

A Prospective Randomized Trial on Preventative Methods for Positional Head Deformity: Physiotherapy versus a Positioning Pillow

Jan-Falco Wilbrand, MD, DMD¹, Maximilian Seidl, MD¹, Martina Wilbrand, MD, DMD¹,
Philipp Streckbein, MD, DMD¹, Sebastian Böttger, MD, DMD¹, Joern Pons-Kuehnemann, PhD²,
Andreas Hahn, MD, PhD³, and Hans-Peter Howaldt, MD, DMD, PhD¹

Objective To evaluate the impact of stretching exercises versus available bedding pillows on positional head deformities.

Study design Fifty children aged 5 months or younger with positional head deformity were included in this prospective clinical trial (n = 20 plagiocephaly, n = 10 brachycephaly, n = 20 combination). A random distribution was performed for treatment with the bedding pillow alone (n = 25) or with stretching exercises (n = 25) for 6 weeks. Anthropometric caliper measurements were done before and after that interval. Cranial vault asymmetry index (CVAI) and cranial index (CI) were calculated and analyzed using a descriptive statistical general linear model.

Results Δ CVAI in the stretching group was 2.09% for plagiocephaly and 2.34% for combined head deformities. Using the bedding pillow, Δ CVAI was 3.01% in plagiocephal children and 2.86% for combined head deformity. The Δ CI in the stretching group was 0.94% for isolated brachycephal children and 2.24% for combined head deformity. Δ CI in the pillow group was 3.63% for brachycephaly and 3.23% in children with combined head deformities, respectively.

Conclusions Bedding pillows and stretching exercises both resulted in improvements in positional cranial deformation. For children with combined plagiocephaly and brachycephaly, improvement in cranial asymmetry was slightly greater when using bedding pillows versus stretching. (*J Pediatr* 2013; ■: ■ - ■).

Positional head deformities in early infancy constitute a frequent issue of international concern after pediatric societies worldwide advocated that parents should exclusively position newborns and infants on their backs during sleep.^{1,2} The most valuable instrument to avert head deformities should be early prevention.³ Primary prevention should be based on perinatal parental education on varying the infant's head position during sleep to avoid the emergence of cranial deformity.⁴ Secondary prevention should include the use of physiotherapy,⁵ osteopathic medicine,⁶ positioning devices,⁷ and particular bedding pillows. These methods should be started at an age of 5 months or younger and should be performed in an adequate manner to achieve improvement.⁸ Nevertheless, if no satisfactory improvement of cranial shape is detectable, orthotic helmet treatment should be initiated at an adequate age^{9,10} for the effective correction of cranial deformities.¹¹

Bedding pillows are designed to unburden the cranial occiput in the supine position. Parents frequently report improvement in head deformities with these pillows, but the efficacy of this method has not yet been systematically analyzed. Physiotherapy, and, in particular, cervical stretching exercises have been characterized as suitable to improve cervical mobility in infants,^{12,13} and thus, have been suggested by the American Academy of Pediatrics (AAP) as the method of choice to correct positional head deformities in early infancy.¹⁴ However, clinical studies examining the effects of physiotherapy show only moderate quality in their study design.¹⁵ Therefore, further investigations have been initiated to clarify the effectiveness of the various proposed methods on deformational plagiocephaly and brachycephaly.¹⁶

The aim of this study was to assess the efficacy of bedding pillows and stretching exercises on the normalization of cranial shape deformities in early infancy.

Methods

A group of 50 infants was included in a randomized prospective trial. Thirty-seven subjects were male and 13 were female. Informed consent was obtained from parents and approval was given by the local ethics committee. Inclusion criteria were age of 5 months or younger at initial assessment and presence of definite nonsynostotic cranial deformity.¹¹ Exclusion criteria constituted premature craniosynostosis, age greater than 5 months,

AAP American Academy of Pediatrics
CI Cranial index
CVAI Cranial vault asymmetry index
Diag Diagonal

From the Departments of ¹Cranio-Maxillofacial Surgery, ²Medical Statistics, and ³Neuropediatrics, University Hospital Giessen, Giessen, Germany

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or a nonsynostotic head deformity not requiring treatment. Infants were diagnosed as having “plagiocephaly” ($n = 20$), “brachycephaly” ($n = 10$), or a “combination of plagiocephaly and brachycephaly” ($n = 20$) following standardized anthropometric measurements.¹⁷ The criteria applied for classifying and grading head deformities are presented in **Table 1** (available at www.jpeds.com).¹¹

In a random distribution, 25 patients (pillow group) were provided with a BabyDorm bedding pillow from the manufacturer (Simonatal, Meerbusch, Germany), and their parents were educated in applying the device (**Figure 1**). Parents were asked to use the pillow exclusively and not to apply any other method to correct cranial shape over a period of 6 weeks.

