Journal of Cranio-Maxillo-Facial Surgery 47 (2019) 720–725

Contents lists available at ScienceDirect

Journal of Cranio-Maxillo-Facial Surgery

journal homepage: www.jcmfs.com

Outcome analysis of molding helmet therapy using a classification for differentiation between plagiocephaly, brachycephaly and combination of both

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ARTICLE INFO

Article history:
Paper received 10 September 2018
Accepted 8 January 2019
Available online 17 January 2019

Keywords:
Plagiocephaly
Brachycephaly
Molding helmet
Molding orthosis

ABSTRACT

Purpose: The incidence of positional head deformation has increased during the last decades. Helmet therapy has been proved to be a reliable method for the treatment of nonsynostotic skull deformities. Until today, a simple classification to differentiate between different head shapes has not been established.
Materials and methods: We suggest a classification system to group patients with plagiocephaly, brachycephaly, and a combination of both, using two simple values: cranial vault asymmetry (CVA), and cephalic index (CI). We further analyzed a study population of 1050 children treated with molding helmets to identify prognostic variables for better outcome within our proposed classification.
Results: In all, 736 patients were male (70.10%) and 314 patients were female (29.90%). Mean improvement of cranial vault asymmetry index (CVAI) ranged from 2.94% to 7.08% (CVA 0.37 cm −0.86 cm) in subgroups of patients defined by classification and severity of deformation. In patients with brachycephaly, CI improved from 4.17% to 8.22%. Duration of therapy differed from 21 weeks to 24 weeks. Children aged 6 months or less showed greater improvement and shorter duration of therapy compared to older patients. In addition to early onset of therapy, classification and severity of deformation were significantly associated with a reduction of the deformation under therapy. There were distinct differences in outcomes between different head shapes.
Conclusion: Helmet therapy should be initiated early. Our analysis suggests that the proposed classification correctly identifies patients whose deformation is reduced under therapy.
Level of evidence: III.

1. Introduction

Since the introduction of the “back to sleep” campaign in 1992 to reduce the incidence of sudden infant death syndrome (SIDS), the occurrence of head deformities in infants has vastly increased. Extended time in the supine position may lead to a symmetrical posterior flattening of the head which is called brachycephaly. If a child turns its head to a preferred side, the skull may flatten asymmetrically, referred to as plagiocephaly. Helmet therapy has been proved to be a reliable method for the treatment of nonsynostotic skull deformities (Teichgraeber et al., 2004; Yoo et al., 2012; Couture et al., 2013). While there is an ongoing discussion about the necessity of helmet therapy, parameters for good outcomes have been identified: young age at initiation of therapy, and proper application of the orthosis (van Wijk et al., 2014; Freudlsperger et al., 2016; Lam et al., 2017).

Young infants presenting with head deformation should be checked carefully to treat the underlying pathology, since there are options to improve the shape of the head (Moss, 1997; Carson et al., 2000; Loveday and de Chalain, 2001; Persing et al., 2003; van Vlimmeren et al., 2008; Wilbrand et al., 2013).

In the literature, there have been few differentiations presented between plagiocephalic and brachycephalic head deformation. The success of helmet therapy has therefore been evaluated with no regard to diverse entities. Wilbrand et al. proposed a classification

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https://doi.org/10.1016/j.jcms.2019.01.011
1010-5182/

in 2012 by using both the cranial vault asymmetry index (CVAI) and the cephalic index, (CI) and grouped deformations into plagiocephaly, brachycephaly and a combination of both according to severity (Wilbrand et al., 2012). In their study, 410 infants had been evaluated by manual caliper measurements. However, no absolute cut-off values for the groups "mild," "moderate" and "severe" were published. Schaaf et al. analyzed a study population of 181 patients with head deformation and a classification for different entities (plagiocephaly [CVAI > 3%], brachycephaly [CI > 92%] and combination of both) using CVAI and CI with the help of 3-dimensional (3D) photogrammetric images (Schaaf et al., 2010). Doerhage et al. grouped their study population similarly without stating which classification was used (Dörhage et al., 2016). In contrast, other authors described the variation of head deformities as a "continuum" without individual entities (Meyer-Marcotty et al., 2014).

