Journal of Paediatrics and Child Health

doi:10.1111/jpc.14717

ORIGINAL ARTICLE

Effect of helmet therapy in the treatment of positional head deformity

Juan Wen,[1,2] Jun Qian,[1] Lei Zhang,[1] Chenbo Ji,[1,2] Xirong Guo,[1,2] Xia Chi[1,3] and Meiling Tong [1,3]

[1]Department of Children Health Care, [2]Nanjing Maternity and Child Health Care Institute, Women's Hospital of Nanjing Medical University, Nanjing Maternity and Child Health Care Hospital and [3]Institute of Pediatrics, Nanjing Medical University, Nanjing, China

Aim: Most positional head deformities can be treated conservatively with postural correction training or a head orthosis ('helmet'). We aimed to investigate whether infants with helmet therapy have cosmetic improvement in head deformity.

Methods: A total of 376 infants at age 2–40 months who were diagnosed with mild–moderate–severe positional head deformity were enrolled. Among these infants, 101 infants were treated with helmet therapy or postural correction training. After matching by infant's age and time of therapy, three retrospective cohort studies of 56 infants were conducted for infants with plagiocephaly, brachycephaly and asymmetrical brachycephaly, respectively. The cephalic ratio (CR), radial symmetry index (RSI), cranial vault asymmetry (CVA) and cranial vault asymmetry index (CVAI) were compared between two groups before and after treatment.

Results: Before treatment, no significant differences in CR, RSI, CVA and CVAI between groups were found. After treatment, compared with the postural correction training group, the helmet therapy group had significant improvements in CR, RSI, CVA or CVAI (Plagiocephaly: P_{CVA} = 0.017, P_{CVAI} = 0.028; Brachycephaly: P_{CR} = 0.002; Asymmetrical brachycephaly: P_{RSI} = 0.002, $P_{CVA} < 0.001$, $P_{CVAI} < 0.001$). Moreover, there was no significant difference in head circumference growth between the groups.

Conclusions: Helmet therapy may be more effective in the treatment of mild–moderate–severe positional head deformity than postural correction training in infants. And helmet therapy may not hinder head circumference growth.

Key words: helmet therapy; infant; positional head deformity; postural correction training.

What is already known on this topic

1. Most positional head deformities can be treated conservatively with postural correction training or a head orthosis ('helmet').
2. Infants with positional head deformity may lead to significant cosmetic and functional consequences, even to psychological consequences.

What this paper adds

1. Helmet therapy may have a better effect in the treatment of positional head deformity.
2. Helmet therapy may not hinder head circumference growth.

In infants with positional head deformity, the occiput is flattened with corresponding facial asymmetry.[1] Since the adoption of the Back to Sleep campaign in 1992 in USA, the prevalence of positional head deformity in early infancy has increased significantly, and the condition now occurs in one of every 60 live births, which have constituted a frequent issue of international concern.[2] Infants with positional head deformity may lead to significant cosmetic and functional consequences, even to psychological consequences.[3,4] Positional head deformity is caused by external pressures on the rapidly developing skull from prolonged exposure to one position. It is reported that the risk factors for positional head deformity included premature delivery, multiple gestation, congenital muscular torticollis, oligohydramnios and other intra-uterine constraint.[5] With early detection and intervention, most positional head deformities can be treated conservatively with postural correction training or a head orthosis ('helmet').[6] In China, there is no guidance on sleeping position of infants and parents put babies in back sleep position traditionally. Although the incidence rate of cranial deformation is unknown since there have been no measurement until recently, the estimated number is in millions given the number of newborns around 15 million a year. Also few infants with positional head deformity have received helmet therapy until the recent China Food and Drug Administration approval and use of helmets in the past 3 years. Therefore, the studies related the effects of helmet therapy are very rare. In this study, we conducted three retrospective cohort studies for infants with plagiocephaly, brachycephaly and asymmetrical brachycephaly, respectively,

Correspondence: Professor Meiling Tong, Department of Children Health Care, Women's Hospital of Nanjing Medical University, Nanjing Maternity and Child Health Care Hospital, No. 123, Tianfeixiang, Mochou Road, Nanjing 210004, China. Fax: +86 25 8446 0507; email: tml_2014@126.com

Juan Wen, Jun Qian and Lei Zhang contributed equally to this work.

Conflict of interest: None declared.

Accepted for publication 25 November 2019.

and aimed to investigate the clinical effect of postural correction training and helmet therapy in the treatment of positional head deformity in a Chinese population.