The parents of the remaining 25 patients (stretching group) were educated on stretching exercises of the cervical muscles (**Figure 2**). These exercises are well-known to improve cervical mobility^{8,13,18} and are typically performed 5 times per day. Additionally, all parents were told to provide adequate “tummy time” while the child was awake during the day.

Anthropometric measurements were performed following a standard protocol¹⁷ by 1 single examiner who was blinded regarding the individual treatment modality. Measurements were obtained immediately before and after 6 weeks of treatment (pillow vs stretching). This interval was chosen to provide the option of helmet therapy in case of an unsatisfactory improvement in cranial shape. An additional interview with the parents at the end of the study interval was performed to assure treatment compliance to the agreed method. The following anthropometric variables were determined: cranial length, cranial width, and the transcranial diagonals (Diag A and B). Thereafter, cranial index (CI) ($\text{width}/\text{length} \times 100$) and cranial vault asymmetry index (CVAI = $\frac{\text{Diag A} - \text{Diag B}}{\text{Diag A}} \times 100$, where $\text{Diag A} < \text{Diag B}$) were calculated. A reduction of the CVAI was thought to reflect improvement of cranial shape of subjects with plagiocephaly and a combination of plagiocephaly and brachycephaly, and a decreasing CI was assumed to indicate amelioration of head shape for individuals with brachycephaly and combined head deformities.

Values are presented as mean and SDs. The pre- and post-treatment CVAI and CI data were analyzed using general linear model descriptive statistics. *P* values of $<.05$ were accepted as significant. An additional covariance analysis adjusted for baseline differences in the severity of cranial deformation between the 2 treatment groups.

Results

The mean age of all the children was 4.0 months and the mean weight was 6.3 kg. The pillow group consisted of 20 male and 5 female subjects, whereas the stretching group comprised 17 male and 8 female individuals. All children were of Caucasian origin. Seven children were born preterm (before 37th week of pregnancy), and there were no twins in our group. Fifty children were randomized at the beginning of our study, 6 of them, however, did not present to our clinic after 6 weeks. In 2 children (4%), the parents indicated that differing nonorthotic treatments were additionally obtained. Therefore, these 2 also had to be excluded from our study. Forty-three parents indicated good compliance to the protocol and did not obtain any other nonorthotic methods during the 6-week period. These children (84%; $n = 42$) were included to the final assessment of this study.

In the stretching group, mean CVAI for plagiocephal patients decreased over the 6-week treatment period, from 10.73% (SD 5.29%) to 8.64% (SD 6.52%) ($\Delta\text{CVAI} = 2.09\%$), and it declined from 12.67% (SD 4.57%) to 10.24% (SD 3.74%) ($\Delta\text{CVAI} = 2.43\%$) in children with combined head deformities. In the pillow group, mean CVAI improved from 13.13% (SD 5.28%) to 10.12% (SD 5.29%) ($\Delta\text{CVAI} = 3.01\%$) in plagiocephal subjects, whereas it changed from 10.68% (SD 3.17%) to 7.82% (SD 2.31%) ($\Delta\text{CVAI} = 2.86\%$) in individuals with combined head deformities. The difference in improvement in CVAI by the 2 methods was statistically significant ($P = .021$; **Figure 3**).

Using an additional covariance analysis to adjust the groups for baseline differences regarding severity of cranial



Figure 1. A, The BabyDorm bedding pillow. B, Use of the bedding pillow.

