Comparison of orthotic helmet and repositioning therapy for treatment of deformational plagiocephaly

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Clinical Question: In infants with deformational plagiocephaly (DP), is orthotic helmet therapy more effective at correcting the cranial deformation compared to repositioning therapy?

Background: Non-synostotic deformational plagiocephaly (DP) is a skull deformity caused by an external pressure on one area of the skull. DP presents as a distinct flattening of the occiput with anterior shift of the ipsilateral ear, protrusion of the ipsilateral forehead and contralateral forehead flattening[1,2,4,5]. Risk factors known to be associated with DP include multiple births, pre-mature birth, unusual positioning during birth, male gender, supine positioning, developmental delay and torticollis[2,6,7]. The Safe to Sleep campaign was started in 1992 to reduce the risk of Sudden Infant Death Syndrome (SIDS)[8,9]. This campaign led to an increase in infants sleeping supine, which is thought to have led to an increase in the prevalence of DP[10,11]. While the prevalence rate of DP is not directly known, several studies have reported it to be between 22.1%-46.6% in infants 7-12 weeks old[12–14].

DP is usually diagnosed by a pediatric primary care provider through visual assessment and anthropometric measurements (e.g., cranial width, cranial length and diagonal measurements)[2]. Primary treatments for DP are orthotic helmet therapy and repositioning therapy[1,4,15]. Helmets provide contact in the bossed region and relief in the flattened region to allow the skull to grow into this space, while also preventing the infants from resting their head on the flat spot[1,15]. Repositioning consists of educating caregivers on ways to prevent the infant from consistently applying pressure to the flat spot[1,15]. These methods are patient specific based on diagnosis and age and include alternating head position during sleeping, increasing tummy time and changing positions for play and feeding[1,15]. The purpose of this CAT is to compare the effectiveness of helmet and repositioning therapies for treatment of DP.

Search Strategy:
Databases Searched: PubMed, CINAHL, Journal of Prosthetics and Orthotics (JPO) website
Search Terms: Plagiocephaly AND ("Repositioning therapy" OR positioning OR therapy) AND (Helmet OR "Helmet therapy" OR orthotic OR orthoses OR orthosis)
Inclusion/Exclusion Criteria: 2000-present, English

Synthesis of Results: Six studies[16–21] assessed the effectiveness of helmet therapy compared to repositioning therapy for the treatment of DP in a total of 5,021 infants (range 70-4378 infants). All studies were observational in nature, with four retrospective cohort studies[16,17,19,21] and two prospective cohort studies[18,20]. Participants were primarily 4-7 months of age, with baseline cranial index (CI) ranging from 88-92% (normal CI = 75-85%)[16], baseline cranial vault asymmetry index (CVAI) ranging from 7-13% (normal CVAI <3.5%)[16] and varied gender. Participants across studies were not randomly assigned to treatment groups[16–21], meaning groups could be unequal based on important clinical characteristics that influence treatment effects.

All six studies[16–21] reported a reduction in asymmetry for both treatment groups, with a greater reduction in the deformity for the helmet group in four studies[17–20]. In some studies[19–21] the helmet group had significantly higher cranial asymmetries at baseline compared to the repositioning group, suggesting that providers often prescribed helmet treatment for infants with more severe deformities. Similarly, several studies[16,17,21] reported infants in the repositioning group transferred to the helmet group if repositioning was not successful; there was no difference in correction rate for those who transitioned between groups compared to those who only received helmet therapy[21]. Two studies[16,18] reported shorter treatment periods for the helmet group, while one study[17] reported a longer treatment period for the helmet group. Effectiveness of treatment may be age dependent, as older infants (>8-9 months of age) had smaller reductions in the deformity[17] and experienced better correction with helmet therapy[16]. Use of 2D measurement techniques[16,17,19,20] and no[16–20] or self-reported[21] compliance data may limit the ability to determine the effectiveness of the treatments. One study[19] included a non-helmet group rather than a repositioning group, which may have included various non-helmet therapies.

Clinical Message: For younger infants with a mild or moderate deformity, repositioning therapy and helmet therapy may have similar results. However, in cases where repositioning therapy was not effective, older infants, or infants with more severe deformities, helmet therapy may be the most successful treatment. As both treatment options can reduce cranial deformities, family preferences should be taken into consideration.

Clinical Question: In infants with deformational plagiocephaly (DP) is orthotic helmet therapy more effective at correcting the cranial deformation compared to repositioning therapy?