According to our own previous experience, we assume that there is a real difference among the various entities of skull deformity, with the need for reliable classification for indication of treatment and evaluation of therapy success. However, eventually a less complex classification system could be appropriate to grade between plagiocephalic and brachycephalic head deformities using a simple parameter for plagiocephaly, namely, cranial vault asymmetry (CVA) and CI for brachycephaly. CVA was selected on purpose since the parameter needs no calculation and the authors wish to propose an easy-to-use classification for clinicians.

For further investigation and hopefully confirmation of this theory, and to show the importance of discrimination among different head shapes, we applied our classification to a study population of 1050 patients treated with molding helmets and analyzed the data for outcomes.

Some authors emphasize the importance of young age and recommend beginning helmet therapy between 4 and 6 months of age (Kelly et al., 1999; Dörhage, 2010; Kluba et al., 2011; Mortenson et al., 2012; Yoo et al., 2012). Han et al. declare the age of 5 months to be the optimal starting point for helmet therapy (Han et al., 2017). However, their recommendation is supported by data from 310 patients with only plagiocephalic deformation. Therefore, another point of interest of the present study was to reproduce the finding that early onset of therapy is positively associated with outcome.

2. Materials and methods

2.1. Study design and study population

A retrospective, non-randomized study was conducted at the "Craniocenter" of an orthopedic department to evaluate patients who were treated for skull deformation between April 2008 and the end of 2012. Indication for helmet therapy was clarified by the same physician for each patient via clinical and photogrammetric aspects. Inclusion criteria for this study required treatment with an orthosis and proper 3D-camera scans before and after treatment. The ethics committee's approval for this study was given on October 14, 2011.

2.2. Helmet therapy

The severity of skull deformation was determined using a 3D camera (Vectra M5, Canfield, Parsippany, NJ) and corresponding software (Cranio Analytics 3.0). Hereby the CVA, CVAI and CI were assessed. CVA is the difference between the longest and the shortest cranial diameter, both measured at a 30° angle from the anterior-posterior line, whereas the CVAI is the ratio of the CVA and the shortest cranial diameter multiplied by 100. Both CVA and CVAI represent plagiocephaly. For evaluation of brachycephaly, CI was used, which is the ratio between width and length of a skull multiplied by 100 (Fig. 1) (Loveday and de Chalain, 2001).

Therapy was initiated when clinical impression indicated the use of an orthosis, mostly if CVA was greater than 1 cm or CI more than 100%. Patients were excluded from therapy if their age exceeded 12 months, if they showed signs of cranial synostosis, or if any other disease prohibited the use of an orthosis. Each individual orthosis was manufactured by the same company (Cranioform AG, Alpnach, Switzerland). The orthosis was then fitted at the Craniocenter by the attending physician to reduce skin irritation and to achieve a comfortable fit. Therapy was managed by the patient's caregivers, who were advised to apply the orthosis for at least 23 hours per day and to perform a daily cleaning. Progress of therapy was monitored every 4–8 weeks using a 3D-camera scan, and the orthosis was altered if necessary. Therapy was ended when the child did not tolerate the helmet any longer or when parameters for plagiocephaly and brachycephaly came close to standard value.

2.3. Measurements and database

Cranio Analytics 3.0 was used to calculate before-therapy and after-therapy measurements. The software divides the skull into 12 horizontal outlines and calculates the corresponding data (Fig. 2). Both measurements were gathered from the outline with the largest circumference. Further information about the patients, such as date of birth and duration of therapy. were taken from the Craniocenter's ambulance software "TurboMed" (CompuGroup Medical Deutschland AG, Molfsee, Germany). Before performing any biometrical analysis, the database was anonymized.

2.4. Classification

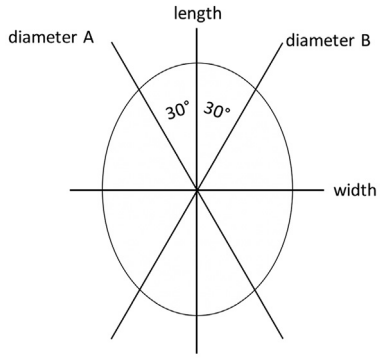
As stated before, we wanted to propose a classification to differentiate among plagiocephaly, brachycephaly, and skull deformations with a combination of both. Therefore, we defined groups using CI and CVA according to our clinical experience (Table 1). Patients with CI of 90% or less and CVA greater than 1 cm were categorized as plagiocephalic (P). Patients with CI more than 90% and CVA of 1 cm or less were categorized as brachycephalic (B). The combination of both (P/B) was defined by CI higher than 90% and CVA greater than 1 cm. Patients with CI of 90% or less and CVA of 1 cm or less were defined to be borderline (X). Persons of this group showed indeed no clear indication for helmet therapy according to our photogrammetric definition; however, clinical impression led to initiation of orthosis treatment as well.