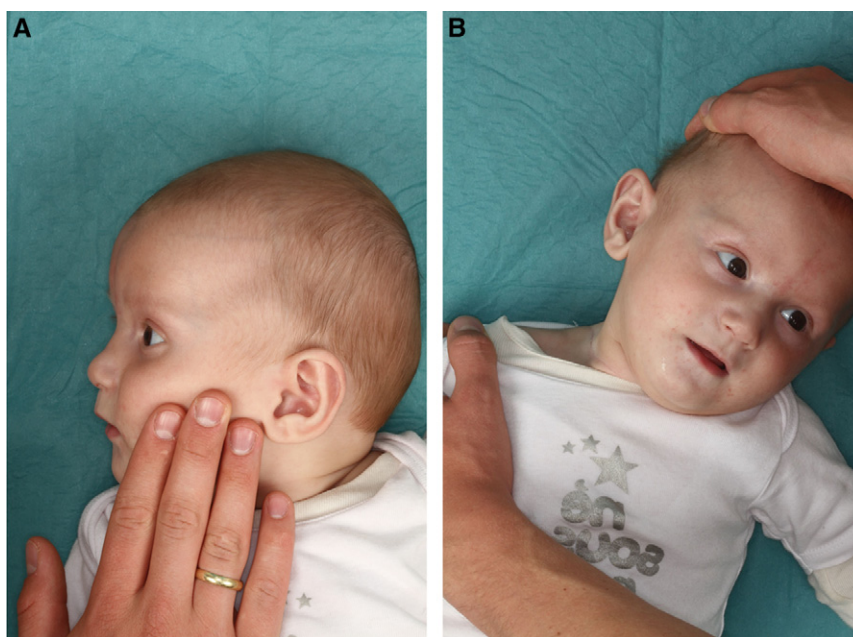


Figure 2. A, Stretching exercise number 1, stretching the cervical musculature in right/left rotation, hold 10 seconds. B, Stretching exercise number 2, stretching the cervical musculature in right/left flexion, hold 10 seconds.

deformation, we found a statistical significant difference in improvement of CVAI for the pillow-treated combination group ($P = .038$) and the significance in the plagiocephaly group disappeared ($P = .177$).

The mean CI of the brachycephal children in the stretching group decreased from 99.30% (SD 3.55%) to 98.36% (SD 2.79%) ($\Delta\text{CI} = 0.94\%$), and it improved from 105.43% (SD 5.92%) to 101.80% (SD 7.11%) in the pillow group ($\Delta\text{CI} = 3.63\%$). Similarly, the mean CI in children with combined head deformities decreased from 101.48% (SD 2.58%) to 98.25% (SD 3.91%) ($\Delta\text{CI} = 3.23\%$) in the pillow group, and from 100.33% (SD 1.89%) to 98.09% (SD 1.89%) ($\Delta\text{CI} = 2.24\%$) in the stretching group. The difference in the improvement in CI was statistically insignificant ($P = .224$) between the groups (Figure 3). The covariance analysis obtained comparability of the 2 groups at the baseline and did not show any statistically significant difference in the correction of brachycephal head deformities ($P = .338$ for brachycephaly and $P = .723$ for combination) after all.

The number of patients with mild, moderate, or severe cranial vault anomalies before and after treatment in relation to type of head deformity and therapy applied (stretching vs pillow) is shown in Table II (available at www.jpeds.com). Overall, the number of infants with moderate and severe deformities decreased by 17.7% in the stretching group, whereas it declined by 19.1% in the pillow group.

Discussion

This prospective randomized clinical trial showed that both stretching exercises and the bedding pillow are associated

with a reduction of moderate and severe positional head deformities when applied for 6 weeks in infants younger than 5 months. The data also suggest that the bedding pillow is more effective in correcting cranial asymmetries in combination head deformities than stretching exercises. The early observation period for this trial was chosen to maintain the option for a correction of cranial deformity with an individual head orthosis, if necessary.

Various suggestions have been made for the initial treatment as a means of secondary prevention of positional head deformity. Among others, the current literature describes the use of physiotherapy,⁹ osteopathic medicine,^{6,19} counterpositioning,²⁰ bedding devices,⁷ and cervical stretching,¹³ but few studies have dealt with the individual impact of those methods on cranial deformity at a high evidential level or even in a prospective and randomized comparative study design.¹⁶

Some authors have claimed that helmet therapy is the most effective method to treat nonsynostotic head deformities in early life.^{21,22} This is consistent with the experience with helmet treatment in our clinic after almost 2 decades.²³ The fate of positional cranial deformity treated by alternative methods, however, is not clear. Loveday and De Chalain found no significant difference between orthotic and nonorthotic methods over a longer period of time.²⁰ Their study showed even slightly better correction of head deformity by physiotherapy, but the observed treatment intervals between the groups differed significantly. Hutchison et al even expected spontaneous correction of cranial deformity without any therapy over time.²⁴ They found a close connection between the course of cervical mobility and the spontaneous

