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Time to Successful Outcome Versus Treatment Duration in Cranial Remolding Orthosis Treatment

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Abstract

Background: Cranial remolding orthoses are an effective treatment for deformational plagiocephaly. Typical treatment durations are well documented. However, treatment duration can be affected by multiple factors and may not be a true representation of the time necessary to achieve a successful clinical outcome.

Objective: This study compared the time to achieve a successful clinical outcome against the total treatment duration for cranial remolding orthosis therapy in infants with deformational plagiocephaly.

Study Design: This is a retrospective study of infants treated for deformational plagiocephaly with a cranial remolding orthosis.

Methods: A total of 300 infants with deformational plagiocephaly who were treated with a cranial remolding orthosis were grouped by corrected age at initiation of treatment and by severity of deformity. A successful outcome was defined as achieving a final cranial vault asymmetry of 5 mm or less. For the 226 infants who achieved a successful outcome, time to successful outcome and treatment duration were compared between the groups.

Results: The time to successful outcome depended on severity but not on age at initiation. The median time to successful outcome ranged from 6 weeks to 17.5 weeks, depending on the severity of the deformity. Time to successful outcome was significantly shorter than treatment duration for infants with an initial cranial vault asymmetry of less than 17 mm.

Conclusion: Current treatment durations for infants with moderate plagiocephaly may be longer than necessary. Estimated treatment timelines should be based on the initial severity of the infant's deformity.

Conflict of interest: The authors worked at the University of Michigan while working on the study and none of them have conflicts of interest to disclose. None of the authors were the treating clinicians of the infants in the study.

Keywords

cranial vault asymmetry (CVA); cranial remolding orthosis; plagiocephaly; treatment duration; treatment outcome; severity; premature birth

BACKGROUND

Families looking to initiate cranial remolding orthosis (CRO) treatment for their infants' plagiocephaly often ask if the treatment works and how long it will take. The efficacy of CRO treatment has been well described in the literature.[1–8] However, predicting length of CRO treatment is complicated due to limited evidence defining the time necessary to achieve a successful clinical outcome.

Plagiocephaly is a common head shape deformity with an asymmetrical flattening of the head that is typically managed with CRO treatment.[2–10] The severity of plagiocephaly is characterized by the cranial vault asymmetry (CVA), measured by the difference in oblique diagonals of the head.[9] The goal of CRO treatment is to normalize the head shape by reducing the CVA. A normal CVA is 0–3 mm.[11] Treatment success is determined by assessing quantitative improvement in the cranial deformity. A successful clinical outcome can be defined in different ways, but the present study defined a successful clinical outcome as a CVA of 5 mm or less. Factors influencing treatment success include corrected age at initiation of treatment, initial severity of the deformity, and family and infant treatment tolerance.[1,5,7,9,10,12–15]

Treatment duration is defined as the time between the fitting of the CRO and the last follow-up appointment.[6,9,12,13] Typical treatment durations are well-documented; averages range from 18 to 25 weeks.[5,12,13] Time to successful clinical outcome is defined as the time between the fitting of the CRO and the first time the CVA measures 5 mm or less. Treatment duration and time to successful outcome may not always be the same because treatment duration is often influenced by factors unrelated to quantitative improvement in the cranial deformity. These factors include family satisfaction with head shape, infant and family treatment tolerance, ability to attend scheduled follow up visits, and achievement of developmental milestones. For example, when an infant reaches a successful clinical outcome, treatment may be continued due to the family's desire for greater improvement or concern over regression of deformity correction. An infant may also be discharged from treatment prior to achieving a successful clinical outcome due to treatment tolerance.

Previous studies have compared treatment durations based on initial severity or age at initiation of CRO treatment.[4,6–10,12–14] Another study created a model for predicting the likely maximum CRO treatment time.[16] However, no studies have reported the time it took to achieve a successful clinical outcome as an outcome measure of its own. Thus, there is limited evidence available to predict the treatment time necessary to achieve a successful clinical outcome.

The purpose of this study was to determine the time to successful clinical outcome based on an infant's initial presentation, which may allow for more accurate estimations of the necessary treatment length for individual infants with plagiocephaly.

METHODS

STUDY DESIGN

This retrospective study evaluated treatment outcomes for patients treated for positional plagiocephaly with a CRO at the University of Michigan Orthotics and Prosthetics Center (UMOPC). It was approved by the University of Michigan Institutional Review Board (HUM00188014). Time to successful outcome and treatment duration were compared across groups of infants, based on age at initiation of CRO treatment and the severity of deformity.

