stretching. It was not clear whether Clarren¹³ used repositioning therapy or active sternocleidomastoid muscle stretching exercises or simply observed the infants in the nonmolding group.

In 3 studies,^{5,20,24} the allocation of the treatment groups was based on physician recommendation or parental preference depending on the age and the severity of the asymmetry prior to the initiation of treatment. In the Moss study,²²

infants with mild to moderate asymmetry were treated with repositioning therapy and compared with a historical cohort treated with molding therapy¹³ in the same institution. In the Clarren study,¹³ the physician offered molding therapy to all patients, but 10 declined. In the Pollack et al study,²³ all the infants were given repositioning therapy. After 2 to 3 months of treatment, if the asymmetry did not improve, the infants were then given molding therapy. In the Loveday and de Chalain study,²¹ no detailed information was given on how the physicians made their treatment recommendations. Finally, in 3 studies,^{20,21,23} a number of infants who had no improvement after initial repositioning therapy were crossed over to the modeling group. In all these studies, the bias seemed to favor the repositioning therapy group.

Table 2. Summary of Results

Source	No. in Molding Therapy (Group A)	No. in Repositioning Group (With or Without Physiotherapy) (Group B)	Age at Treatment Start, mo, Mean	Treatment Length, mo, Mean	Magnitude of Net Benefit of Intervention ^a	P Value ^b	RR (95% CI) ^c	Efficacy (95% CI) ^d	NNT (95% CI)
Clarren, ¹³ 1981	28	10; Parents declined molding therapy. Active sternomastoid muscle stretching exercises were applied.	A: 5.5 (range, 4-10) B: Comparable age, provided means	A: 5.3 B: Comparable length, provided means	A. Effective in 19 infants, noneffective in 9. B. Effective in zero infants, noneffective in 10.	.001	14.793 (0.974-224.568)	0.627 (0.416-0.838)	2 (1-2)
Graham et al, ²⁰ 2005	159	176 with physiotherapy.	A: 6.6 (SD, 1.7) B: 4.8 (SD, 1.7)	A: 4.2 (SD, 2.2) B: 3.5 (SD, 3.5)	A. Effective in 122 infants, noneffective in 9. B. Effective in 139 infants, noneffective in 37. In anthropometric measurements, the reduction of cranial diagonal differences in the helmet group (including 37 infants crossed over from repositioning group) was 0.71 cm, statistically significantly larger than in the repositioning group (0.55 cm).	<.001	1.264 (1.170-1.365)	0.208 (0.147-0.269)	5 (4-7)
Loveday and de Chalain, ²¹ 2001	29	45; Physiotherapy was not mentioned.	A: 8.5 B: 8.8	A: 5.1 B: 14.7	Both treatments were effective and anthropometric improvements were comparable. However, the length of treatment in the repositioning group (14.7 mo) was 3 times longer than the molding group. In addition, the molding group contained a number of the infants whose previous repositioning therapy failed.				
Moss, ²² 1997	66	46 with neck-stretching exercises	A: 5.9 B: 6.4	A: 4.3 B: 4.5	The head symmetry of the infants was improved by using repositioning therapy in 65 of 66 infants with mild to moderate deformity. However, because of the different definition of the anthropometric measurements between 2 studies, the results between repositioning therapy from this cohort and molding therapy from the historical cohort could not be compared.				

(continued)

Was the Exposure Accurately Measured to Minimize Bias?

In all 7 studies, repositioning therapy and physiotherapy were described briefly but did not contain information about what specific techniques were used. In 3 studies,^{20,22,23} physiotherapy was given during repositioning therapy. However, the indication for the physiotherapy for infants with associated torticollis was only given in the Pollack et al study.²³

Was the Outcome Accurately Measured to Minimize Bias?

The outcomes were measured either subjectively^{23,24} or objectively^{5,21,22} in 5 studies. Only the Clarren¹³ and the Graham et al²⁰ studies included both subjective and objective measurements. In addition, the masking of outcome assessment was not mentioned in any of the studies. Moreover, in the Mulliken et al study,³ the anthropometric measurements were not performed in the whole cohort. Only

Table 2. Summary of Results (cont)