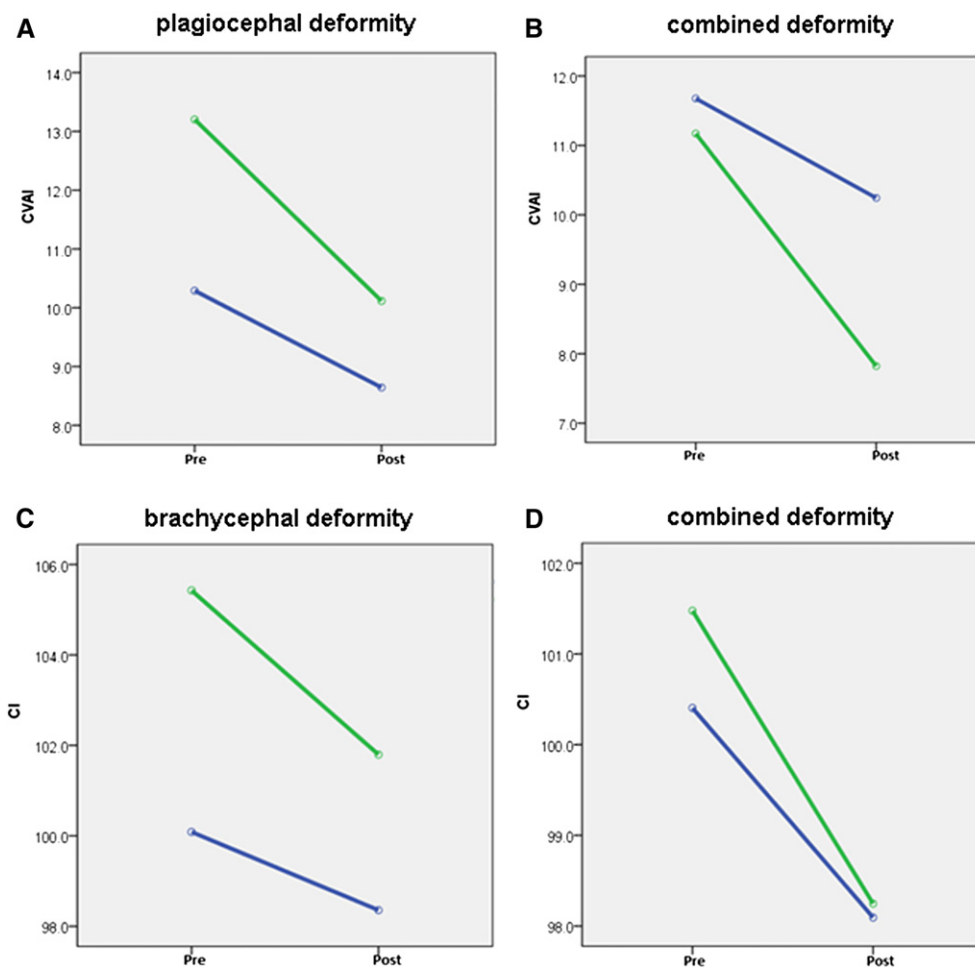


Figure 3. Mean CVAI (A + B) and CI (C + D) before and after 6 weeks of treatment with the bedding pillow (green lines) or stretching exercises (blue lines), respectively (n = 42).

improvement of cranial shape. This is not our clinical experience after evaluating the changes of either treated or untreated cranial deformation in many children over more than a decade.

Although many alternative methods to helmet therapy are suggested and the effectiveness of many is assumed, we sought to discover what would be the most appropriate non-orthotic method to correct cranial deformity and what we should advocate to affected parents to avoid any unnecessary helmet therapy.

Teichgraber et al found helmet therapy to be largely appropriate for correcting an asymmetric skull shape, but it was less suitable for the correction of brachycephaly.²⁵ We found similar correction of brachycephaly by the 2 non-orthotic methods evaluated in this study and a small but statistically significant benefit in the correction of cranial asymmetry using the bedding pillows. Although we expected superior correction of brachycephaly by use of the occipital hollowing in the bedding pillow, this could not be demonstrated in this study.