Non-compliance was defined as growth of the skull in the opposite direction as guided by the orthosis. For children with brachycephaly, non-compliance was assumed if the width of the head increased by more than a 0.5 cm. For children with plagiocephaly or a combination of plagiocephaly and brachycephaly, non-compliance was assumed when the larger diagonal increased by more than 1 cm.

2.5. Data analysis

According to our classification, we checked the distribution of patients among the groups. We determined baseline values for each parameter.

The main aim of further analyses was to identify potential variables associated with outcome of patients treated with helmet therapy. Therefore, analyses of covariance (ANCOVA) were performed on the outcomes CVA, CVAI, CI, and ear offset, each adjusted for duration of treatment, onset of treatment, baseline value of the respective outcome variable classification (P, P/B, B), compliance with therapy, and year of therapy onset. The latter was included as a nuisance parameter to correct for potential changes in standard of care at the clinic (such as learning effects or change in clinical



$$\text{Cranial Vault Asymmetry (CVA)} = \text{longest diameter} - \text{shortest diameter}$$

$$\text{Cranial Vault Asymmetry Index (CVAI)} = \frac{\text{CVA}}{\text{shortest diameter}} \times 100$$

$$\text{Cranial (craniproportional) Index (CI)} = \frac{\text{width}}{\text{length}} \times 100$$

Fig. 1. Calculation of cranial vault asymmetry (CVA), cranial vault asymmetry index (CVAI) and cephalic index (CI).

infrastructure or personnel). Borderline patients were not included in this analysis. The significance level was set to 5% for all analyses. Multiplicity was not corrected for due to the exploratory nature of the analysis.

ANCOVA was performed using SAS (SAS software, Version 9.3 of the SAS System for Windows; SAS Institute, Cary, NC) and by the authors using Microsoft Excel (Microsoft Corporation, Redmond, WA).

The mean improvement in CVA, CVAI, CI, and ear offset was calculated for each group, and each group was divided into subgroups defined by age.

3. Results

3.1. Classification, age, and sex

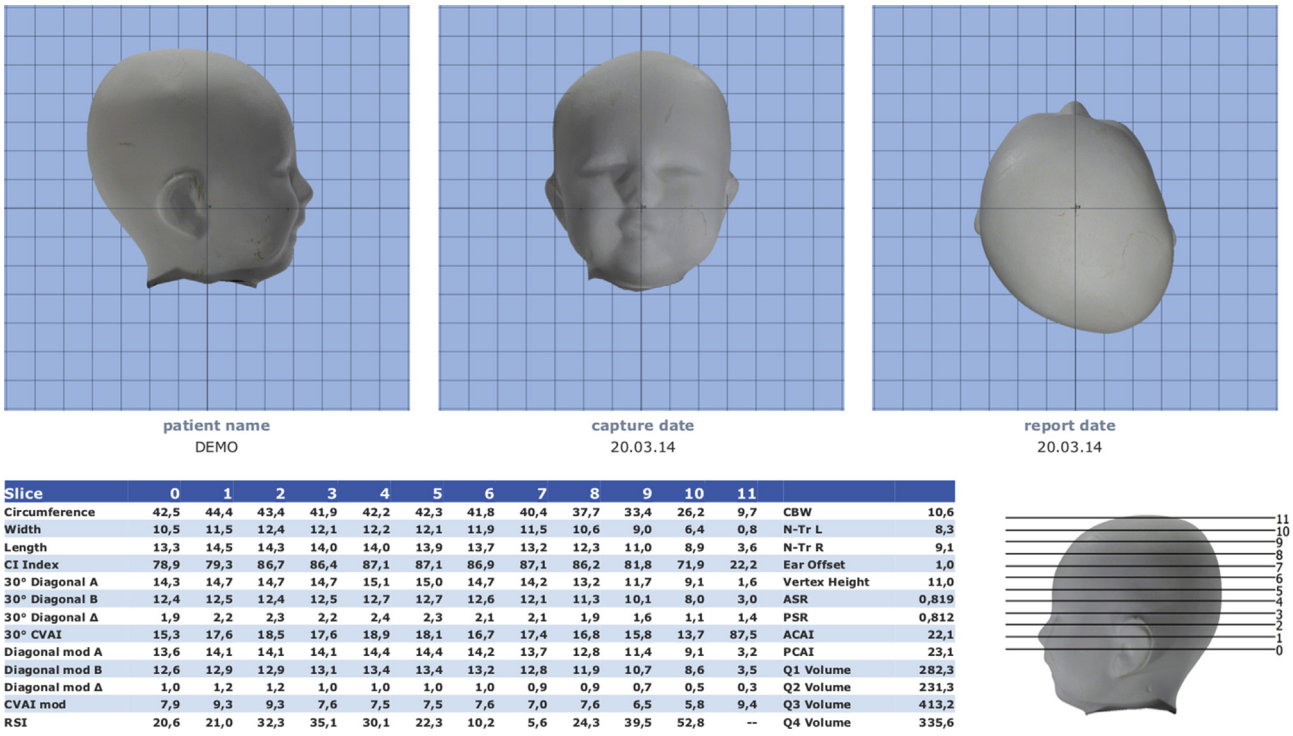
A total of 1050 patients were included in this study; another further 108 patients had been disqualified because of missing/unuseable 3D images or unfinished therapy. In all, 736 patients were male (70.10%) and 314 patients were female (29.90%). When applying our classification for head deformities, we found 410 (39.04%) patients to be strictly plagiocephalic (P). A total of 406 (38.67%) children showed a combination of plagiocephaly and brachycephaly (P/B). A total of 182 (17.3%) patients were grouped as brachycephalic (B). In all, 52 (4.95%) infants were grouped as borderline (X). At the start of therapy 30.57% (n = 321) of the study's population were at the age of 4–6 months, 56.48% (n = 593) between 7 and 9 months, and 12.95% (n = 136) 10 months and above.