Methods

Study design

This study was conducted according to the guidelines in the Declaration of Helsinki and all procedures involving infants were approved by the Institutional Review Board of Nanjing Maternity and Child Health Care Hospital. In this retrospective study, we analysed the medical records of patients diagnosed and treated for positional head deformity at our department, part of Nanjing Maternity and Child Health Care Hospital in China, between March 2016 and April 2018. All infants with a diagnosis of positional head deformity were evaluated for study inclusion. Positional head deformity was characterised as flattened occiput with corresponding facial asymmetry, including plagiocephaly, brachycephaly, asymmetrical brachycephaly and scaphocephaly. Plagiocephaly occurs on one side of the head, common in the lateral side sleeping babies, making the left and right side of the head become asymmetric. Brachycephaly occurs directly behind the head, common in babies who are excessively supine, making the occiput flat and giving the head a flat and short shape. Asymmetrical brachycephaly combines plagiocephaly and brachycephaly characteristics. Scaphocephaly, which occurs on both sides of the head, is commonly seen in babies who sleep on their side or stomach, giving the head a long and narrow shape. For the diagnosis of positional head deformity,[1] examination begins with inspection, palpation and cranial measurements to preliminarily determine the type of head deformity. Then, three-dimensional computed tomography imaging can provide a clear picture of the head and an accurate three-dimensional analysis of the bone structure of the skull, to help clinicians determine the type and severity of head deformity. Infants with congenital muscular torticollis, craniosynostosis, cephalhematoma, cerebral palsy, neurodevelopmental disorders and metabolic diseases were excluded. Infants of consideration were <10 months of age. At our clinic, the parents and care givers of infants meeting these criteria were given information about helmet therapy and postural correction training. Then, the parents made the treatment decision based on various factors. Infants who received helmet therapy were designated as the helmet therapy group, and infants who received postural correction training were designated as the postural correction training group. The positional head deformity included plagiocephaly, brachycephaly, asymmetrical brachycephaly and scaphocephaly. As infants with scaphocephaly were rare in this study, we conducted three retrospective cohort studies for infants with plagiocephaly, brachycephaly and asymmetrical brachycephaly, respectively, after matching by age of initiation and time of therapy.

Anthropometric cranial vault analysis

Anthropometric measurements were performed using the Spectra 3D Scanner (Vorum Inc., Vancouver, Canada) and analysed using CCU computer software (Vorum Inc.) by a trained orthotist who was blinded regarding the individual treatment status.[7] Measurements were obtained immediately before and after treatment. The following anthropometric variables were determined (Fig. 1): cranial length, cranial width and the transcranial diagonals (Diag) A and B. Then, cephalic ratio (CR = width/length), CVA (Diag A - Diag B, where Diag A > Diag B) and cranial vault asymmetry index (CVAI = CVA/Diag B × 100) were calculated.[8,9] A decreasing CR was assumed to reflect improvement of head shape for infants with brachycephaly and asymmetrical brachycephaly, and a reduction of CVA and CVAI was thought to indicate amelioration of cranial shape of infants with plagiocephaly and asymmetrical brachycephaly.[8] Radial symmetry index (RSI) is another measurement that has been cited as a valid assessment of CVA (Fig. 1). It is a measurement unique to the STARscanner. Starting at the front of the head, vector lengths were measured at 15° intervals and summed for each side of the head. The absolute value of the difference between the right-sided sum and the left-sided sum was the RSI. Perfect symmetry is indicated by an RSI of 0 mm.[10] The clinical severity classification of positional head deformity is determined by skull asymmetry, most commonly expressed as the CVA (Diag A–Diag B). The classification system proposed by Hutchison *et al.*, defined mild positional head deformity as a CVA between 3 and 10 mm, moderate as a CVA between 10 and 12 mm, and severe as a CVA >12 mm.[11]

Therapy protocols

Helmet therapy involved daily wearing (23 h) of a STARband customised cranial orthotic moulding helmet (Orthomerica Products, Inc., Orlando, FL, USA) according to the STARband Caregiver's Guide. The Helmet was precisely fabricated by an orthotic specialist from 3D data of Spectra Scanner (Vorum Inc., Vancouver, Canada).[12] Helmets alleviate the pressure on the flattened area of the occiput and allow the skull to grow faster in the desired directions. Infants' head growth was evaluated at each visit and helmet was adjusted by the orthotist if needed.