	Loveday and Chalain 2001[16]	**Graham 2005**[17]	**Lipira 2010**[18]	**Kluba 2014**[19]	**Naidoo 2015**[20]	**Steinberg 2015**[21]
Population	Total Sample Size: 74 *Orthotic Helmet Group:* n=29 Gender: Not specified Average age at initial treatment: 36.6 weeks Initial CVAI: 8.0% Initial CI: 89.6% Average duration of treatment: 36.6 weeks *Repositioning Group:* n=45 Gender: Not specified Average age at initial treatment: 38.1 weeks Initial CVAI: 7.3% Initial CI: 88.2% Average duration of treatment: 38.1 weeks	Total Sample Size: 298 *Orthotic Helmet Group*: n=159 Gender: Not specified Average age at initial treatment: 6.6 mos. (SD 1.7) Average age at end of treatment: 10.9 mos. Initial DD: 1.13 cm (SD 0.38) (SD 2.7) Average duration of treatment: 4.2 mos. (SD 2.2) *Repositioning Group*: n= 176 Gender: Not specified Average age at initial treatment: 4.8 mos. (SD 1.7) Average age at end of treatment: 8.3 mos. (SD 3.7) Initial DD: 1.05 cm (SD 0.45) Average duration of treatment: 3.5 mos. (SD 3.5)	Total Sample Size: 70 *Orthotic Helmet Group:* n=35 Gender: 29 male, 6 female Average age at initial treatment: 4.9 mos. Initial CVA: 0.84 Initial CI: 91.0 Mean head circumference at intake: 43.2 cm Average mean Asym(p) at intake: 3.5% Average initial max Asym(p) : 12.9% Average duration of treatment: 3.1 mos. *Repositioning Group:* n=35 Gender: 26 male, 9 female Average age at initial treatment: 4.8 mos. Initial CVA: 0.83 Initial CI: 90.2 Mean head circumference at intake: 42.4 cm Average mean Asym(p) at intake: 3.5% Average initial max Asym(p): 13.0% Average duration of treatment: 5.2 mos.	Total Sample Size: 128 *Orthotic Helmet Group*: n=62 Gender: 40 male, 22 female Average age at initial treatment: 6.3 mos. (SD = 1.44) Average age at end of treatment: 10.2 mos. (SD 1.17) Initial median CVAI: 13.3% (min = 9.1%, max = 19.4%, SD = 2.69) *Non-Helmet Group*: n=66 Gender: 34 male, 32 female Average age at initial treatment: 6.2 mos. (SD = 2.14) Average age at end of treatment: 18.5 mos. (SD 2.28) Initial median CVAI: 9.3% (min = 3.0%, max = 18.5%, SD = 3.12)	Total Sample Size: 73 *Orthotic Helmet Group:* n=50 (37 in final analysis) Gender: 39 male, 11 female Average age at initial treatment: 4.87 mos. (SD 1.06) Average age at follow up: 4.66 years (SD 1.88) Initial CVA: 10.81 Initial CI: 92.7% *Repositioning Group:* n=50 (36 in final analysis) Gender: 34 male, 16 female Average age at initial treatment: 4.42 mos. Average age at follow up: 4.43 years (SD 1.42) Initial CVA: 8.37 Initial CI: 90.3%	Total Sample Size: 4378 *Orthotic Helmet Group*: n=997 Gender: 565 male, 432 female Average age at initial treatment: 7.1 mos. +-3.8 Average age at end of treatment: Not specified Diagnosis: 186 brachycephaly, 412 plagiocephaly, 389 combination Cranial ratio: 0.99 +- 0.28 DD: 12.8 +- 4.7 *Repositioning Group*: n=3381 Gender: 1860 male, 1521 female Average age at initial treatment: 5.1 mos. +-2.1 Average age at end of treatment: Not specified Diagnosis: 839 brachycephaly, 861 plagiocephaly, 1681 combination Cranial ratio: 0.92 +- 0.25 DD: 9.2 +- 3.8 *Crossover Group* (Subset of repositioning group that failed, transferred to helmet): n=534 Gender: 285 male, 249 female Average age at initial treatment: 5.7 mos. +-2.6 Average age at end of treatment: Not specified Diagnosis: 131 brachycephaly, 139 plagiocephaly, 264 combination Cranial ratio: 0.94 +- 0.35 DD: 10.3 +- 4.1
Recruitment Source	Random sample	Convenience sample	Convenience sample	Convenience sample	Convenience sample	Convenience sample

