Treated Versus Untreated Positional Head Deformity

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Background: Positional head deformity in early childhood is asserted to be a benign and in some cases spontaneously correcting entity encountered in craniofacial surgery. Although many authors have stated that helmet therapy is indicated in moderate and severe cases of deformational plagiocephaly and brachycephaly; others have reported resolution of these conditions within the first 2 to 3 years of life. A recent randomized controlled trial found that helmet therapy does not have beneficial effects for patients with positional head deformity.

Methods: The authors evaluated the clinical course of positional cranial deformation during a period of 5 years and compared the anthropometric parameters of orthotically treated versus untreated children within this timeframe.

Results: Although the patients were matched with respect to their cranial deformation at baseline, there were significant differences in the cranial vault asymmetry (CVA), cranial vault asymmetry index (CVAI), and oblique cranial length ratio (OCLR) between Groups 1 and 2 at the initial point ($P < 0.05$). The mean CVA was 0.95 cm in Group 1 (no helmet) and 1.74 cm in Group 2 (helmet). The mean CVAI at baseline was 7.25 for Group 1 and 13.77 for Group 2. Approximately 5 years after the first examination, the authors found clear improvement in the mean CVA in Group 2 (ΔCVA 1.35 cm) compared with Group 1 (ΔCVA 0.01 cm) and the mean CVAI.

Conclusions: In contrast to recently published studies, the authors found clear improvement in nonsynostotic head deformity treated with an individual molding helmet and no clear evidence of improvement of absolute measurements in untreated cranial deformity within a 5-year follow-up period.

Key Words: Anthropometry, follow-up, helmet therapy, plagiocephaly

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A recently published randomized controlled trial regarding helmet versus no helmet therapy for early infant cranial deformation reported no benefit of orthotic treatment compared with a control group.[1] Based on these findings and data reported by others,[2,3] pediatricians, craniofacial surgeons, physiotherapists, and other professionals engaged in cranial deformation are becoming increasingly divided into advocates and opponents of orthotic correction of significant aberrances of cranial shape in early infancy. Opponents describe side effects, such as discomfort to the child,[1] the high cost of helmet therapy to the health care system,[4], skin irritation,[5–7] and absence of functional impairment caused by an abnormal cranial shape.[8] Recently presented data from the Netherlands and New Zealand seem to support the notion that nonsynostotic cranial deformity may spontaneously resolve.[1–3]. In contrast to those publications, advocates of helmet therapy cite data regarding the persistence of significant deformation,[9] mandibular asymmetry,[10,11] and neurocognitive deficiency as more of a trigger than a consequence of cranial deformity.[12] Advocates also state that sociopsychologic impairment might justify early correction of nonsynostotic deformity.[13–15] A study that evaluated the course of cranial deformation in two parallelized groups during 6 months by three-dimensional photogrammetry showed spontaneous correction of brachycephaly but minor improvement in plagiocephaly.[16] The children in that study were not randomized to helmet and nonhelmet treatment groups, but rather the 2 groups were parallelized according to their degree of cranial deformation at baseline to ensure equality and comparability of the groups. Data in that study were collected by three-dimensional photogrammetry in an automated manner to avoid inter- and intrarater variation in the measurements. Three-dimensional photogrammetry is known to produce reproducible results with high accuracy.[17,18] Two-dimensional cranial measurements have also shown good repeatability[19,20] and therefore are suitable for use in everyday practice. The results of the matched pair photogrammetric study from 2013,[16] however, are in high contrast to those of the randomized controlled trial performed in 2014,[1] although the latter was performed with approximately the same number of children and during the same period of time (N = 84 children examined within 6 months). The current manuscript presents data collected during a time frame of 5 years after the first assessment of children with nonsynostotic cranial deformity that were either treated with an individual molding helmet or left untreated.