3.2. Baseline values

Baseline values for plagiocephaly in groups P and P/B were 1.561 cm and 1.551 cm for CVA and 11.34% and 11.49% for CVAI. Baseline CI in group B was 98.73% and increased in group P/B to 95.60%. The highest mean ear-offset was calculated for patients grouped P with 0.74 cm. Patient age at initiation of therapy ranged from 7.82 months (P/B) to 8.88 months (X) (Table 2).

3.3. Duration of therapy

The mean duration of therapy was 24.21 weeks in group P and 24.70 weeks in P/B. For patients grouped as B, treatment was finished after an average of 21.73 weeks. Patients classified as borderline (X) needed an average of 18.88 weeks to complete therapy.



Slice	0	1	2	3	4	5	6	7	8	9	10	11		
Circumference	42,5	44,4	43,4	41,9	42,2	42,3	41,8	40,4	37,7	33,4	26,2	9,7	CBW	10,6
Width	10,5	11,5	12,4	12,1	12,2	12,1	11,9	11,5	10,6	9,0	6,4	0,8	N-Tr L	8,3
Length	13,3	14,5	14,3	14,0	14,0	13,9	13,7	13,2	12,3	11,0	8,9	3,6	N-Tr R	9,1
CI Index	78,9	79,3	86,7	86,4	87,1	87,1	86,9	87,1	86,2	81,8	71,9	22,2	Ear Offset	1,0
30° Diagonal A	14,3	14,7	14,7	14,7	15,1	15,0	14,7	14,2	13,2	11,7	9,1	1,6	Vertex Height	11,0
30° Diagonal B	12,4	12,5	12,4	12,5	12,7	12,7	12,6	12,1	11,3	10,1	8,0	3,0	ASR	0,819
30° Diagonal Δ	1,9	2,2	2,3	2,2	2,4	2,3	2,1	2,1	1,9	1,6	1,1	1,4	PSR	0,812
30° CVAI	15,3	17,6	18,5	17,6	18,9	18,1	16,7	17,4	16,8	15,8	13,7	87,5	ACAI	22,1
Diagonal mod A	13,6	14,1	14,1	14,1	14,4	14,4	14,2	13,7	12,8	11,4	9,1	3,2	PCAI	23,1
Diagonal mod B	12,6	12,9	12,9	13,1	13,4	13,4	13,2	12,8	11,9	10,7	8,6	3,5	Q1 Volume	282,3
Diagonal mod Δ	1,0	1,2	1,2	1,0	1,0	1,0	1,0	0,9	0,9	0,7	0,5	0,3	Q2 Volume	231,3
CVAI mod	7,9	9,3	9,3	7,6	7,5	7,5	7,6	7,0	7,6	6,5	5,8	9,4	Q3 Volume	413,2
RSI	20,6	21,0	32,3	35,1	30,1	22,3	10,2	5,6	24,3	39,5	52,8	--	Q4 Volume	335,6

Fig. 2. Measurements gathered from a 3-dimensional model using Cranio Analytics 3.0.

