What Is the Optimal Time to Start Helmet Therapy in Positional Plagiocephaly?

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Background: Although helmet therapy is widely accepted in the treatment of severe positional plagiocephaly, treatment regimens, especially regarding starting age, are controversial. This study investigated the importance of starting age to optimize the management of helmet therapy.

Methods: Sixty-two infants with severe positional plagiocephaly were enrolled in this prospective longitudinal study. Twenty-four started helmet therapy before 6 months of age (group 1) and 38 were older than 6 months (group 2). Cranial diagonal measurements were taken. Resulting differences and Cranial Vault Asymmetry Index values were compared and categorized by age at initiation of therapy. The Mann-Whitney U test was used for statistical analysis.

Results: Duration of therapy was significantly shorter in group 1 (14 weeks) compared with group 2 (18 weeks) \((p = 0.013)\), with significantly better outcomes. The Cranial Vault Asymmetry Index in group 1 was reduced to a normal mean value less than 3.5 percent. Infants in group 2 did not achieve normal values (index value, 4.5 percent) \((p = 0.021)\). The relative improvement in asymmetry was significantly better in group 1 (75.3 percent) compared with group 2 (60.6 percent) \((p = 0.001)\). After 4 to 11 weeks of treatment, group 1 already showed a better absolute reduction \((p < 0.001)\) and a better relative reduction \((p = 0.002)\).

Conclusions: Optimal starting age for helmet therapy is months 5 to 6 of life, and early recognition of infants in need is essential. Delaying the onset of treatment significantly deteriorates the outcome. The still often-practiced regimen of starting helmet therapy after physiotherapy should be replaced by a combined therapy in severe cases. (Plast. Reconstr. Surg. 128: 492, 2011.)

CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, II.

Although positional plagiocephaly of infants was not a major issue in medicine in the past, it has increasingly become the focus of medical interest over the past few years. With the Back to Sleep campaign, a rapid increase in the incidence of deforming positional plagiocephaly was seen. Data differ in the literature. Some authors estimate the prevalence to be 22.1 percent by 7 weeks of age,\(^5\) compared with one in 300 live births in 1974\(^4\) and one in 60 live births in 1996.\(^2\) Parents are more aware of the problem because of the increasing incidence and the use of Internet forums. Because the demand for medical counseling is growing continuously, we set up a special outpatient clinic in our department that focused on these patients.

Postnatal positioning is not the only reason for the development of deformational plagiocephaly. It is a multifactor disorder. Preterm infants are more likely to develop a positional plagiocephaly,\(^5\) and male sex,\(^6\) intrauterine forces,\(^7\) multiple births,\(^6,8\) traumatic delivery,\(^6,9\) and limitations in head movement because of torticollis\(^6,10,11\) are also risk factors. Treatment options such as repositioning and physiotherapy are common and were already in use before the rapid increase in prevalence.\(^9\) If necessary, a cranial orthosis (helmet) can be used in more severe cases\(^9,12\) (Figs. 1 and 2).
Deformational plagiocephaly does not cause any life-threatening or debilitating neurologic deficits, and most specialists do not fear serious long-term consequences. However, although it is not a widely held belief, persisting asymmetry and the need for special assistance in school or negative social consequences such as teasing\textsuperscript{13–16} are described in the literature and can be wearing for the children and their families. The parental fear of potential consequences of neglected positional plagiocephaly should not be underestimated, and these aspects should be taken into consideration when discussing the problem.

Despite the growing attention to the problem and the increasing numbers of publications dealing with it, treatment regimens are inconsistent because of the preference of the physician and because of geography.\textsuperscript{16} Helmet therapy is controversial in practice, although it is mostly supported in the literature.\textsuperscript{9,17–19} Many infants are presented too late for the first consultation at a specialized clinic, often not at the recommendation of their pediatrician but on the parents’ own initiative or at the recommendation of friends or a physiotherapist. The achievable results with helmet therapy under these circumstances are frequently unsatisfactory. The aim of the present study was therefore to evaluate the optimal age at which to start helmet therapy, and the treatment progress and results depending on age to adjust treatment regimens.