MATERIALS AND METHODS

We selected 41 children (21 boys, 20 girls) with the greatest degree of cranial deformation from an overall cohort of 390 children who underwent anthropometric measurements and who were not treated with individual molding orthoses from January 2006 to December 2008. These patients constituted Group 1. For comparison to the results of previous studies, cranial deformation was judged by aberrance in the cranial vault asymmetry (CVA) (diagonal B – diagonal A), cranial vault asymmetry index (CVAI) (diagonal

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A – diagonal B/diagonal A × 100, where diagonal A < diagonal B),[7] cranial index (CI) (cranial width/cranial length × 100), and oblique cranial length ratio (OCLR) (diagonal B/diagonal A × 100).[19,21,22] All patients were anthropometrically re-evaluated approximately 5 years after the first assessment according to a previously standardized protocol.[20] Informed consent was provided by the patients' parents, and the collection of data was approved by the local ethics committee.

A blinded investigator (Nikolai Lautenbacher) compared the patients' data to the anthropometric data of 40 children (28 boys, 12 girls) treated with individual molding orthoses during the first year of life. These children were selected from a group of 859 children treated from January 2006 to December 2008. To the greatest extent possible, these children's cranial deformation at baseline was matched to that of the patients in Group 1 by selecting those with rather mild aberrances in the CVA, CVAI, and CI. These patients constituted Group 2.

All 81 patients were re-evaluated by 1 experienced examiner (Jan-Falco Wilbrand) with respect to their anthropometric measurements. The examiner was blinded to the group allocation of the individual children as well. Standard anthropometric examination included measurement of the cranial circumference, cranial length [glabella (g)–opisthocranion (op)], cranial width [eurion (eu)–eu], and transcranial diagonals A and B [frontotemporale (ft)–lambdoid (ld)]. Measurements were performed with a metric tape and spreading calipers following a previously established protocol[20] and fixed skeletal landmarks (Fig. 1).

Pairwise comparison was used for descriptive statistics. Data analysis was performed using SPSS version 20 software (IBM SPSS Statistics 20, IBM GmbH, Munich, Germany). If data were asymmetrically distributed, normalization was performed by logarithmic transformation. A linear mixed model was used to analyze the repeated-measure design. Statistical significance was assumed if $P < 0.05$. Differences between groups are presented as median with range or mean with standard deviation (SD).

For Group 2, a third anthropometric evaluation was performed approximately 6 months after the first assessment at the endpoint of helmet therapy.

In addition, photogrammetric scans were performed at the 5-year evaluation. The scans were automatically evaluated using Cranioform Analytics 4.0 software (Cranioform AG, Alpnach, Switzerland). Because photoscans were not yet being performed in a standard manner from 2006 to 2008, we could not compare the photogrammetrically collected data during the 5-year period.

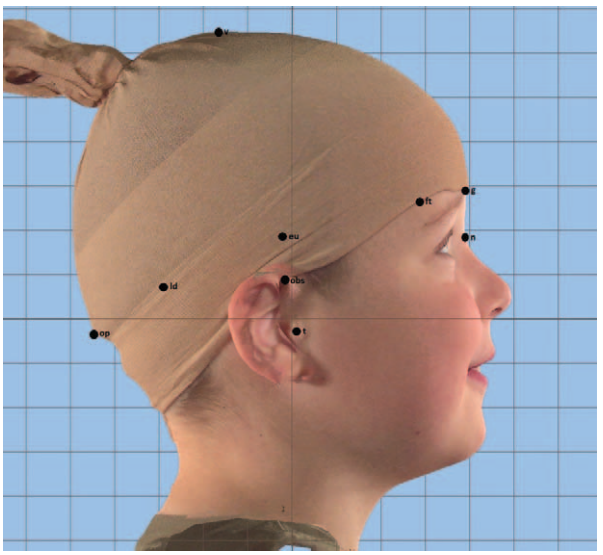

FIGURE 1. Skeletal landmarks of anthropometric cranial measurement as defined in[20] shown in a photogrammetric scan of a 5-year-old child. g, glabella, n, nasion, ft, frontotemporale, eu, eurion, obs, otobasion superius, t, tragus, v, vertex, ld, lambdoid, op, opisthocranion.