Table 1
Definition of groups.

P	P/B	B
CI ≤ 90%; CVA ≥1 cm	CI > 90%; CVA >1 cm	CI > 90%; CVA ≤1 cm

Each group is defined by a combination of cranial index (CI) and cranial vault asymmetry (CVA). P = plagiocephaly, B = brachycephaly.

3.4. Analysis of covariance

ANCOVA was conducted for the parameters CVA, CVAI, CI, and ear-offset for the groups P, P/B, and B. Tables 3–5 present the values for estimator with p-values. The analysis of covariance for CVA [CVAI in brackets] showed an estimator of 0.003 [0.038] for the variable "duration" (p-values 0.436 and 0.185), −0.066 [−0.483] for the variable "age at initiation" (p-values <0.0001), and 0.477 [0.557] for the variable "baseline" (p-values < 0.0001). When analyzed for CI, the estimator for "duration" was 0.199, for "age at initiation" −0.217, and for "CI baseline" 0.341 (all p-values <0.0001).

For the variable "compliance," the estimators are 0.18 (CVA), 1.02 (CVAI), and −1.24 (CI).

3.5. Improvement of parameters

The mean improvements in the parameters CVA, CVAI, CI, and ear-offset of each group are shown in Tables 6–8. Each group was divided into three subgroups (4–6 m, 7–9 m, ≥10 m). Group 4–6 m included children aged 4 to less than 7 months. In group 7–9 m, infants were included who were aged 7 to less than 10 months. Group ≥10 m included children aged 10 months or above.

Patients grouped as plagiocephalic (P) showed a mean reduction of 0.63 cm (CVA) or 5.14% (CVAI). For the parameters CVA, CVAI and ear-offset subgroup 4–6 m demonstrated the greatest improvement of all groups (0.85 cm; 6.99%; 0.25 cm) whereas the mean duration of therapy was almost equal to the entire group P (24.04 weeks vs. 24.20 weeks). Initial asymmetry was equally spread over all groups, with a small peak in the age group between 4 and 6 months (CVA 1.63 cm; CVAI 12.22%).

For infants considered to be plagiocephalic and brachycephalic (P/B) at the same time, asymmetry improved of about 0.72 cm (CVA) or 5.92% (CVAI). In total, the CI was reduced by 6.00%. The subgroup 4–6 m showed the greatest improvement of all of the parameters (CVA 0.86 cm; CVAI 7.08%; CI 6.59%), with the shortest duration of therapy (22.29 weeks) compared to the other subgroups.

Group B (brachycephaly) presented the greatest overall improvement of CI (7.07%) compared to group P and P/B. Subgroup 4–6 m showed a greater improvement than subgroups 7–9 m and ≥10 m (8.22% vs. 5.43%). Also, the duration of therapy was shorter in the younger age groups. For example, the mean duration of therapy was 19.29 weeks in subgroup 4–6 m and 26.52 weeks in subgroup ≥10 m.

In summary, each subgroup 4–6 m within the groups P, P/B, and B showed the greatest improvement in the relevant parameters. The mean duration of therapy was shorter in younger subgroups (P/B and B) or equal to the other subgroups (P).

4. Discussion

The presented study population is one of the largest ever published in the literature. The distribution of sex in our study, with the majority of patients (70.10%) being male, complies with other collectives (Kluba et al., 2011, 2014). Patients with moderate to severe plagiocephaly (CVAI 11.34% and 11.49%) and persons with moderate to severe brachycephaly (CI 95.60%–98.73%) were treated with

Table 2
Baseline values for each group.