About postural correction training,[13] based on age and specific needs determined at the first visit, an initial home programme was draw up, followed by continued regimented exercises. In automatic head righting reflexes, any asymmetry was addressed with active rather than passive exercises. Postural correction training is aimed to educate the infant's parents and care givers about positional head deformity and to teach them exercises that will correct the shortening of the sternocleidomastoid muscle.[1] Paediatric physical therapists can teach parents and care givers how to carry the child to lengthen the sternocleidomastoid muscle, how to encourage prone playing, and how to alter eating positions to diminish the side preference. Training included discussion of positional preference, emphasising the importance of 'tummy time' lasting greater than 50% of awake time, repositioning techniques to stretch tightened neck muscles, and promoting independent development of neck and truncal muscle.[14]

Statistical analysis

Differences in the infants basic characteristics between groups were calculated by the Student's *t*-test, one-way analysis of variance (for continuous variables) and χ^2 test (for categorical variables). We further compared CR, RSI, CVA and CVAI before and after treatment, and their difference between helmet therapy

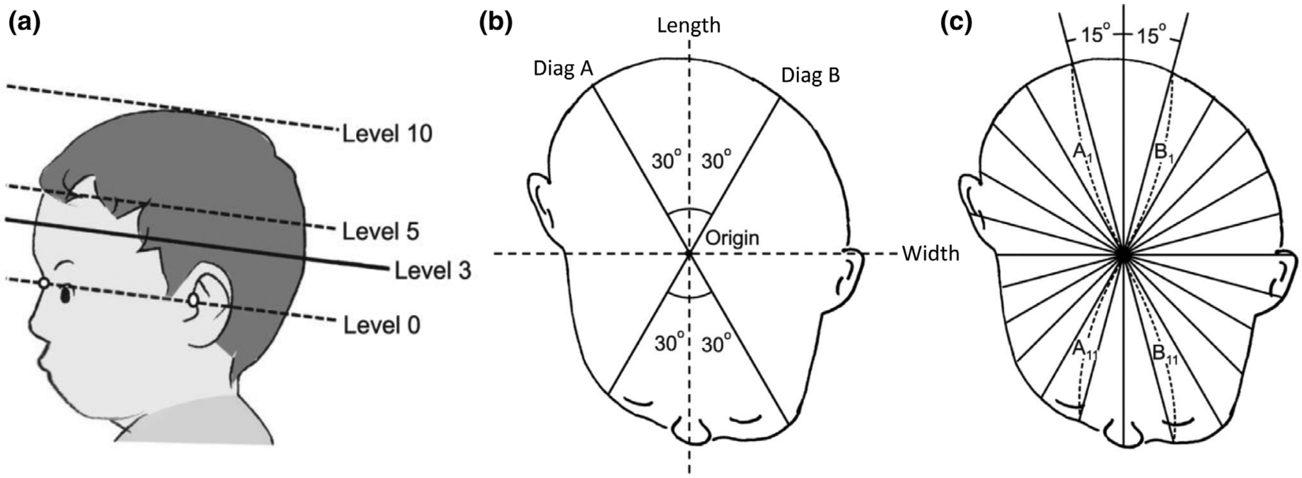

Fig. 1 Cranial measurements obtained with a three-dimensional laser surface scanner. Cranial width is the distance from left to right euryon. Cranial length is the distance from glabella to opisthocranio. The origin is set at the midpoint between the right and left tragia. Level 0 is the reference cross-sectional plane including sellion and both tragia. The portion of the cranium superior to the reference plane was divided into nine equally spaced cross-sectional planes, each parallel to the reference plane, where the level 10 is the plane through vertex. (a) Level 3, which is one-third of the distance from the reference plane to the vertex, was used to calculate cranial measurements in all patients. (b) Cephalic ratio = width/length × 100, cranial vault asymmetry = Diag A – Diag B, where Diag A > Diag B, and cranial vault asymmetry index = CVA/Diag B × 100. (c) Radial symmetry index = (A1 + A2 + … + A11) – (B1 + B2 + … + B11).

Table 1 Characteristics of 376 infants who were diagnosed with mild–moderate–severe positional head deformity

Variable	Plagiocephaly *n* = 124 (33.0%)	Brachycephaly *n* = 82 (21.8%)	Asymmetrical brachycephaly *n* = 156 (41.5%)	Scaphocephaly *n* = 14 (3.7%)	*P* value
Age, month, mean (SD)	6.52 (3.66)	7.34 (4.95)	5.78 (3.21)	6.29 (3.43)	0.026
Gender, *n* (%)					0.118
Boys	80 (64.5)	49 (59.8)	104 (66.7)	5 (35.7)	
Girls	44 (35.5)	33 (40.2)	52 (33.3)	9 (64.3)	
Twins, *n* (%)					0.003
Yes	19 (15.3)	2 (2.4)	28 (17.9)	0 (0.0)	
No	105 (84.7)	80 (97.6)	128 (82.1)	14 (100.0)	
Delivery mode, *n* (%)					0.180
Caesarean section	42 (33.9)	25 (30.5)	66 (42.3)	7 (50.0)	
Spontaneous delivery	82 (66.1)	57 (69.5)	90 (57.7)	7 (50.0)	
Preterm birth, *n* (%)					<0.001
Yes	38 (30.6)	8 (9.8)	60 (38.5)	2 (14.3)	
No	86 (69.4)	74 (90.2)	96 (61.5)	12 (85.7)	
NICU care, *n* (%)					0.008
Yes	23 (18.5)	8 (9.8)	42 (26.9)	1 (7.1)	
No	101 (81.5)	74 (90.2)	114 (73.1)	13 (92.9)	
Severity level of positional head deformity, *n* (%)					<0.001
Mild	36 (29.0)	24 (29.3)	16 (10.3)	-	
Moderate	62 (50.0)	23 (28.0)	62 (39.7)	-	
Severe	26 (21.0)	35 (42.7)	78 (50.0)	-	
Head circumference, cm, mean (SD)	43.08 (2.39)	43.68 (2.32)	42.70 (2.07)	43.97 (3.20)	0.007
CR, mean (SD)	0.86 (0.03)	1.02 (0.57)	0.96 (0.04)	0.73 (0.02)	<0.001
RSI, mm, mean (SD)	44.29 (14.53)	13.55 (6.17)	43.42 (14.04)	11.29 (4.31)	<0.001
CVA, mm, mean (SD)	11.82 (3.91)	2.96 (1.81)	11.43 (3.59)	2.95 (1.70)	<0.001
CVAI, mean (SD)	8.01 (2.62)	2.08 (1.27)	7.97 (2.43)	1.95 (1.06)	<0.001