Source, Year	No. in Molding Therapy (Group A)	No. in Repositioning Group (With or Without Physiotherapy) (Group B)	Age at Treatment Start, mo, Mean	Treatment Length, mo, Mean	Magnitude of Net Benefit of Intervention ^a	P Value ^b	RR (95% CI) ^c	Efficacy (95% CI) ^d	NNT (95% CI)
Mulliken et al, ⁵ 1999	51 (only 36 with measurements)	63 (only 17 with measurements); physiotherapy was not mentioned.	A: 5.4 B: 5.6	A: 4.6 B: 4.8	Both treatments were effective. Using anthropometric measurement, the improvement in the molding group was statistically significantly greater.				
Pollack et al, ²³ 1997	34 (had previous treatment with group B therapy fail)	69 (35 with this therapy alone and 34 who continued with group A therapy) with neck-stretching exercises. Physiotherapy was given to the infants with torticollis.	A: 2-3 mo later when repositioning therapy failed B: <6 (35 infants); 6-12 (34 infants)	A: No duration was given. Helmet therapy was discontinued after a symmetrical calvarial contour had been established. B: 2 to 3	All infants were started with repositioning therapy. The head shape of 34 infants was not improved after 2-3 mo, and they subsequently were given molding therapy. All but 5 infants, who were older than 6 mo at initial intervention, developed a normal or nearly normal head shape.				
Vles et al, ²⁴ 2000	66	39; Physiotherapy was not mentioned.	Both groups: <10	A: 1.2 (SD, 0.9) B: 5.6 (SD, 6.2)	The improvement in the molding group was significantly greater than in the repositioning group, despite the more severe deformity in the molding group. Also, treatment length in the repositioning group was statistically significantly longer (4.6 times) than the molding group.				

Abbreviations: CI, confidence interval; NNT, number needed to treat; RR, relative risk.

^aThe effectiveness was defined as within normal range of the head shape using anthropometric measurements and/or visual judgment.

^bBy simple χ^2 .

^cRepresents the successful treatment in molding therapy vs repositioning therapy.

^dRepresents the percentage of infants' improvement using molding therapy vs repositioning therapy.

36 of 51 infants in the molding group and 17 of 63 infants in the repositioning group were measured. Finally, as Moss acknowledged in his study,²² the anthropometric measurements obtained in his study were not equivalent to the historical data from infants treated with molding therapy.¹⁵ This likely resulted in a significant measurement bias.

Have the Authors Identified All Important Confounding Factors? Have They Taken Account of the Confounding Factors in the Design and/or Analysis?

Starting Age of the Treatment. All infants were younger than 12 months when their treatment was initiated. In 4 studies, molding and repositioning therapies started at a comparable age, 5.5 and 5.5 months,¹³ 8.5 and 8.8 months,²¹ 5.9 and 6.4 months,²² and 5.4 and 5.6 months.⁵ The Vles et al study²⁴ only stated that both treatments were started prior to 10 months of age. In the Pollack et al study,²³ molding therapy started 2 to 3 months after repositioning therapy failed to correct the asymmetry. In the Graham et al study,²⁰ repositioning therapy (4.8

months of age) started statistically significantly earlier than molding therapy (6.6 months of age). In this study, they offered molding therapy to infants who were 6 months or older or had more than moderate head asymmetry regardless of age. Repositioning therapy was offered to infants who were younger than 4 months and had moderate or less head asymmetry. Therefore, the bias would likely have favored the repositioning therapy group. However, none of the studies performed stratified analysis during the evaluation of treatment outcome.

Severity of the Plagiocephaly. At the beginning of the treatment, the severity of the plagiocephaly in the molding group was more severe than in the repositioning group in 3 studies.^{20,21,24} In the Clarren study,¹³ the physician offered molding therapy to all patients, but 10 (6 mild and 4 moderate) declined the molding treatment, resulting in 28 infants with more severe plagiocephaly in the molding group (19 severe, 8 moderate, and 1 mild). In 3 studies,^{20,21,23} infants were treated with molding therapy after they failed to respond to repositioning therapy. Therefore, the baseline severity of the asymmetry in the

molding group was greater than in the repositioning group in all of these studies. The biases favored the repositioning therapy group. Only the Graham et al study²⁰ offered molding therapy to the infants with more severe deformity regardless of age and repositioning therapy to the infants with less severe deformity who were younger than 4 months of age. However, none of the studies performed stratified analysis during the evaluation of treatment outcome.

Was the Follow-up of Subjects Complete Enough?

In all 7 studies, follow-up measurements were completed at the end of the treatment. However, in the Mulliken et al study,³ only 71% in the molding therapy group and 27% in the repositioning therapy group were followed up. It is unclear how this differential loss to follow-up might have affected the findings.

WHAT ARE THE RESULTS?