RESULTS

Anthropometric Measurements at First Examination

The median age at baseline (first examination) was 6.90 months (0.13–17.10 months) in Group 1 and 7.12 months (4.20–15.53 months) in Group 2 ($P = 0.6523$). The median cranial circumference was 44.50 cm (39.60–47.00 cm) in Group 1 and 43.95 cm (40.70–47.20 cm) in Group 2 ($P = 0.1147$). The cranial width was 12.80 cm (11.40–14.00 cm) in Group 1 and 12.65 cm (10.40–13.80 cm) in Group 2 ($P = 0.1297$). The cranial length was 13.70 cm (12.20–15.20 cm) in Group 1 and 13.6 cm (12.50–15.80 cm) in Group 2 ($P = 0.8780$). No statistically significant differences in age or cranial circumference, width, or length at baseline were found between the 2 groups.

The median CI at baseline was 92.43 (81.58–108.53) in Group 1 and 92.70 (72.15–110.40) in Group 2 ($P = 0.3735$). There were no significant differences between the 2 groups.

We, however, did find significant differences in the anthropometric values of the CVA and CVAI between the 2 groups. The baseline median CVA was 1.00 cm (0.10–2.00 cm) in Group 1 and 1.65 cm (0.10–4.10 cm) in Group 2 ($P < 0.05$). The baseline median CVAI was 7.35 (0.77–15.00) in Group 1 and 12.85 (0.74–39.42) in Group 2 ($P < 0.05$). The OCLR as presented by Hutchison[21] was 107% (101%–115%) in Group 1 and 113% (101%–139%) in Group 2.

Anthropometric Measurements After Helmet Therapy

An additional dataset was collected for Group 2 at the end point of helmet therapy. We found a median cranial circumference of 45.95 cm (42.90–49.60 cm), width of 13.00 cm (10.70–14.40 cm), length of 14.70 cm (13.50–16.50 cm), CVA of 0.20 cm (0.00–1.70 cm), CVAI of 1.42 (0.00–13.28), and OCLR of 101% (1.00%–1.13%).

Anthropometric Measurements at the 5-Year Control Assessment

After approximately 5 years [median age in Group 1: 71.30 months (57.03–88.80); median age in Group 2: 80.32 months (39.00–99.97)] ($P < 0.05$), a control assessment was performed. There was a significant difference in age between the 2 groups at this 5-year control assessment ($P < 0.05$). The median cranial circumference was 51.50 cm (49.00–55.10 cm; Δcircumference, 7 cm) in Group 1 and 51.40 cm (44.20–55.80 cm; Δcircumference, 7.45 cm) ($P = 0.0973$) in Group 2. The median cranial width after 5 years was 14.60 cm (13.30–16.00 cm; Δwidth, 1.80 cm) and 14.25 cm (11.60–16.00 cm; Δwidth, 1.60 cm) ($P = 0.2239$), respectively. The median cranial length was 17.10 cm (15.60–18.70 cm; Δlength, 3.40 cm) and 17.15 cm (14.60–19.10 cm; Δlength, 3.55 cm) ($P = 0.3864$). The median CVA was 1.00 cm (0.00–2.20 cm; ΔCVA, 0.00 cm) and 0.30 cm (0.00–1.70 cm; ΔCVA, 1.35 cm) ($P < 0.05$). The mean CVA changed from 0.95 cm (SD, 0.48) to 0.94 cm (SD, 0.45) in Group 1 and from 1.74 cm (SD, 0.73) to 0.39 cm (SD, 0.36) in Group 2. The median CVAI changed to 6.17 (0.00–13.25; ΔCVAI, 1.18) in Group 1 and to 1.83 (0.00–13.28; ΔCVAI, 11.02) in Group 2 ($P < 0.05$). The mean CVAI changed from 7.25 (SD, 3.76) to 5.99 (SD, 2.85) in Group 1 and from 13.77 (SD, 6.54) to 2.47 (SD, 2.49) in Group 2. The median OCLR was 106% (100%–113%) in Group 1 and 102% (100%–139%) in Group 2 (Table 1). There were no significant

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differences in the circumference, width, or length between the 2 groups at the 5-year control assessment.