CR, cephalic ratio; CVA, cranial vault asymmetry; CVAI, cranial vault asymmetry index; NICU, neonatal intensive care unit; RSI, radial symmetry index.

Table 2 Characteristics between the 376 infants with positional head deformity and the 56 treated infants

Variable	All infants (n = 376)	Treated and matched infants (n = 56)	P value
Age, month, mean (SD)	6.09 (2.72)	5.65 (1.56)	0.084
Gender, n (%)			0.687
Boys	238 (63.3)	37 (66.1)	
Girls	138 (36.7)	19 (33.9)	
Twins, n (%)			0.327
Yes	49 (13.0)	10 (17.9)	
No	327 (87.0)	46 (82.1)	
Delivery mode, n (%)			0.580
Caesarean section	140 (37.2)	23 (41.1)	
Spontaneous delivery	236 (62.8)	33 (58.9)	
Preterm birth, n (%)			0.285
Yes	108 (28.7)	20 (35.7)	
No	268 (71.3)	36 (64.3)	
NICU care, n (%)			0.016
Yes	74 (19.7)	19 (33.9)	
No	302 (80.3)	37 (66.1)	
Classification of positional head deformity, n (%)			0.025
Plagiocephaly	124 (33.0)	16 (28.6)	
Brachycephaly	82 (21.8)	21 (37.5)	
Asymmetrical brachycephaly	156 (41.5)	19 (33.9)	
Scaphocephaly	14 (3.7)	0 (0)	
Severity level of positional head deformity (Scaphocephaly not included), n (%)			0.474
Mild	76 (21.0)	8 (14.3)	
Moderate	147 (40.6)	26 (46.4)	
Severe	139 (38.4)	22 (39.3)	
Head circumference, cm, mean (SD)	43.06 (2.27)	42.75 (1.65)	0.207
CR, mean (SD)	0.93 (0.27)	0.93 (0.06)	0.932
RSI, mm, mean (SD)	35.99 (18.39)	32.07 (16.61)	0.132
CVA, mm, mean (SD)	9.39 (5.04)	8.38 (4.65)	0.158
CVAI, mean (SD)	6.47 (3.43)	5.84 (3.16)	0.194

CR, cephalic ratio; CVA, cranial vault asymmetry; CVAI, cranial vault asymmetry index; NICU, neonatal intensive care unit; RSI, radial symmetry index.

group and postural correction training group to assess the effect of helmet therapy in the treatment of positional head deformity. And head circumference before and after treatment were also compared between groups to assess the side effect of helmet therapy in growth of head circumference. Values are presented as mean and SDs. All statistical analyses were performed with the R software (version 2.13.0, Free Software Foundation, Inc., Boston, USA), and $P \leq 0.05$ in a two-sided test was considered statistically significant.

Ethics

The study was approved by the Institutional Review Board of Nanjing Maternity and Child Health Care Hospital. All participants provided written informed consent.

Results

In total, 405 infants at age 2–40 months were diagnosed with mild–moderate–severe positional head deformity in our hospital from March 2016 to April 2018, and the related health information were available for 383 (94.6%). We excluded seven infants who had congenital muscular torticollis, craniosynostosis or cephalhematoma. At last, 376 infants (124 infants with plagiocephaly, 82 infants with brachycephaly, 156 infants with asymmetrical brachycephaly and 14 infants with scaphocephaly) were included in the analysis (Table 1). Among the 362 infants with plagiocephaly and/or brachiocephaly, 286 infants were diagnosed with moderate–severe positional head deformity. Plagiocephaly, brachycephaly and asymmetrical brachycephaly were more common in boys than in girls, while scaphocephaly was more common in girls than in boys. Plagiocephaly and asymmetrical brachycephaly were more frequent than brachycephaly and scaphocephaly in twins, preterm infants and infants who had been moved to the neonatal intensive care unit (NICU) after birth. And caesarean section was more prevalent in the infants with asymmetrical brachycephaly and infants with scaphocephaly. Furthermore, head circumference, CR, RSI, CVA and CVAI were found to differ significantly between the four groups.