Outcomes between the groups could be compared in 5 of the 7 included studies.^{5,13,20,23,24} These studies showed evidence that molding therapy is more effective than repositioning therapy. This result was observed despite the selection bias that resulted in more severe asymmetry in the molding group than in the repositioning group. The Loveday and de Chalain study²¹ showed evidence that there was a comparable effectiveness between molding therapy and repositioning therapy. However, the average treatment length for repositioning therapy was 14.7 months, 3 times longer than the molding group. In this study, an unknown number of infants whose initial repositioning therapy failed were also included in the molding therapy group. Finally, the Moss study²² compared the results of repositioning therapy with a historical control group of infants who received molding therapy 4 years previously. However, the same anatomical landmarks for anthropometric measurements were not used in both arms of the study. These biases made the outcomes of these 2 studies^{21,22} difficult to assess.

The average length of both treatments was within 6 months in all but one study.²¹ In 4 studies, the treatment length in both treatment groups was comparable: 5.3 and 5.3 months,¹³ 4.2 and 3.5 months,²⁰ 4.3 and 4.5 months,²² and 4.6 and 4.8 months.⁵ In 2 studies, repositioning therapy was considerably longer than molding therapy (14.7 vs 5.1 months in the Loveday and de Chalain study²¹ and 5.6 vs 1.2 in the Vles et al study²⁴). In these studies, the bias clearly favored the repositioning therapy group. The Pollack et al study²³ stated that the length of repositioning therapy was 2 to 3 months and molding therapy was discontinued after a symmetrical calvarial contour had been established, usually within 6 months. However, no definitive duration of the treatment was described.

Finally, the magnitude of the effects was calculated. Among the selected 7 cohort studies, 3 studies^{5,21,24} did not provide detailed information on the numbers of infants who were normalized or achieved a near normal head shape. They presented the average improvement using quantitative anthropometric measurements. The Moss study²² had a significant measurement bias and was not included. Since

it was not clear whether Clarren¹³ applied repositioning therapy or just simply observation to his nonmolding group, it was not included. The infants treated with molding therapy in the Pollack et al study²³ were crossed over after failure of repositioning therapy. It was also not included. Therefore, the magnitude of the treatment effects was calculated based on the Graham et al study.²⁰

The relative risk was calculated as the proportion of successful molding therapy vs repositioning therapy. The infants who crossed over from repositioning therapy to molding therapy were only counted as failure of repositioning therapy. Based on the Graham et al study²⁰ (Table 2), the relative risk and its 95% confidence interval were 1.3 (1.2-1.4), favoring the treatment with molding therapy. The improvement with molding therapy was about 1.3 times more effective than with repositioning therapy. The absolute risk reduction for the proportion of infants who improved was 0.21 (95% confidence interval, 0.15-0.27), representing the efficacy of using molding therapy over repositioning therapy. Finally, the number need to treat was 5.0 (95% confidence interval, 4-7), representing the number of infants who need to be treated using molding therapy to improve deformational plagiocephaly.

COMMENT

Randomized controlled trials would be ideal to address questions regarding therapeutic efficacy. Unfortunately, there were no RCT studies on the treatment of deformational plagiocephaly. Therefore, only 7 cohort studies were included in this study. Five^{5,13,20,23,24} of the 7 selected studies presented evidence that molding therapy is more effective than repositioning, even with the biases that seemed to predominantly favor the repositioning groups. However, unmasked outcome evaluations could have favored the molding groups. The impact of assessment bias on the findings is impossible to determine. The treatment outcomes from the other 2 studies^{21,22} were difficult to assess because of flaws in their study design.

The magnitude of the molding therapy effects was seen from the Graham et al study.²⁰ The relative improvement of using molding therapy was about 1.3 times more efficient than repositioning therapy (relative risk, 1.3). It could be estimated that in treatment of patients with deformational plagiocephaly, 21% more patients (absolute risk reduction, 0.21) will be improved with molding therapy than with repositioning therapy. Nonetheless, the benefit of using molding therapy over repositioning therapy may have been underestimated because there were significant selection biases observed in this study. The expected biases would be toward worse outcomes in the molding group; however, the outcomes of molding therapy were better nonetheless. Therefore, the biases become less of a concern and may strengthen the evidence of effectiveness and benefit of molding therapy.

The age at which treatment is begun and the severity of the plagiocephaly are important considerations in whether the infant should be treated by repositioning or molding therapy. The general consensus^{10,12,20,21,23,28} (based on expert opinion) is that repositioning therapy is pre-

ferred over molding therapy in patients 4 months or younger and in whom the severity is moderate or less. In patients 6 months or older, or in patients with more than moderate asymmetry regardless of age, molding therapy is preferred. In patients between 4 and 6 months of age, the treatment choice is controversial. However, the general consensus is not well supported by the literature since none of the studies stratified the data by age and severity.