**PATIENTS AND METHODS**

The study was designed as a longitudinal prospective study of 62 infants with positional plagiocephaly. Inclusion criteria were the presence of nonsynostotic plagiocephaly, completion of helmet therapy, and regular follow-up during therapy and complete documentation. Every child underwent an ultrasound examination before starting helmet therapy to exclude synostoses of the cranial sutures.

After acquiring a three-dimensional surface scan, the helmet was made individually for every child by Cranioform (Siegen, Germany). The parents were instructed to ensure that the helmet was worn for 23 hours/day.

The following data were collected: date of birth and consultation; duration of treatment (in weeks); and cranial diagonal measurements (in millimeters) at the start, 4 to 11 weeks after the start, and at the end of therapy. The measurements were taken with an anthropometric metal cranial caliper by a single person.

The difference of the cranial diagonal diameters (in millimeters) and the Cranial Vault Asymmetry Index (in percent) according to the description of Loveday and de Chalain\textsuperscript{20} were calculated from these data. The Cranial Vault Asymmetry Index represents the individual asymmetry of the cranial vault. A score of 0 percent means perfect symmetry and a score of greater than 3.5 percent means significant asymmetry. The index considers the variation in the infant’s head size and allows a better value comparison than the nominal value difference in cranial diagonal diameters.\textsuperscript{20}

\[
\text{Cranial Vault Asymmetry Index} = \frac{\text{difference in cranial diagonal diameters}}{\text{shorter cranial diagonal}} \times 100.
\]
Data were made anonymous and exported into the statistical analysis program SPPS 17.0.2 (SPSS, Inc., Chicago, Ill.). Labels of variables were added and abbreviations defined.

The sample of infants was divided into two treatment subgroups for further analysis: infants younger than 6 months (group 1) and infants older than 6 months at the start of helmet treatment (group 2). The allocation of the patients to one of these groups was dependent on age at first consultation.

The changes of the Cranial Vault Asymmetry Index from the start of therapy to the first control and to the end of therapy, respectively, were determined as the two primary parameters. Further variables were sex, duration of treatment, change in the difference in cranial diagonal diameters, and age at initial consultation.

The null hypothesis was defined as no difference between the two patient groups concerning the development of the Cranial Vault Asymmetry Index. Because of two primary parameters (multiple testing), the significance level was corrected from α = 0.05 to α = 0.025 according to the Bonferroni rule. In the descriptive part of the statistics, the distribution of all collected parameters was analyzed for the complete sample and for the age-specific subgroups.

We tested whether all continuous variables followed a normal distribution with the Shapiro-Wilks test. As most of the parameters did not show a normal distribution (p < 0.05), statistical analyses were performed with the nonparametric Mann-Whitney U test, and the median was calculated for evaluation. For comparison of the dichotomous variable “sex,” the chi-square test was used.

RESULTS

Age

In 24 of 62 infants, the first consultation at our clinic took place before 6 months of age (group 1, age younger than 6 months). Thirty-eight patients were included in group 2 (age older than 6 months). The age at initial consultation ranged from 4.1 to 10.7 months. Helmet therapy started 2 weeks later.

Sex

More boys were treated overall and in both groups (Table 1). The chi-square test confirmed a similar distribution of sex in both groups.

<table>
<thead>
<tr>
<th>Age</th>
<th>&lt;6 Months</th>
<th>&gt;6 Months</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td>Female</td>
<td>7</td>
<td>15</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>17</td>
<td>23</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>24</td>
<td>38</td>
</tr>
</tbody>
</table>

Duration of Therapy

The 62 infants were treated for a mean of 16 ± 5.61 weeks (minimum, 4 weeks; maximum, 28 weeks). The mean duration of treatment in group 1 (younger than 6 months) was 14 weeks, which was significantly shorter than in group 2 (age > 6 months), with 18 weeks (p = 0.013).

Outcome of Helmet Therapy (Cranial Vault Asymmetry Index and Difference in Cranial Diagonal Diameters Values)

The mean Cranial Vault Asymmetry Index for all patients at the start was 13.3 percent (difference in cranial diagonal diameters, 17 mm) and ranged from 9.1 percent (difference in diameters, 12 mm) to 19.4 percent (difference in diameters, 26 mm). The initial mean INDEX value (group 1, 13.6 percent; group 2, 13.1 percent) did not differ significantly between the two groups (p = 0.326, Mann-Whitney U test); thus, the severity of cases in both groups was similar.