Among the 376 infants with positional head deformity, 101 infants were treated with helmet therapy or postural correction training. After matching by age of initiation and time of therapy, 30 infants treated with helmet therapy and 26 infants treated with postural correction training participated in our study

Table 3 Characteristics of infants diagnosed with positional head deformity between groups

Variable	Plagiocephaly			Brachycephaly			Asymmetrical brachycephaly		
	Helmet therapy group (*n* = 7)	Postural correction training group (*n* = 9)	*P* value	Helmet therapy group (*n* = 13)	Postural correction training group (*n* = 8)	*P* value	Helmet therapy group (*n* = 10)	Postural correction training group (*n* = 9)	*P* value
Age of initiation, month, mean (SD)	5.80 (1.36)	4.84 (0.45)	0.116	5.80 (1.49)	4.70 (1.68)	0.135	6.63 (1.61)	5.89 (1.84)	0.362
Age at the end of treatment, month, mean (SD)	7.91 (1.57)	7.34 (1.46)	0.465	8.39 (2.25)	6.75 (2.43)	0.131	9.14 (1.82)	10.19 (4.56)	0.533
Durations of therapy, month, mean (SD)	2.10 (1.11)	2.52 (1.70)	0.579	2.58 (1.23)	2.03 (1.47)	0.360	2.51 (0.57)	4.30 (2.97)	0.110
Gender, *n* (%)			1.000			0.673			1.000
Boys	6 (85.7)	7 (77.8)		8 (61.5)	4 (50.0)		6 (60.0)	6 (66.7)	
Girls	1 (14.3)	2 (22.2)		5 (38.5)	4 (50.0)		4 (40.0)	3 (33.3)	
Twins, *n* (%)			1.000			0.381			1.000
Yes	1 (14.3)	2 (22.2)		0 (0.0)	1 (12.5)		3 (30)	3 (33.3)	
No	6 (85.7)	7 (77.8)		13 (100.0)	7 (87.5)		7 (70.0)	6 (66.7)	
Delivery mode, *n* (%)			1.000			0.253			1.000
Caesarean section	4 (57.1)	4 (44.4)		1 (7.7)	3 (37.5)		6 (60.0)	5 (55.6)	
Spontaneous delivery	3 (42.9)	5 (55.6)		12 (92.3)	5 (62.5)		4 (40.0)	4 (44.4)	
Preterm birth, *n* (%)			0.315			0.133			0.370
Yes	2 (28.6)	6 (66.7)		0 (0.0)	2 (25.0)		4 (40.0)	6 (66.7)	
No	5 (71.4)	3 (33.3)		13 (100.0)	6 (75.0)		6 (60.0)	3 (33.3)	
NICU care, *n* (%)			0.596			0.531			0.650
Yes	3 (42.9)	2 (22.2)		1 (7.7)	2 (25.0)		5 (50.0)	6 (66.7)	
No	4 (57.1)	7 (77.8)		12 (92.3)	6 (75.0)		5 (50.0)	3 (33.3)	
Severity level of positional head deformity, *n* (%)			0.959			0.422			0.356
Mild	1 (14.3)	1 (11.1)		2 (15.4)	3 (37.5)		0 (0.0)	1 (11.1)	
Moderate	5 (71.4)	7 (77.8)		4 (30.8)	1 (12.5)		4 (40.0)	5 (55.6)	
Severe	1 (14.3)	1 (11.1)		7 (53.8)	4 (50.0)		6 (60.0)	3 (33.3)	
Head circumference before treatment, cm, mean (SD)	43.03 (1.28)	41.85 (2.03)	0.201	43.37 (1.52)	42.50 (2.60)	0.345	43.07 (0.74)	42.37 (1.15)	0.140
Head circumference after treatment, cm, mean (SD)	44.36 (1.63)	43.47 (2.15)	0.381	44.78 (1.19)	44.19 (3.15)	0.623	44.53 (0.83)	44.92 (2.06)	0.610
CR before treatment, mean (SD)	0.85 (0.04)	0.87 (0.02)	0.116	0.97 (0.04)	0.97 (0.05)	0.995	0.96 (0.03)	0.95 (0.04)	0.385
CR after treatment, mean (SD)	0.84 (0.03)	0.87 (0.03)	0.066	0.92 (0.03)	0.96 (0.06)	0.138	0.92 (0.03)	0.91 (0.04)	0.783
CR difference, mean (SD)	-0.01 (0.02)	0.00 (0.02)	0.589	−0.05 (0.02)	−0.01 (0.02)	0.002	−0.05 (0.02)	−0.04 (0.03)	0.374
RSI before treatment, mm, mean (SD)	41.31 (8.18)	44.09 (8.29)	0.515	13.75 (4.55)	14.71 (3.96)	0.629	42.51 (15.41)	43.14 (10.44)	0.919
RSI after treatment, mm, mean (SD)	24.17 (10.26)	69.56 (96.99)	0.241	10.85 (3.98)	14.12 (5.13)	0.118	23.58 (11.64)	39.21 (12.37)	0.011
RSI difference, mm, mean (SD)	−17.14 (10.18)	25.47 (95.02)	0.261	−2.90 (2.77)	−0.59 (5.04)	0.189	−18.93 (7.37)	−3.93 (9.97)	0.002
CVA before treatment, mm, mean (SD)	11.30 (2.13)	11.92 (2.41)	0.598	2.89 (1.44)	3.94 (2.11)	0.188	11.42 (3.91)	11.09 (2.20)	0.826
CVA after treatment, mm, mean (SD)	6.16 (2.80)	10.26 (2.56)	0.009	1.62 (1.21)	3.01 (1.91)	0.053	5.86 (3.26)	10.63 (2.65)	0.003
CVA difference, mm, mean (SD)	−5.14 (2.87)	−1.67 (2.26)	0.017	−1.26 (1.27)	−0.93 (1.05)	0.539	−5.56 (2.50)	−0.46 (2.29)	< 0.001
CVAI before treatment, mean (SD)	7.67 (1.48)	8.32 (1.78)	0.448	2.02 (1.00)	2.90 (1.41)	0.109	7.85 (2.42)	7.84 (1.50)	0.995
CVAI after treatment, mean (SD)	4.14 (1.97)	6.97 (1.71)	0.008	1.12 (0.83)	2.08 (1.38)	0.059	3.90 (2.09)	7.08 (1.58)	0.002
CVAI difference, mean (SD)	−3.53 (1.93)	−1.36 (1.62)	0.028	−0.90 (0.90)	−0.83 (0.76)	0.847	−3.95 (1.64)	−0.77 (1.52)	< 0.001