Group	N	Variable	Mean	SD	Minimum	Maximum
P	410	CVA	1.56	0.35	1.10	2.90
M 65.85%		CVAI	11.34	2.77	7.43	21.77
F 34.15%		CI	84.64	3.92	70.25	90.00
		ear-offset	0.74	0.37	0.00	2.10
		width	12.55	0.60	10.10	14.20
		age	7.95	1.90	4.06	15.27
P/B	406	CVA	1.55	0.35	1.10	3.10
M 76.60%		CVAI	11.49	2.86	7.19	23.77
F 23.40%		CI	95.60	4.34	90.07	115.74
		ear-offset	0.57	0.31	0.00	1.60
		width	13.42	0.63	11.60	15.40
		age	7.82	1.83	4.39	15.90
B	182	CVA	0.66	0.29	0.00	1.00
M 69.23%		CVAI	4.76	2.13	0.00	8.06
F 30.77%		CI	98.73	4.79	90.13	111.85
		ear-offset	0.30	0.27	0.00	1.80
		width	13.68	0.63	11.80	15.70
		age	8.37	1.77	4.65	14.88
X	52	CVA	0.838	0.202	0.000	1.000
M 55.77%		CVAI	5.887	1.452	0.000	7.752
F 44.23%		CI	84.206	4.083	73.885	90.000
		ear-offset	0.542	0.349	0.000	1.300
		width	12.537	0.726	10.700	13.800
		age	8.888	2.281	4.492	16.918

Baseline values for each group. CVA, ear-offset and width in centimeters; CVAI and CI in percentage; age in months. N = number of patients. M = male; F = female. P = plagiocephaly, B = brachycephaly, X = borderline. Each variable is a mean value with standard deviation (SD) and minimum/maximum.

Table 3
Analysis of covariance for CVA.

Variable	estimator	p-value	95% confidence interval	
Duration	0.00	0.44	−0.01	0.01
Age at initiation	−0.07	<0.0001	−0.075	−0.06
CVA Baseline	0.48	<0.0001	0.43	0.53
Compliance y/n	0.18	<0.0001	0.11	0.24
P vs B	−0.11	0.001	−0.18	−0.05
P/B vs B	−0.02	0.48	−0.09	0.04
2012 vs 2008	0.06	0.15	−0.02	0.14
2011 vs 2008	0.07	0.03	0.01	0.13
2010 vs 2008	0.07	0.02	0.01	0.14
2009 vs 2008	0.01	0.8	−0.06	0.07

Analysis of covariance for the parameter CVA. A positive estimator indicates positive association with the target variable, while a negative estimator indicates negative association with the target variable. Significant results are marked grey.

Table 4
Analysis of covariance for CVAI.

Variable	estimator	p-value	95% confidence interval	
Duration	0.04	0.19	−0.02	0.1
Age at initiation	−0.48	<0.0001	−0.551	−0.416
CVAI Baseline	0.56	<0.0001	0.512	0.603
Compliance y/n	1.02	<0.0001	0.55	1.48
P vs B	−1.03	<0.0001	−1.47	−0.59
P/B vs B	−0.37	0.1	−0.81	0.07
2012 vs 2008	0.44	0.12	−0.12	0.1
2011 vs 2008	0.5	0.03	0.06	0.94
2010 vs 2008	0.22	0.01	0.11	0.98
2009 vs 2008	0.04	0.85	0.4	0.49

Analysis of covariance for the parameter CVAI. A positive estimator indicates positive association with the target variable, while a negative estimator indicates negative association with the target variable. Significant results are marked grey.

Table 5
Analysis of covariance for CI.

Variable	estimator	p-value	95% confidence interval	
Duration	0.2	<0.0001	0.12	0.27
Age at initiation	−0.22	<0.0001	−0.31	−0.13
CI Baseline	0.34	<0.0001	0.3	0.38
Compliance y/n	−1.24	0.0002	−1.9	−0.58
P/B vs P	−0.19	0.49	−0.74	0.36
B vs P	0.13	0.73	−0.58	0.84
2012 vs 2008	1.04	0.009	0.26	1.82
2011 vs 2008	0.38	0.23	−0.24	0.99
2010 vs 2008	0.78	0.01	0.178	1.38
2009 vs 2008	0.66	0.04	0.04	1.29

Analysis of covariance for the parameter CI. A positive estimator indicates positive association with the target variable, while a negative estimator indicates negative association with the target variable. Significant results are marked grey.

molding helmets (Moss, 1997; Hutchison et al., 2005; Mortenson and Steinbok, 2006; Wilbrand et al., 2012; Yoo et al., 2012).

The analysis of covariance shows a significant negative association between age at initiation of therapy and improvement of parameters CVA, CVAI, or CI. This means that younger children show greater improvement. The duration of therapy was not significantly associated with changes in CVA, CVAI, and ear-offset but significantly correlated with a positive development of CI. Higher baseline values correlate with greater improvement. This is true for all three groups. For the variables CVA and CVAI, compliance showed a positive association, and for the variable CI a negative association.