A significant reduction of head asymmetry was observed after helmet therapy in both groups. The mean Cranial Vault Asymmetry Index (13.3 ± 2.68 percent) at the start was reduced to 4.1 ± 2.61 percent for all 62 patients. The cranial asymmetry was improved by a mean of 68.3 ± 16.2 percent (from 29 percent to 100 percent).

Younger infants showed a greater decrease of Cranial Vault Asymmetry Index from 13.6 percent to 3.1 percent at the end compared with group 2 with 13.1 percent to 4.5 percent, respectively. The difference in the results between the two groups was statistically significant (p = 0.021). In group 1, the initial index was reduced on average 11.1 percent absolutely and showed a relative improvement of 75.3 percent of cranial asymmetry under treatment. Children starting therapy later showed significantly less absolute improvement (change in index, –8.5 percent; p < 0.001) than in group 1. There was also significantly less relative improvement of the initial asymmetry of the head (60.2 percent, p = 0.001). The evaluation of the difference in cranial diagonal diameters showed a similar result. Starting with an initial mean differ-
ence of 17 mm in both groups, the group of infants with an entrance age of older than 6 months had a persistent mean difference in the cranial diagonals of 6.5 mm at the end of therapy in comparison with 4.5 mm in group 1 ($p = 0.016$). The difference between the two groups was also statistically significant ($p = 0.016$). The further distribution is presented in Table 2.

**Dynamics of Helmet Therapy**

To evaluate the time-related progress during helmet therapy, the measurements at the time of the first control, on average after 6 weeks (Table 3), were evaluated. Depending on the age of the treated infant and the expected progress of therapy, the time for the first control was set between 4 and 11 weeks.

After 4 to 11 weeks of treatment, the mean Cranial Vault Asymmetry Index was reduced to 5.2 percent in group 1 and 7.1 percent in group 2. The difference in cranial diagonal diameters showed a corresponding development, with a decrease to 7 mm in group 1 compared with 10 mm in group 2. At the time of the first control, the index value was not significantly different between the two groups ($p = 0.036$), but the changes in difference in cranial diagonal diameters differed significantly ($p = 0.024$). The major changes in both groups occurred (Fig. 3) until the time of the first control (81.1 percent of total reduction in group 1 and 75.3 percent in group 2).

The improvement was already significantly better in infants with an entrance age of younger than 6 months compared with group 2 at this time ($p < 0.001$ for absolute change of Cranial Vault Asymmetry Index and $p = 0.002$ for relative improvement). Although the group with the early onset of therapy showed an absolute mean index reduction of 8.97 percent, group 2 had a reduction of only 6.39 percent within the first 4 to 11 weeks of treatment. The distribution of the Cranial Vault Asymmetry Index changes—absolutely and relatively related to the duration of therapy—is presented in Figure 4.

**DISCUSSION**

Positional plagiocephaly has become a common problem among infants within the past two

### Table 2. Cranial Vault Asymmetry Index and Cranial Diagonal Diameter Values and Differences before and after Helmet Therapy

<table>
<thead>
<tr>
<th></th>
<th>$T_i$</th>
<th>$T_e$</th>
<th>Difference CVAI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CVAI (%)</td>
<td>DCD (mm)</td>
<td>CVAI (%)</td>
</tr>
<tr>
<td>Group 1 (&lt;6 mo, n = 24)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>13.6</td>
<td>17</td>
<td>3.1</td>
</tr>
<tr>
<td>SD</td>
<td>2.5</td>
<td>2.98</td>
<td>2.3</td>
</tr>
<tr>
<td>Minimum</td>
<td>10.7</td>
<td>14</td>
<td>0</td>
</tr>
<tr>
<td>Maximum</td>
<td>19.4</td>
<td>24</td>
<td>7.1</td>
</tr>
<tr>
<td>Group 2 (&gt;6 mo, n = 38)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>13.1</td>
<td>17</td>
<td>4.5</td>
</tr>
<tr>
<td>SD</td>
<td>2.8</td>
<td>3.48</td>
<td>2.6</td>
</tr>
<tr>
<td>Minimum</td>
<td>9.1</td>
<td>12</td>
<td>0.7</td>
</tr>
<tr>
<td>Maximum</td>
<td>19.4</td>
<td>26</td>
<td>13.8</td>
</tr>
</tbody>
</table>

$T_i$, start of helmet therapy; $T_e$, end of helmet therapy; CVAI, Cranial Vault Asymmetry Index; DCD, difference in cranial diagonal diameters.