CR, cephalic ratio; CVA, cranial vault asymmetry; CVAI, cranial vault asymmetry index; NICU, neonatal intensive care unit; RSI, radial symmetry index.

to assess the effect of helmet therapy in the treatment of positional head deformity. The characteristics between the 376 infants with positional head deformity and the 56 treated infants are shown in Table 2. Most variables are comparable between the total population and the 56 treated infants, except variables of 'NICU care' (P = 0.016) and 'Classification of positional head deformity' (P = 0.025). Then three retrospective cohort studies were conducted for infants with plagiocephaly, brachycephaly and asymmetrical brachycephaly, respectively (Table 3). The variables of age of initiation, age at the end of treatment, durations of therapy, gender, twins, delivery mode, preterm birth, NICU treatment and severity level of positional head deformity did not differ between the cohort groups (all $P > 0.05$), indicating the comparability of the groups.

For infants with plagiocephaly, seven infants received helmet therapy and nine infants received postural correction training. The characteristics of the 16 infants between groups are shown in the left side of Table 3. The average age of treatment initiation of the helmet therapy group and postural correction training group were 5.8 and 4.8 months, respectively. And the average time of therapy of the groups were 2.1 and 2.5 months, respectively. Before treatment, no significant differences in CR, RSI, CVA and CVAI between groups were found (all $P > 0.05$). After treatment, the helmet therapy group had significant improvements in CVA and CVAI compared with the postural correction training group (CVA difference: -5.14 ± 2.87 vs. -1.67 ± 2.26, $P = 0.017$; CVAI difference: -3.53 ± 1.93 vs. -1.36 ± 1.62, $P = 0.028$).

For infants with brachycephaly, 13 infants received helmet therapy and 8 infants received postural correction training. Before treatment, there were no significant differences in CR, RSI, CVA and CVAI between groups (all $P > 0.05$). After treatment, the helmet therapy group had significant improvement in CR compared with the postural correction training group (CR difference: -0.05 ± 0.02 vs. -0.01 ± 0.02, $P = 0.002$).