Photogrammetric Measurements at the 5-Year Control Assessment

Although photogrammetric measurements are known to be highly reproducible and comparable with caliper measurements in early infancy,[23] we found that the early measurements differed from those at the age of 5 years. This aberrance was primarily because of the greater amount of hair in older children, which cannot be excluded from the photographic scan and anthropometric measurement dataset (Fig. 2).

The median circumference at the 5-year control scan was 52.40 cm (49.60–56.60 cm) in Group 1 and 53.35 cm (48.70–57.00 cm) in Group 2. The median width was 14.70 cm (12.10–17.20 cm) and 14.70 cm (13.00–16.40 cm), respectively. The median length was 17.75 cm (15.90–19.40 cm) and 18.10 cm (16.00–19.50 cm). The median CI was 83.15 (67.22–90.53) and 81.25 (73.86–90.36). The median CVA was 0.75 cm (0.00–1.50 cm) and 0.70 cm (0.00–1.70 cm). The median CVAI was 4.31 (0.00–9.09) and 3.97 (0.61–11.64). No photoscans of the patients at baseline were available to compare the photogrammetric results at that point in time.

DISCUSSION

In contrast to the results of other authors,[1–3] our data did not show significant spontaneous improvement in cranial deformation within a timeframe of 5 years (median CVA at baseline, 1.00 cm; after 5 years with calipers, 1.00 cm; after 5 years with photogrammetry, 0.75 cm). To the best of our knowledge, the current study is the first trial to investigate treated versus untreated cranial deformation during 5 years in a parallelized and simple-blinded design. We matched groups of treated and untreated children instead of performing a randomized study with a possible lack of comparability between the 2 groups in the end.

Unfortunately, the matching process was not perfect because we still found significant differences between the 2 groups at baseline. The degree of cranial deformation, however, was mild to moderate (OCLR of 107%) in Group 1 and severe (OCLR of 113%) in Group 2 as defined in a recent article (OCLR of $\geq$108%).[1] Following the definition of Hutchison,[2] both groups met the "case" definition. Following our own 2012 definition of cranial deformity based on normative percentiles during the first year of life,[24] both groups exhibited the degree of moderate to severe cranial asymmetry.

The anthropometric examiner in this study was blinded to the group allocation of the individual patients. This approach was chosen to ensure objectivity.

We found significant differences between the groups regarding the changes in CVA, CVAI, and OCLR during the 5-year period. van Wijk et al[1] concluded that the only parameter influencing changes in the cranial shape was the severity of cranial deformation at baseline. We cannot disprove this statement with our data, but we did take notice of the clear differences in the changes of deformities with and without orthotic therapy. Nevertheless, using the definition reported by van Wijk et al (ie, that an OCLR of <104% indicates full recovery), we assert that only children with a history of helmet therapy recovered in our study population (Fig. 3A-B). It is crucial to consider the individual changes in calculated anthropometric parameters, such as the CVAI[7] or OCLR[2] [also termed the oblique diameter difference index (ODDI)][1] during time. Spontaneous improvement in these parameters will likely be seen only according to the amount of cranial growth. As absolute cranial asymmetry stagnates, other cranial dimensions change, and the calculated parameters will dissolve to some extent.

TABLE 1. Results of Anthropometric Measurements After Statistical Analysis for Group 1 (Untreated) and Group 2 (Treated) at Origin, After Treatment (for Group 2 Only) and After 5 Years