Study Design	Retrospective cohort study	Retrospective cohort study	Prospective cohort study	Retrospective cohort study	Prospective cohort study	Retrospective cohort study
Intervention	Orthotic Helmet Therapy: Custom made out of polypropylene in house from cast.	Orthotic Helmet Therapy: Custom made in house from cast. 3/8" polypropylene with ¼" plastizote liner	Orthotic Helmet Therapy: Custom plastic helmet made by Orthotic and Prosthetic Lab Inc, St. Louis	Orthotic Helmet Therapy: Custom made from 3D-scan by Cranioform. Infants reviewed every 6-8 weeks.	Orthotic Helmet Therapy: Helmet details not mentioned	Orthotic Helmet Therapy: Custom STARband helmet made from STARscanner data.
Comparison	Repositioning Therapy: Caregivers instructed to prevent pressure on flat spot whenever possible, specifically when sleeping. Instructions included rearranging the infants room, changing position of car seat, and modifying nursing and carrying positions.	Repositioning Therapy: Repositioning details not mentioned	Repositioning Therapy: Caregivers instructed to prevent pressure on flat spot whenever possible, specifically when sleeping. Instructions included rearranging the infants room, changing position of car seat, modifying nursing and carrying positions, and increased "tummy-time".	No helmet therapy: Caregivers in both groups asked to continue with other therapies that were already being done including: physical therapy, osteopathy and repositioning. Infants reviewed after one year.	Repositioning Therapy: Repositioning details not mentioned	Repositioning therapy: Caregivers educated about positional preference, techniques to stretch neck muscles, increased "tummy'time", carrying techniques and limiting walking devices. Some infants in repositioning group also received physical therapy which consisted of a home program followed by in office visits with specific exercises.
Inclusion Criteria	Infants referred for treatment of positional plagiocephaly between Jan 1998-Oct 1999	Infants referred for treatment of plagiocephaly at Cedars-Sinai Medical Center between Jan 1994-Dec 2001	Infants treated for deformational plagiocephaly at St. Louis Children's Hospital, dates not specified	Infants with positional plagiocephaly with regular referral and complete documentation, dates not specified	Infants currently between 2-10 yrs old who were evaluated for DP at 6 mos. or younger at St. Louis Children's Hospital DP clinic, dates not specified	Infants who were treated for nonsynostotic DP by a single surgeon between 2004-2011
Exclusion Criteria	Lambdoid synostosis	Infants referred for torticollis who did not develop plagiocephaly	Infants that switched to helmet therapy in the middle of repositioning therapy	Infants with brachycephaly, severe diseases or severe developmental delay	Other craniofacial deformities, anomalies, syndromes, or diagnosed after 6 mos. of age	Infants who received formal repositioning/PT before evaluation, infants who's treatment protocol deviated from standard treatment, infants with incomplete scanner data, those who failed to follow up
Torticollis Present	Not reported	100% of helmet group, 100% of repositioning group	Not reported	Not reported	26% of helmet group, 14% of repositioning group	49% of helmet group, 40% of repositioning group
Helmet Wear Time (Recommended)	22-23 hours/day	Not specified	23 hours/day	23 hours/day	Not specified	23 hours/day
Relevant Outcome(s)	Diagonal asymmetry (CVAI) Length-width ratio (CI)	Diagonal asymmetry (DD, RDD)	Diagonal asymmetry (CVA) Length-width ratio (CI) Total asymmetry (Asym(p))	Diagonal asymmetry (CVAI)	Diagonal asymmetry (CVA) Length-width ratio (CI)	Diagonal asymmetry (DD) Length-width ratio (Cranial ratio)
Measurement Technique(s)	Circumferential head tracings using artist's flexicurve	Cranial calipers	Cranial calipers (CVA), 3D scans using a 4-pod stereophotogrammetric imagining system	Cranial calipers	Cranial calipers	3D laser scanner (STARscanner Laser Data acquisition system)
Correction Success Criteria	Normal CI = 75-85%, Non-significant head asymmetry CVAI <3.5%	Target DD = 0.3 +- 0.1 cm (Normal DD in 36 healthy infants)	Not specified	Non-significant head asymmetry CVAI <3.5%	Normal CI = 75-85%, Normal CVA <= 4mm	Complete correction = DD < 5mm for DP, cranial ratio <0.85 for DB. Treatment considered failed if they did not obtain the values above by 18 mos. of age.