For infants with asymmetrical brachycephaly, 10 infants received helmet therapy and 9 infants received postural correction training. Before treatment, there were also no significant differences in CR, RSI, CVA and CVAI between groups (all $P > 0.05$). After treatment, the helmet therapy group had significant improvements in RSI, CVA and CVAI compared with the postural correction training group (RSI difference: -18.93 ± 7.37 vs. -3.93 ± 9.97, $P = 0.002$; CVA difference: -5.56 ± 2.50 vs. -0.46 ± 2.29, $P < 0.001$; CVAI difference: -3.95 ± 1.64 vs. -0.77 ± 1.52, $P < 0.001$).

We also compared head circumference before and after treatment between the helmet therapy group and the postural correction training group. No significant differences in head circumference before and after treatment between groups were found in these three cohort studies (all $P > 0.05$), suggesting that the helmet therapy did not limit the growth of head circumference.

Discussion

To the best of our knowledge, our study is the first Chinese report to compare the efficacy of helmet therapy and postural correction training on correcting of positional head deformity. In this study, for infants with plagiocephaly, the helmet therapy group had a statistically significant reduction of CVA and CVAI, indicating amelioration of cranial shape of infants. The RSI has cited as a valid assessment of CVA. However, their RSI difference was not significant, which may be related to our relatively small sample size. A decreasing CR was assumed to reflect improvement of head shape for infants with brachycephaly. As expected, for infants with brachycephaly, the helmet therapy group had significant improvement in CR after treatment compared with the postural correction training group. For infants with asymmetrical brachycephaly, the helmet therapy group had significantly lower RSI, CVA and CVAI, consistently indicating amelioration of cranial shape of infants. In brief, our study found that infants treated with helmet therapy had statistically significantly improvements in head deformity when compared to infants undergoing postural correction training. Helmet therapy did not appear to influence head growth.

For the treatment of positional head deformity, helmet therapy and postural correction training are the major therapeutic option. A systematic review focusing on the nonsurgical treatment of positional head deformity showed considerable evidence that helmet therapy may reduce skull asymmetry more effectively than postural correction training.[15] However, definitive conclusions on the relative effectiveness of these treatments were tempered due to potential biases in prior studies, such as different treatment techniques, different age of therapy initiation, varying durations of therapy, inconsistent diagnostic criteria and varying severity level of positional head deformity.[16,17] For younger infants with mild positional head deformity, most of their care givers would refuse helmet therapy and choose postural correction training, which resulted in a larger number of relatively older infants with moderate to severe positional head deformity in the helmet therapy group. Moreover, some infants received helmet therapy only after they failed to respond to postural correction training.[18] Postural correction training may have roles in correcting mild positional head deformity, but it seems less effective in correcting moderate to severe positional head deformity. In this study, age of initiation, durations of therapy and severity level of positional head deformity were comparable between groups. Our results suggest that helmet therapy may be superior to postural correction training in correcting cranial asymmetry and that helmet therapy should be considered, especially for moderate to severe positional head deformity.

The natural processes of positional head deformity and the long-term effects of helmet therapy and postural correction training are not fully clear. In a large Dutch study, 7609 infants below the age of 6 months were screened for positional preference. They found the prevalence of positional preference was 8.2% and was highest in children below 16 weeks of age. And 45% of these infants had an asymmetric flattening of the occiput after 2 years of follow-up.[19] Another prospective cohort study assessed the prevalence and natural processes of positional head deformity in 200 normal infants in the first 2 years of life, and showed that the prevalence of positional head deformity increased to 4 months but diminished as infants grew older.[20] Mild positional head deformity may be solved by the natural processes, but moderate to severe positional head deformity may persistent despite some natural improvement. However, the extent of natural improvement and the long-term effects of physical therapy was lack of data. Few studies have followed the infants who received helmet therapy or postural correction training through adulthood. In our study, we only assessed the infants immediately after therapy. Further studies evaluating the long-term effects of helmet therapy and postural correction training are needed.

We used the STARscanner Laser Data Acquisition System to analyse the head asymmetry, which could provide repeatable and precise measurements. Four most valuable measurements (CR, RSI, CVA and CVAI) were obtained in this study to assess head shape in infants with positional head deformity. Head circumference in both groups before and after therapy was also measured. Our results implied that helmet therapy did not influence the growth of head circumference. However, our study has some limitations. First, helmet therapy is relatively expensive, and it is not well received by Chinese parents, which results in fewer infants treated with helmet therapy. Also the subjects' inclusion criteria and matching criteria in this study were strict, thus our sample size was relatively small. Second, the treatment choices are not random, and it was made by parental preference. Third, the compliance was not exactly assessed as both treatments were performed in home, and the compliance was reported by care giver. Fourth, after therapy, we did not evaluate the development in terms of motor ability, language, cognition and social ability, all of which are important aspects in the treatment of positional head deformity. Last, several associations reported will not reach significance after multiple comparison correction, which was another drawback of this study. Further prospective, randomised controlled trial with a large sample of infants could help to objectively evaluate and validate the effects of helmet therapy and postural correction training.