	First Evaluation (1)			After Helmet Treatment (2)			Five-Year Assessment (3)				
	Group 1 (Untreated)	Group 2 (Treated)	P	Group 1 (Untreated)	Group 2 (Treated)	P	Group 1 (Untreated)	Δ_1 (1–3)	Group 2 (Treated)	Δ_2 (1–3)	P
N	41	40		0	40		41		40		
Sex (m/f)	21 m/20 f	28 m/12 f			28 m/12 f		21 m/20 f		28 m/12 f		
Median age	6.90 months	7.12 months	0.652 months		13.52 months		71.30 months	64.40 months	80.32 months	73.20 months	<0.05
Median CVA	1.00 cm	1.65 cm	<0.05		0.20 cm	/	1.00 cm	0.00 cm	0.30 cm	1.35 cm	<0.05
Mean CVA	0.95 cm	1.74 cm					0.94 cm	0.01 cm	0.39 cm	1.35 cm	<0.05
Median CVAI	7.35	12.85	<0.05		1.42	/	6.17	1.18	1.83	11.02	<0.05
Mean CVAI	7.25	13.77					5.99	1.26	2.47	11.30	<0.05
Median CI	92.43	92.70	0.373		88.44	/	85.38	7.05	83.09	9.61	0.305
Median OCLR	107%	113%	<0.05		101%	/	106%	1%	102%	12%	<0.05

Mean values are shown for asymmetric distributed data normalized by logarithmic transformation. CI, cranial index, CVA, cranial vault asymmetry, CVAI, cranial vault asymmetry index, OCLR, oblique cranial length ratio.

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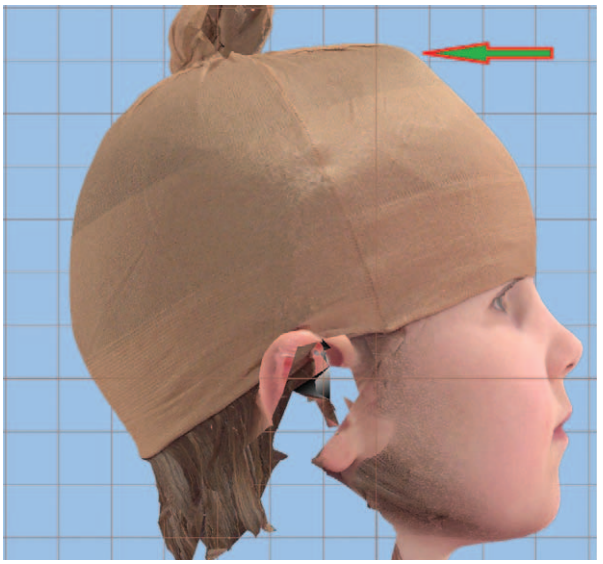

FIGURE 2. Bad quality and impairment of measurability of a photogrammetric scan is mainly because of an accumulation of hair (arrow).