Key Findings	*Diagonal asymmetry:* Both groups showed similar correction (repositioning ΔCVAI = -1.9%, helmet ΔCVAI = -1.8%) *Length-width ratio:* Both groups showed similar correction (repositioning ΔCI = -2.0%, helmet ΔCI = -1.8%)	*Diagonal asymmetry:* Helmet group had a greater mean RDD (0.71cm vs 0.55cm, p<0.0001) Final mean DD in helmet group (0.42cm) was closer to target DD (0.3cm) than repositioning (0.5cm). Helmet therapy showed a greater reduction in deformity than repositioning therapy (helmet: 61%, repositioning: 52%)	*Diagonal asymmetry:* No significant difference in mean CVA reduction between groups *Total asymmetry:* Helmet group had a significantly greater change in mean asym(p) (helmet: 0.9%, repositioning: 0.5%, p=0.02). and Max asym(p) (helmet: 4.0%, repositioning: 2.5%, p=0.02). Greater change in mean asym(p) for helmet was located on the posterior head (helmet: 2.0%, repositioning: 1.1%, p=0.001)	*Diagonal asymmetry:* Asymmetry decreased significantly in both groups, but neither group got below the normal CVAI value of <3.5% (Helmet final CVAI = 4.10%, non-helmet final CVAI = 6.29%) Helmet group had greater median reduction in CVAI (helmet = 9.2%, non-helmet =2.7%) and reduction in initial asymmetry (helmet = 68.3%, non-helmet = 30.7%)	*Diagonal asymmetry:* Mean change in CVA higher in helmet group (Helmet = 6.65, repositioning = 3.32, p=0.000) *Length-width ratio:* Mean change in CI higher in helmet group (Helmet = 7.8%, repositioning = 4.9%, p=0.001)	*Diagonal asymmetry/Length-width ratio:* 77.1% of repositioning group achieved complete correction (15.8% transitioned to crossover group, 7.1% failed to achieve complete correction) 95.0% of all infants with helmets achieved complete correction (helmet group + crossover group, n=1531)
Additional Findings	Average treatment period for helmet group was shorter (helmet: 21.9 weeks, repositioning: 63.7 weeks) Infants <9 mos. at basline had better correction with repositioning (helmet: ΔCVAI = -1.5%, ΔCI = -1.2%, repositioning: ΔCVAI = -2.4%, ΔCI = -2.9%); infants >9 mos. old at basline had better correction with helmet therapy (helmet: ΔCVAI = -2.2%, ΔCI = -2.6%, repositioning: ΔCVAI = -1.5%, ΔCI = -1.3%) Infants with brachycephaly had better correction with repositioning (helmet: ΔCVAI = -1.8%, ΔCI = -2.6%, repositioning: ΔCVAI = -2.1%, ΔCI = -4.1%)	Infants >8 mos. old at start had a larger final mean DD than infants <8 mos. at start (0.51cm vs 0.38cm). Infants >8 mos. old at baseline had a smaller RDD than infants <8 mos. (0.58cm vs 0.76cm); infants >8 mos. old at baseline had a smaller % decrease in DD (51% vs 65%). 37 infants failed initial treatment with repositioning and were transitioned to helmets.	Helmet group had a shorter treatment period (Helmet = 3.1 mos., repositioning = 5.2 mos., p<0.001) No statistically significant difference in average head growth between groups.			There was no significant difference in correction rate between those who started helmet therapy right away and those who transitioned to helmet therapy in the crossover group (Helmet = 94.4%, crossover = 96.1%, p=0.375) Compliance rate higher in the helmet group (Helmet = 94%, repositioning = 87%, p=0.001) Repositioning therapy risk factors include: low compliance, older age at initial treatment, torticollis, development delay, severe cranial deformity. Helmet therapy risk factors include: older age at initial treatment, low compliance.
Limitations	No random assignment, helmet group had greater asymmetry at baseline, compliance not reported, 2D measurement technique (error reported at +-4-5%), lack of generalizability due to one data collection site, limited sample size for statistical analysis	No random assignment, compliance not reported, 2D measurement technique, lack of follow-up after one year of age, lack of generalizability due to one data collection site	No random assignment, compliance not reported, majority of patients were brachycephalic, lack of generalizability due to one data collection site	No random assignment, helmet group had greater asymmetry at baseline, compliance not reported, 2D measurement technique, lack of strict guidelines for non-helmet group, different follow up times between groups, lack of generalizability due to one data collection site	No random assignment, helmet group had greater asymmetry at baseline, compliance not reported, 2D measurement technique, only looked at long term follow up and not immediately after treatment, lack of generalizability due to one data collection site	No random assignment, helmet group had greater asymmetry at baseline, self-reported compliance rates
Study Quality	Medium	Medium	Medium	Low	Medium	High

Abbreviations Used: CI: Cranial Index CVAI: Cranial Vault Asymmetry Index Δ: Change in DD: Cranial Diagonal Difference RDD:

Reductions in Cranial Diagonal Difference
CVA: Cranial Vault Asymmetry
Asym(p): Asymmetry of a point P
DP: Deformational plagiocephaly
DB: Deformational brachycephaly

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