Patients with plagiocephaly or a combination of plagiocephalic and brachycephalic component showed a mean improvement of CVAI from 2.94% to 7.08% (CVA 0.37 cm–0.86 cm). In patients with brachycephaly, CI improved from 4.17% to 8.22%. These results are similar to or slightly lower than other authors' findings. However, 3D-photogrammetry was used in our study to acquire data instead of the manual caliper measurements performed in other investigations (Teichgraeber et al., 2004; Meyer-Marcotty et al., 2014; Yoo et al., 2012; Kluba et al., 2014; Han et al., 2017). For example, Skolnick et al. found caliper measurements to be 1–4 mm shorter than the digital correlates, which might explain the differences among author reports (Skolnick et al., 2015). Table 9 gives an overview of results of other studies.

Of great importance is the difference in outcome among the three different age groups. When therapy was initiated at age 4–6 months, patients showed greater improvement of the relevant parameters at the same or even shorter duration of treatment. This is true for all three skull deformation types. Children aged 10 months or above had only a few change in head shape. This might be explained by hardening of the cranial bones and the decreasing growth of skull.

Table 6
Improvement of parameters group P.

age subgroup	CVA	CVAI	CI	ear	duration	CVA init.	CVAI init.	
4–6 m	0.85	6.99	2.30	0.25	24.04	1.63	12.22	Mean
n = 126	0.36	2.87	2.90	0.31	11.37			SD
7–9 m	0.55	4.47	2.43	0.15	24.02	1.52	10.92	Mean
n = 256	0.30	2.30	2.79	0.29	8.84			SD
= /> 10 m	0.37	2.94	2.45	0.03	26.62	1.59	11.28	Mean
n = 28	0.21	1.45	1.76	0.24	8.63			SD
total	0.63	5.14	2.39	0.17	24.20	1.56	11.34	Mean
n = 410	0.35	2.76	2.76	0.30	9.67			SD

Improvement of parameters within group P and each subgroup ("4–6 m", "7–9 m" and " = />10 m"). For each parameter mean values and standard deviation (SD) are shown. CVA, CVA init. and ear in centimeters; CVAI, CVAI init. and CI in percentage; duration of therapy in weeks. m = months, init = initial, P = plagiocephaly.

Table 7
Improvement of parameters group P/B.

P/B	CVA	CVAI	CI	EAR cm	duration	CVA init.	CVAI init.	
4–6 m	0.86	7.08	6.59	0.17	22.29	1.59	12.01	Mean
n = 148	0.37	2.95	3.48	0.26	10.49			SD
7–9 m	0.68	5.53	5.97	0.08	25.44	1.53	11.27	Mean
n = 213	0.30	2.34	2.69	0.29	10.52			SD
= /> 10 m	0.48	3.89	4.17	0.09	29.09	1.51	10.88	Mean
n = 45	0.27	2.12	2.84	0.25	10.25			SD
total	0.72	5.92	6.00	0.11	24.70	1.55	11.49	Mean
n = 406	0.34	2.75	3.09	0.28	10.67			SD

Improvement of parameters within group P/B and each subgroup ("4–6 m", "7–9 m" and " = />10 m"). For each parameter mean values and standard deviation (SD) are shown. CVA, CVA init. and ear in centimeters; CVAI, CVAI init. and CI in percentage; duration of therapy in weeks. m = months, init = initial, P = plagiocephaly, B = brachycephaly.

Table 8
Improvement of parameters group B.

B	CVA	CVAI	CI	EAR	duration	CVA init.	CVAI init.	
4–6 m	0.39	3.11	8.22	0.08	19.29	0.72	5.37	Mean
n = 37	0.30	2.24	3.25	0.38	5.67			SD
7–9 m	0.25	2.26	7.14	0.00	21.20	0.62	4.45	Mean
n = 114	0.28	2.09	3.73	0.30	7.66			SD
= /> 10 m	0.28	2.19	5.43	0.01	26.56	0.72	5.14	Mean
n = 31	0.23	1.64	3.69	0.25	12.79			SD
total	0.29	2.25	7.07	0.02	21.73	0.66	4.76	Mean
n = 31	0.28	2.02	3.71	0.31	8.69			SD

Improvement of parameters within group B and each subgroup ("4–6 m", "7–9 m" and " = />10 m"). For each parameter mean values and standard deviation (SD) are shown. CVA, CVA init. and ear in centimeters; CVAI, CVAI init. and CI in percentage; duration of therapy in weeks. m = months, init = initial, B = brachycephaly.