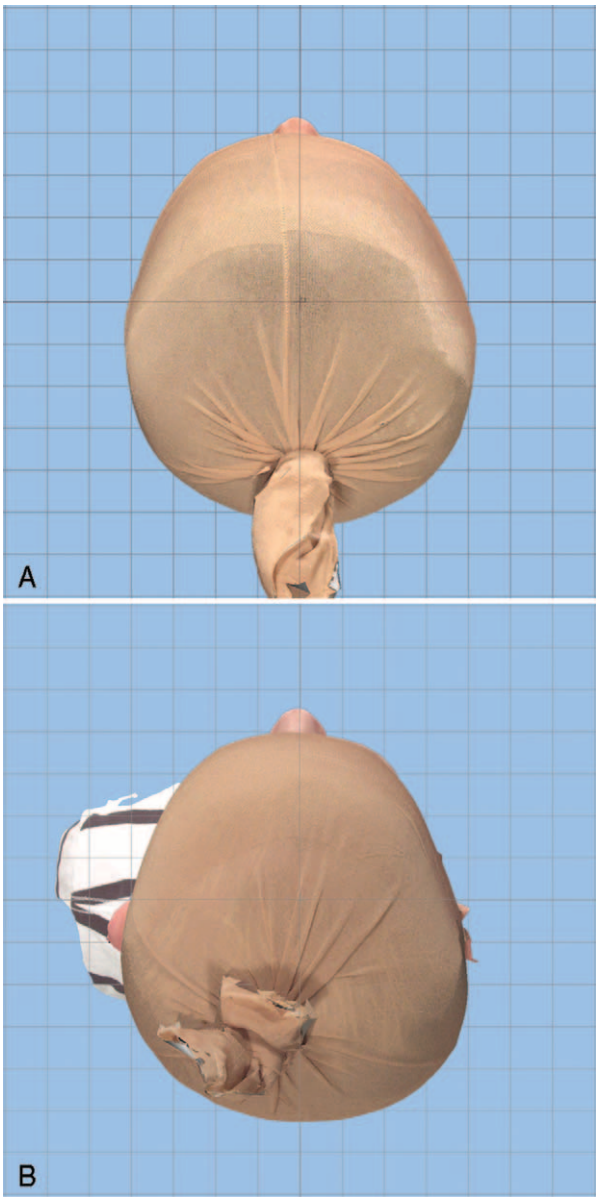

FIGURE 3. A, Vertex view of a photogrammetric scan of a 5-year-old child with history of helmet therapy (exemplary case, initial CVA at 6 months of age = 1.5 cm). B, Vertex view of a photogrammetric scan of a 5-year-old child without history of helmet therapy (exemplary case, initial CVA at 6 months of age = 1.6 cm). CVA, cranial vault asymmetry.

The absolute anthropometric value of cranial asymmetry measured in centimeters, CVA, did not significantly improve during cranial growth in the current cohort. Cranial length, however, increased more rapidly than cranial width, giving the cranium a more elliptical shape overall. This is in line with the physiological growth of the human neurocranium during childhood. The CI spontaneously improves to some degree and does not necessarily require treatment with an individual molding helmet in mild to moderate cases.[16,25] In contrast, cranial asymmetry remains largely unchanged during the years but becomes more inconspicuous because of the greater increase in cranial circumference and length compared with cranial width. The CVAI and OCLR/ODDI somewhat diminish spontaneously during time (Fig. 4A-B). This improvement is relative, not absolute.[26] Hutchison et al[2] also described this phenomenon. The mean differences between the transcranial diagonals in their cohort were 9.8 mm at 6 weeks, 11.3 mm at 4 months, 10.3 mm at 8 months, 11.1 mm at 12 months, and 12.0 mm at 24 months of life. Although spontaneous improvement in plagiocephaly as measured by the OCLR was reported in that article, the absolute values of cranial asymmetry remained unchanged. Regrettably, absolute cranial measurements were not provided by van Wijk et al[1] Eighty-four children were included and randomly allocated to one or the other treatment protocol. The groups in that study also showed statistically significant differences in the degree of cranial deformation at baseline. The helmet group in their study had a lower ODDI (107.2) than did the untreated group (109.2). This contrasts with our study (107 in the untreated group versus 113 in the treated group). The changes in absolute cranial measures found in the current study significantly differ from their results (untreated group: median ΔCVA, 0.00 cm; treated group: median ΔCVA, 1.35 cm). Therefore, we remain confident that significant nonsynostotic cranial deformity can be corrected with individual molding helmets in early infancy.

Side effects, parental anxiety, quality of life, motor development, and other parameters were not statistically addressed in the current study. Some parents in both groups reported that they still recognized some degree of deformity of their child's head. This, however, occurred in sporadic cases. The frequency of complications associated with helmet therapy has been previously evaluated[6] and has not perceivably changed since then. In contrast, the number of complications observed by van Wijk et al[1] seems very high (up to 96%) compared with the data of other authors[27,28]. This might be an important cause of the discouraging results in the treated group and equality of effects between the groups. van Wijk et al[1] reported that 75% of all children had persistent skull deformation at 2 years of age regardless of whether the children were treated with an individual molding helmet. Such a high degree of uncorrected cranial deformities could lead practitioners to forgo performing any therapeutic procedure for clinically significant cranial deformity and define nonsynostotic cranial deformity in early childhood as an incurable burden. The disturbance in the individual effectiveness of the molding helmets used in van Wijk et al study—which might possibly be because of the high number of side effects—was not discussed by the authors.