### Table 3. Cranial Vault Asymmetry Index and Cranial Diagonal Diameter Values at Different Consultations

<table>
<thead>
<tr>
<th></th>
<th>$T_i$</th>
<th>$T_c$</th>
<th>$T_e$</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CVAI (%)</td>
<td>DCD (mm)</td>
<td>CVAI (%)</td>
</tr>
<tr>
<td>Group 1 (&lt;6 mo, n = 24)</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>13.6</td>
<td>17</td>
<td>5.2</td>
</tr>
<tr>
<td>SD</td>
<td>2.5</td>
<td>2.98</td>
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<tr>
<td>Minimum</td>
<td>10.7</td>
<td>14</td>
<td>0</td>
</tr>
<tr>
<td>Maximum</td>
<td>19.4</td>
<td>24</td>
<td>13.3</td>
</tr>
<tr>
<td>Group 2 (&gt;6 mo, n = 38)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>13.1</td>
<td>17</td>
<td>7.1</td>
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<tr>
<td>SD</td>
<td>2.8</td>
<td>3.48</td>
<td>3.3</td>
</tr>
<tr>
<td>Minimum</td>
<td>9.1</td>
<td>12</td>
<td>1.4</td>
</tr>
<tr>
<td>Maximum</td>
<td>19.4</td>
<td>26</td>
<td>17.5</td>
</tr>
</tbody>
</table>

$T_i$, start of helmet therapy; $T_c$, first control after 4–11 wk of treatment; $T_e$, end of helmet therapy; CVAI, Cranial Vault Asymmetry Index; DCD, difference in cranial diagonal diameters.
decades. Parents are also more aware of the condition after exchanging experiences by means of the Internet. Not only aesthetic reasons but also an uncertainty about potentially resulting functional problems have led to a rising demand for information and treatment. Primary care physicians and specialists are confronted with an increasing number of consultations and higher expectations of parents. In addition to the formerly often practiced “watch-and-wait” policy—expecting for the natural course to resolve the problem—and physical therapy, helmet therapy offers another treatment option.

This situation is also mirrored in the literature, with an increasing number of publications dealing with this topic. There is consensus about possible treatment options such as repositioning, physiotherapy, and helmet therapy. The outcome and effectiveness of each of these options in comparison with the others was also often investigated. Although helmet therapy is discussed critically, especially with regard to high costs and possible commercial involvements, the benefit for children with severe positional plagiocephaly is widely accepted. For this reason, our study was focused not on a general outcome analysis after helmet therapy but on an outcome evaluation with special consideration to the starting time of therapy. There is no doubt that mild to moderate cases are optimally treated with regular observed “tummy time,” repositioning, and/or physiotherapy if relevant limitations in head movement exist. For this reason, only severe cases with a difference of 12 mm or more in cranial diagonals were included in our study.

Despite the known fact that the effectiveness of helmet therapy is dependent mainly on the remaining growth potential, treatment regimens, especially with regard to starting time, are still diverse. Although the cranial growth dynamics are well understood, only a few studies have examined this factor in connection with helmet therapy. It is frequently recommended in the literature to delay treatment with a cranial orthosis until other options such as physiotherapy and repositioning have failed, mostly after the sixth month of life. Our results indicate that this might be adequate for mild to moderate cases, as was shown, for example, in a study by Moss, but it is too late for severe cases. The starting time of helmet therapy is a very important, and perhaps the most important, factor influencing the outcome. Although in our study infants with an early entrance age could reduce their ini-
tial asymmetry to a median 3.1 percent Cranial Vault Asymmetry Index and so by definition to a normal value (<3.5 percent).20 children starting later than the sixth month of life did not. Of course, the clinical relevance of a discrepancy of a few millimeters in outcome between the two groups can be discussed critically, but with regard to the standard values in the literature they are relevant.20 Whether an index value of 3.5 percent is the correct limit of the normal distribution of head shapes may be questioned. However, as they are set, our results show that delaying the start of helmet therapy from the critical time of age 5 to 6 months to age 6 to 8 months results in a significant deterioration in outcome. To evaluate the significance of the different outcome later in life and any negative ramifications, further investigations with a long-term follow-up are necessary. Considering our results, an age of 8 months as recommended by Graham et al.25 is too late to start.