Since there are no rigorously designed trials to compare the treatment outcomes for molding therapy and repositioning therapy, we would like to recommend further research on the following aspects:

1. *A rigorously designed clinical trial on the evaluation of molding vs repositioning therapies.* The existing evidence for the effectiveness of molding and repositioning therapies was not sufficient to definitively conclude which therapy is better, although the trend was that molding therapy was more effective than repositioning therapy in the treatment of infants with deformational plagiocephaly. It may not be feasible or ethical to propose an RCT to compare molding vs repositioning therapy. However, it may be feasible to improve on existing design.^{20,23} A multicenter randomized trial may be used to compare early molding therapy with repositioning therapy followed by later molding therapy if needed. Patients whose repositioning therapy failed and who “crossed over” would have their outcomes assessed and analyzed in the repositioning group. The real comparison would be between molding first and repositioning followed by molding as needed. If their outcomes were the same, even if some or many crossed over, one might conclude that repositioning therapy followed by molding therapy as needed is more cost-effective than initial treatment with a helmet. If almost all crossed over to achieve these comparable outcomes, one might conclude that it is not worth wasting the time on repositioning therapy.

2. *Uniform evaluation criteria for treatment outcome.* A disadvantage of anthropometric measurements is that they are directly performed on the infant. The measurements are operator dependent, relying heavily on the judgment of the examiner to determine the exact point of the landmarks at each visit. The recorded measurements may not be useful for future studies unless the measurements between studies are identical.^{29,30} In addition, the severity of head asymmetry indicated by the anthropometric measurements failed to correlate to the severity indicated by the visual judgment.²⁹ Furthermore, when the motion of a typical, active infant is added, the differences in measurements of mere millimeters become questionable. Another disadvantage of anthropometric measurements is that the measurements are only 2-dimensional.³¹ On scientific grounds, it would be better to record the 3-dimensional geometry of an infant’s head (ie, 3-dimensional cranial imaging system).³² It is especially important that this 3-dimensional surface imaging system be fast enough to mitigate the infant’s movement. One may consider a study using such a device to establish a set of 3-dimensional anthropometric normative values for different age and sex groups. One may also consider establishing a set of surface imaging-based, 3-dimensional cephalometric analy-

sis schemes in different planes based on a unique head orientation (eg, natural head position). This may greatly help clinicians to compare measurements within a patient or among different patients.

The ultimate treatment goal of deformational plagiocephaly is to correct the infant’s abnormal head shape. There is a human tolerance for a range of mild deformation (ie, nearly normal head shape) that may not be noticeable to the evaluators. It may be more important to reshape the infant’s head to this range rather than reshape it to an absolute symmetry as indicated by anthropometric measurements.³³ However, this magnitude of human visual tolerance still remains to be determined in outcome analysis. A cross-sectional study to compare the outcomes of visual judgment and quantitative anthropometric measurements may be helpful to determine the magnitude of this visual tolerance.

3. *Cost-effectiveness of molding therapy.* Even with the approval by the US Food and Drug Administration, third-party payers (insurance companies) are increasingly unwilling to cover molding therapy.³⁰ In today’s health care environment, even if a medical device is safe and effective, its use is often dependent on justifying its cost.³⁴⁻³⁶ Third-party payers may promote repositioning therapy well beyond when it is considered effective (< 6 months), regardless of the severity of the deformity, because of its cost savings.³⁰ Therefore, further study on cost-effectiveness of molding therapy vs repositioning therapy is warranted, in conjunction with rigorously designed clinical trials comparing the therapies and the natural history of untreated deformational plagiocephaly.

4. *Treatment options for infants older than 12 months.* Treatment for children with deformational plagiocephaly who are 12 months or older is controversial. There has been only a case study³⁷ using molding therapy in the treatment of infants who are older than 12 months of age. However, as the authors noted, additional prospective studies are warranted to present more definitive data demonstrating the efficacy of nonsurgical treatment after 1 year of age.

CONCLUSIONS

The studies showed considerable evidence that molding therapy may reduce skull asymmetry more effectively than repositioning therapy. However, definitive conclusions on the relative effectiveness of these treatments were tempered by potential biases in these studies. Further research is warranted.

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interpretation of data: Xia, Kennedy, and Teichgraber. Drafting of the manuscript: Xia and Teichgraber. Critical revision of the manuscript for important intellectual content: Xia, Kennedy, Teichgraber, Wu, Baumgartner, and Gateno. Statistical analysis: Xia and Kennedy. Administrative, technical, and material support: Xia, Wu, Baumgartner, and Gateno. Study supervision: Kennedy, Teichgraber, and Gateno.

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