Conclusion

Helmet therapy in infants with positional head deformity may result in more favourable outcomes than postural correction training. And the treatments may not influence head circumference growth.

Acknowledgements

This work was supported in part by the National Natural Science Foundation of China (81600685) and the Natural Science Foundation of Jiangsu Province (BK20160141).

References

1 Biggs WS. Diagnosis and management of positional head deformity. *Am. Fam. Physician* 2003; **67**: 1953–6.
2 Mawji A, Vollman AR, Hatfield J, McNeil DA, Sauve R. The incidence of positional plagiocephaly: A cohort study. *Pediatrics* 2013; **132**: 298–304.
3 Martiniuk AL, Vujovich-Dunn C, Park M, Yu W, Lucas BR. Plagiocephaly and developmental delay: A systematic review. *J. Dev. Behav. Pediatr.* 2017; **38**: 67–78.
4 Aihara Y, Komatsu K, Dairoku H, Kubo O, Hori T, Okada Y. Cranial molding helmet therapy and establishment of practical criteria for management in Asian infant positional head deformity. *Childs Nerv. Syst.* 2014; **30**: 1499–509.
5 De Bock F, Braun V, Renz-Polster H. Deformational plagiocephaly in normal infants: A systematic review of causes and hypotheses. *Arch. Dis. Child.* 2017; **102**: 535–42.
6 Mortenson P, Steinbok P, Smith D. Deformational plagiocephaly and orthotic treatment: Indications and limitations. *Childs Nerv. Syst.* 2012; **28**: 1407–12.
7 Wilbrand JF, Wilbrand M, Pons-Kuehnemann J *et al*. Value and reliability of anthropometric measurements of cranial deformity in early childhood. *J. Craniomaxillofac. Surg.* 2011; **39**: 24–9.
8 Wilbrand JF, Seidl M, Wilbrand M *et al*. A prospective randomized trial on preventative methods for positional head deformity: Physiotherapy versus a positioning pillow. *J. Pediatr.* 2013; **162**: 1216–21.
9 Kim SY, Park MS, Yang JI, Yim SY. Comparison of helmet therapy and counter positioning for deformational plagiocephaly. *Ann. Rehabil. Med.* 2013; **37**: 785–95.
10 Skolnick GB, Naidoo SD, Patel KB, Woo AS. Analysis of digital measures of cranial vault asymmetry for assessment of plagiocephaly. *J. Craniofac. Surg.* 2014; **25**: 1178–82.
11 Hutchison BL, Hutchison LA, Thompson JM, Mitchell EA. Quantification of plagiocephaly and brachycephaly in infants using a digital photographic technique. *Cleft Palate Craniofac. J.* 2005; **42**: 539–47.
12 Plank LH, Giavedoni B, Lombardo JR, Geil MD, Reisner A. Comparison of infant head shape changes in deformational plagiocephaly following treatment with a cranial remolding orthosis using a noninvasive laser shape digitizer. *J. Craniofac. Surg.* 2006; **17**: 1084–91.
13 Steinberg JP, Rawlani R, Humphries LS, Rawlani V, Vicari FA. Effectiveness of conservative therapy and helmet therapy for positional cranial deformation. *Plast. Reconstr. Surg.* 2015; **135**: 833–42.
14 Laughlin J, Luerssen TG, Dias MS. Prevention and management of positional skull deformities in infants. *Pediatrics* 2011; **128**: 1236–41.
15 Xia JJ, Kennedy KA, Teichgraeber JF, Wu KQ, Baumgartner JB, Gateno J. Nonsurgical treatment of deformational plagiocephaly: A systematic review. *Arch. Pediatr. Adolesc. Med.* 2008; **162**: 719–27.
16 Han MH, Kang JY, Han HY, Cho YH, Jang DH. Relationship between starting age of cranial-remolding-orthosis therapy and effectiveness of treatment in children with deformational plagiocephaly. *Childs Nerv. Syst.* 2017; **33**: 1349–56.
17 Bialocerkowski AE, Vladusic SL, Howell SM. Conservative interventions for positional plagiocephaly: A systematic review. *Dev. Med. Child Neurol.* 2005; **47**: 563–70.
18 Graham JM Jr, Gomez M, Halberg A *et al*. Management of deformational plagiocephaly: Repositioning versus orthotic therapy. *J. Pediatr.* 2005; **146**: 258–62.
19 Boere-Boonekamp MM, van der Linden-Kuiper LL. Positional preference: Prevalence in infants and follow-up after two years. *Pediatrics* 2001; **107**: 339–43.
20 Hutchison BL, Hutchison LA, Thompson JM, Mitchell EA. Plagiocephaly and brachycephaly in the first two years of life: A prospective cohort study. *Pediatrics* 2004; **114**: 970–80.