Looking at the dynamics of helmet therapy, we could show that especially the first weeks of treatment were most effective. In fact, the main improvement was reached in both groups then. Already during this time, the absolute reduction of asymmetry was better in the group with early treatment onset (−8.97 percent versus −6.39 percent). The changes of cranial diagonal diameters were significantly different between the two groups at the time of the first control (−10 mm in group 1 versus −7 mm in group 2; \( p = 0.0024 \)).

Not only was the outcome of children with early treatment onset significantly better, but also the duration of treatment was shorter at 14 weeks compared with 18 weeks on average. Because helmet therapy is associated with some burden (e.g., checking correct fit, cleaning) for the parents, reduction of the duration of therapy is also an important factor. Considering the better outcome and the shorter duration of therapy, our data are important for optimizing helmet therapy.

As in most other studies, there are a few critical aspects remaining that we cannot eliminate. First, there is a certain impreciseness concerning reliability and validity of the collected data.31 Measuring without exactly reproducible landmarks and on a moving infant head undoubtedly has a level of uncertainty, even for experienced examiners. However, this is a problem with which each study has to deal, and up to now no method, even indirect three-dimensional methods, could fully eliminate this problem. Another critical point is the study design. A randomized and blinded study with an adequate control group would obviously be preferable. However, this would mean that infants with severe plagiocephaly are excluded from helmet treatment. In our opinion, it is problematic to deny these infants an available, simple, and low-risk treatment option simply for scientific reasons. Furthermore, concerned parents will probably refuse to agree with such a study design. In addition, the chosen study design may have the potential for different biases such as difference in the compliance of parents or subjective bias caused by a single observer in a nonblinded study.

Although the age-dependent growth potential of the head and the principles of helmet treatment are well understood, essential conclusions are not consequently used in practice. Still, the first consultation with a specialist often takes place too late. In our study group, more than half of the infants (61.3 percent) were presented for the first time after their sixth month of life. In addition, considering that preparing and initiating helmet therapy also takes time, the optimal entrance age has already been missed for these children.

The goal of the present study was neither to decrease the importance of “conservative” treatment nor to promote indications for helmet treatment. Without any doubt, rapid natural cranial growth within the first months of life and repositioning and physiotherapy will lead to satisfying improvements in most mild and moderate cases.16,27 In our opinion, an observant regimen until the fourth month is justified. Helmet therapy should be an option reserved for severe cases. The results of our study highlight the importance of early recognition of such severe cases to not miss the optimal time. Although there is agreement on this point,16,25,30 consistent statements regarding what is early enough are not found. Thompson et al.29 showed that the best outcome for helmet therapy started between 4 and 6 months of age. Our data support this statement. Expecting a satisfying improvement in severe cases by a wait-and-see approach or repositioning and physiotherapy alone can be disappointing for the parents and for the treating physicians. A few studies report on remaining problems for these children later in life.13–16 To achieve the best outcome, early diagnosis and treatment is essential. The first consultation with a specialist should be arranged at 5 months of age at the latest.

**CONCLUSIONS**

With the increasing incidence and rising awareness of parents, management of positional plagiocephaly has become a matter of growing medical interest. There are still a lot of different,
inconsistent treatment regimens, and helmet therapy itself is controversial. Our study demonstrates that starting helmet therapy early (age 5 to 6 months) is important and leads to a significantly better outcome in a shorter treatment time. Early recognition of infants in need of helmet treatment and early consultation with a specialist are essential. Early corrective action should be taken into consideration in severe cases. Helmet therapy, as a low-risk, noninvasive therapy can be a reasonable complement to existing conservative therapies.

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REFERENCES