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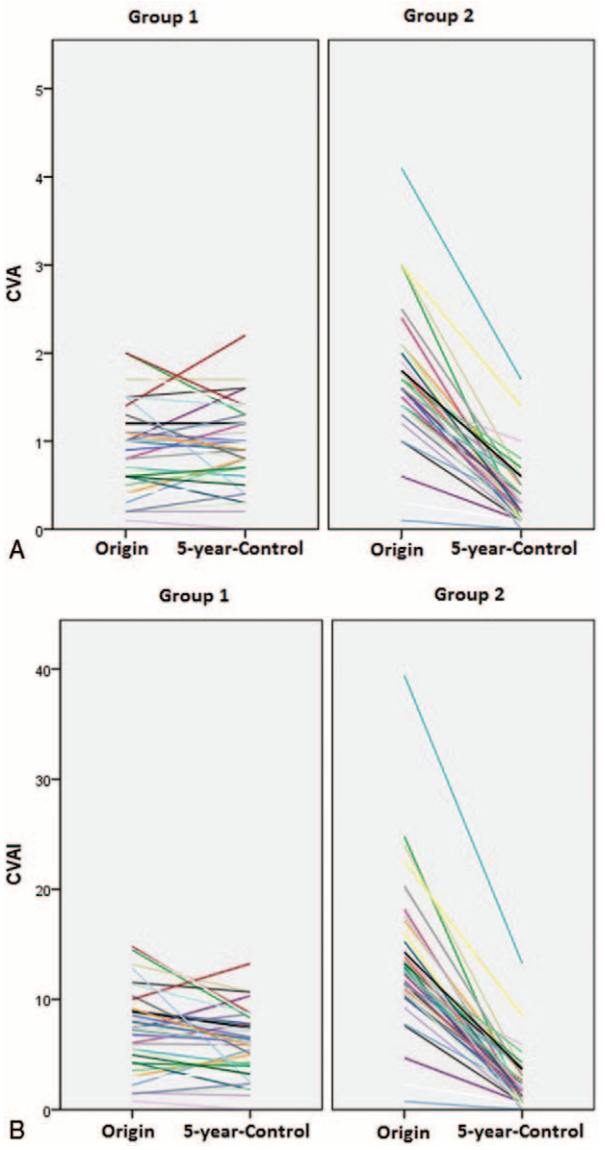

FIGURE 4. A, Individual development of cranial vault asymmetry for Group 1 (N = 41) and Group 2 (N = 40). B, Individual development of cranial vault asymmetry index for Group 1 (N = 41) and Group 2 (N = 40).

Although the results of the current study might not represent the final conclusion regarding the use of helmets for infant nonsynostotic cranial deformation, we have shown that helmet therapy does have a significant effect and nonsynostotic cranial deformity is correctable. It would have been remarkable if directing the cranial growth for >23 hour per day in a corrective manner did not lead to any improvement of cranial deformation compared with natural growth. Considering the physiological background of the development of infant cranial deformity, we know that this deformation emerges because of imbalanced bedding and unilaterally restricted growth of the head. Deliberately induced cranial deformity can remain unchanged for a lifetime.[29] Improvement in cranial deformation by nonorthotic methods is assured if it is addressed early by physiotherapy, bedding pillows, osteopathic medicine, or similar means.[30–32] Physiotherapy leads to improved mobility of a child. It, however, is not allegeable that nonyielding growth after removal of the imbalance inducing cranial deformation should take place exclusively in a corrective direction and spontaneously normalize the cranial shape after the sixth month of life, for instance. If the mobility of the child normalizes, cranial growth would physiologically take place equally in all directions and the head would increase in size and become more elliptical, but not more symmetric, in absolute numbers. The currently available data of all authors (1–3, 16), however, shows no full correction of nonsynostostic cranial deformity by natural growth if it is measured in absolute numbers. This is valid for asymmetry of the head and for most cases (75% in the randomized controlled trial). The absence of correction of cranial deformation in infancy despite helmet therapy cannot be reproduced by our data.

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