The use of pillows is easy, cost-effective, and may be easier for parents to implement at home than stretching exercises,⁸

although there might be risk of unsatisfactory use of the pillow.

The AAP recommendation on a safe environment for young children suggests omitting pillows in beds,¹ so the use of such pillows might not be consistent with the current AAP recommendations. According to those recommendations, other bedding devices, such as the Safe-T-sleep device (Safe T Sleep, Auckland, New Zealand)⁷ or even helmet therapy, should be discussed in the same way. Further studies on practicability or safety of the individual approaches are warranted. Considering the available data regarding those bedding devices or helmet therapy,¹⁵ the individual risk for sudden infant death syndrome was never monitored.

Some parents have indicated the occurrence of bilateral apostasis of the external ear after use of the pillow. We assume that this might be produced by the continuous rest of the external ear on the pillow and consecutive anterior shifting of the auricle (Figure 1, B). This was not studied or quantified in this trial. Further studies may be warranted to analyze this field.

Stretching exercises are well-known to be a suitable method for improving cervical mobility and, thus, reduce

the danger of severe cranial deformation.⁵ As a limitation of our study, it must be admitted that measures of range of motion were not collected. Although an ANCOVA diminished the explanatory power of our results to some extent, the respective impact of the 2 methods on cranial shape was demonstrated based on the repeatable anthropometric measurements in our study. Parents were advised to solely apply the agreed method during the 6-week study interval. The only possibility for the examiners to test treatment fidelity, however, was an additional interview at the study termination.

The classification of cranial deformities in this study is based on an established method¹¹ (Table I). This model was in use when our study was implemented. Currently, we would recommend the application of recently published classification models with higher clinical reproducibility.²⁶

The assessment of cranial deformity can additionally be obtained with a high level of reliability by 3-dimensional photography.^{27,28} We chose standardized anthropometric measurements in this study because infants often were not able to hold their heads in an adequate manner for photography at the initial assessment because of their young age.

The time interval of our study was short to maintain the option of starting helmet therapy at an appropriate age.¹⁰ Definite positive changes were observed with both stretching exercises and the bedding pillow. In no case did the cranial deformity deteriorate, so the indication for early implementation of these methods is clear. It must be remembered, though, that close observation of cranial shape by 3-dimensional photography²⁷ or anthropometric measurements¹⁷ is required to assure feasibility of helmet therapy, if it becomes necessary.

The small sample of children and the short study interval might raise questions regarding the generalizability of results. Our results do not consider long-term-effects of various management regimens regarding craniofacial deformity or even spontaneous correction over the years. The number of children is sufficient, however, to achieve explanatory power regarding the individual impact of the evaluated treatment methods on cranial deformity. Our study reliably illustrates improvements in cranial shape evoked by the analyzed non-orthotic methods. ■

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Reprint requests: Jan-Falco Wilbrand, MD, DMD, Department of Cranio-Maxillofacial Surgery, University Hospital Giessen, Klinikstr. 33, 35385 Giessen, Germany. E-mail: jan-falco.wilbrand@uniklinikum-giessen.de

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Table I. Classification and grading of nonsynostotic head deformities as defined in reference 11¹¹

	Normal	Mild	Moderate	Severe
Plagiocephaly (CVAI)	0%-3%	3%-7%	7%-12%	>12%
Brachycephaly (CI)	81-92	92-97	97-102	>102
Combination		Mild plagiocephaly plus mild brachycephaly	eg, mild plagiocephaly + moderate brachycephaly or vice versa or moderate plagiocephaly plus moderate brachycephaly	Severe plagiocephaly plus mild/moderate brachycephaly or vice versa or severe plagiocephaly plus severe brachycephaly

Table II. Number of infants with positional head deformities before and after 6 weeks of treatment with stretching exercises or bedding pillow in relation to degree and type of head deformity (n = 42)

	Plagiocephaly		Brachycephaly		Combination	
	Pre	Post	Pre	Post	Pre	Post
Stretching-group						
Severe	1	1	1	0	5	3
Moderate	5	2	2	3	3	5
Mild	2	5	1	1	0	0
Pillow-group						
Severe	6	3	3	1	6	1
Moderate	2	3	1	3	3	6
Mild	1	3	0	0	0	2