There are various publications about the influence of age at the onset of therapy, but the authors included only plagiocephalic patients in their studies (Dörhage, 2010; Kluba et al., 2011).

In this study, the onset of helmet therapy was evaluated using a classification for different entities of head deformation. Our data emphasize the importance of an early start for patients with only plagiocephalic deformation. For these infants, the average improvement of CVAI decreased from 6.99% (4–6 m) to 4.47% (7–9 m), corresponding to a decrease of 36%. For patients with both plagiocephaly and brachycephaly, the decrease was only 22% (7.08%–5.58%).

When brachycephaly was the only head deformation, the relevant outcome decreased by 13% from the young (4–6 m) to the medium (7–9 m) age group (CI 8.22%–7.14%).

With these data, we can support Han et al.'s statement that the age of 5 months is a good starting point for helmet therapy (Han et al., 2017). However, we need to add that this might be true only for patients with plagiocephalic head deformation. Our findings show that in children with an additional brachycephalic component or sole brachycephaly, helmet treatment could be initiated even later than 6 months of age without relevant limitation regarding outcome parameters.

Duration of therapy differed from 24 weeks (groups P and P/B) to 21 weeks (group B). In group P, the difference in duration from the youngest to the oldest group was only 2 weeks, whereas in groups P/B and B it was 7 weeks. A possible explanation is that the brachycephalic component needs more cranial volume to grow posteriorly and therefore requires more time, whereas the plagiocephalic component lacks cranial volume only on one side.

Also, duration of therapy seems to be limited to a certain point in time. This could be due to the child's refusal of the orthosis, exhaustion of the caregivers, or absence of further improvement. These findings are supported by the results of the analysis of variance, which showed that the length of treatment did not influence the outcome.

Table 9
Results of other authors.

Author	Year	n	Measurement	Outcome (improvement)		
				CVA	CVAI	CI
Han	2017	310	3D-laser scans		5.7%	
Doerhage	2016	102	3D-photogrammetry		4.07%	4.96%
Kluba	2014	128	metal cranial caliper		9.19%	
Yoo	2012	108	spreading calipers	1.13 cm	7.678%	
Schaaf	2010	181	3D-photogrammetry	0.71–0.86 cm	5.77–7.16%	5.48–7.32%
Teichgraeber	2004	292	calibrated calipers	x	x	2.6–2.8%

Outcome results of the parameters CVA, CVAI and CI published by other authors.
x = CVA was not used, but "forehead asymmetry", improvements from 4.7 mm to 5.6 mm.

Patients grouped as borderline (group X) showed the greatest mean age at initiation of therapy. In these cases, caregivers might have waited for spontaneous recovery but in the end decided to correct head shape. It is uncertain whether head deformity would have resolved by itself, if examiners had waited even longer.

The classification proposed and used in this study presents an easy and effective method to differentiate among various head shapes. In comparison to previous publications by different authors, the proposed classification was stated clearly using simple parameters. The classification was then tested using a very large study population with 3D-photogrammetric measurements. Our results support the thesis that there are several entities of head deformation in young children. There are also differences in outcome between the groups defined according to measuring parameters and subgroups based on age at the initiation on treatment. We believe that it is crucial to use a reliable classification when comparing head shapes and therapy results. Furthermore, using the same classification system might help physicians when comparing outcomes between different patient collectives. Our classification of compliance might not be feasible and future studies should include a questionnaire for the caregivers.

Our study is limited by its retrospective and monocentric design. The classification used for data analysis was developed after treatment of patients. It also does not include any information about the severity of head deformation. Furthermore, no control group could be included in the analysis, which limits the value of this study. Findings should be reproduced with independent data at another clinic and a prospective study design.

5. Conclusion

Our analysis confirms that early onset of therapy most likely improves outcome. Furthermore, compliance was overall associated with better outcomes. A classification to differentiate between entities of head deformation should be used when analyzing for outcomes.

Funding

No internal or external support was received for this study.

There was no funding used for this study from the NIH, HHMI, or other sources.

Conflicts of interest

The authors declare no conflicts of interest.

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