CRANIAL REMOLDING ORTHOSIS TREATMENT

Infants with positional plagiocephaly were evaluated and treated by one of several certified orthotists at UMOPC as part of their standard of care. At the initial evaluation, the treating orthotist calculated the CVA using diagonal transcranial diameter measurements taken with wooden or metal infant ML calipers. For those pursuing CRO treatment, a 3D light scan of the infant's head was taken with an OMEGA® Scanner 3D from WillowWood (Mt. Sterling, OH). The scan was modified by the orthotist using OMEGA® Tracer v12 CAD software (Mt. Sterling, OH) to prepare it for fabrication of the CRO. The CROs were fit by the treating orthotist 2 weeks after the initial evaluation. All infants included in this study were fit with the Michigan Cranial Reshaping Orthosis fabricated by Danmar Products Inc. (Ann Arbor, MI) (Figure 1).

Families were instructed to have the infant wear the CRO approximately 23 hours per day, following a four-day break-in period. Follow-up appointments occurred approximately every 6 weeks to assess CRO fit and to re-measure the CVA, until treatment was stopped. Measurements at follow-up visits were taken with wooden or metal infant ML calipers. The decisions to discontinue treatment were made based on a combination of factors: quantitative improvement in the cranial deformity, family satisfaction with the head shape, achievement of gross motor developmental milestones, resolution of torticollis, rate of head growth, and treatment tolerance. Some challenges of CRO treatment can be skin irritation from the CRO, increased sweating on the cranium, and social stigma for the family.

DATA SOURCE AND ABSTRACTION

A retrospective search of the electronic healthcare record was performed using the University of Michigan's EMERSE (Electronic Medical Record Search Engine) program.[17] The search criteria included: patients with a diagnosis of plagiocephaly, deformational plagiocephaly, nonsynostotic plagiocephaly, or positional plagiocephaly and a prescription for a CRO.

Specific data were extracted from the infants' charts: date of birth, gestational age at birth, initial CVA, date of CRO fitting, date of follow-ups, and CVA at follow-ups. Chronological age at initiation of CRO treatment was calculated for each infant. Corrected age at initiation

of CRO treatment was used for the preterm infants (those born prior to 37 weeks gestational age) because correlation of CVA correction between preterm and full-term infants is stronger when the preterm infants' corrected ages are used.[1] Corrected age at initiation was calculated by subtracting the number of days preterm the infant was born from their chronological age at initiation. Initiation of CRO treatment was the date they were fit with the CRO. For infants who presented with both plagiocephaly and brachycephaly, data extraction was stopped once the CVA was no longer changing, even if they continued with treatment for the brachycephaly.

PARTICIPANTS

The medical records of 606 infants treated at University of Michigan Orthotics and Prosthetics Center (UMOPC) between 2013 and 2020 were reviewed. Of these 606 infants, 300 infants met the inclusion criteria and were included in the study. Subjects were included in the study if they had nonsynostotic deformational plagiocephaly, had an initial CVA of 6 mm or greater, were fit with a CRO as an outpatient at UMOPC locations in Ann Arbor or Northville, Michigan, and followed up at least once after the initial fitting of the CRO. Infants were excluded if they had a sole diagnosis of brachycephaly or scaphocephaly, they had a CVA of 5mm or less at initiation, they were fit with a CRO as an inpatient, their care was disrupted due to the COVID-19 pandemic or they had significant, documented nonadherence to recommended CRO wear time. Infants with suspected but nondocumented nonadherence were included. Infants with a dual diagnosis of brachycephaly were included.

The infants were stratified into clinically relevant groups for comparisons. Infants were categorized into four relatively evenly distributed groups based on their corrected age at initiation of CRO treatment: <22 weeks, 22–25 weeks, 26–30 weeks, and >30 weeks. Infants were also categorized into four groups by severity of initial CVA: 6–9 mm, 10–12 mm, 13–16 mm, and 17+ mm. At UMOPC, moderate plagiocephaly is defined as a CVA of 6–12 mm and severe plagiocephaly is defined as a CVA of 13 mm or greater. Although there is no universally agreed upon severity scale for deformational plagiocephaly, a CVA greater than 12 mm is commonly used as the threshold for describing plagiocephaly as severe.[11,18–20] The moderate and severe categories were subdivided to create more sensitivity when looking at the possible effects of severity on time to successful outcome and treatment duration.

OUTCOMES

Outcomes of CRO treatment were defined as treatment success, time to successful outcome, and treatment duration. Treatment success was defined as achieving a CVA of 5 mm or less. This represents normal head shape (0–3 mm CVA) or mild plagiocephaly (4–5 mm CVA).[11] This threshold for success was chosen because CRO treatment would not be recommended given this initial presentation. For infants achieving a successful outcome, time to successful outcome was defined as the time between CRO fitting and the first CVA measurement of 5 mm or less. Treatment duration was defined as the time between fitting and final follow-up visit for the plagiocephaly.

STATISTICAL METHODS

Data were summarized using n (%) for categorical variables and mean ± SD, minimum, and maximum for continuous variables. The number (%) of infants achieving a successful outcome of final CVA of 5mm or less was computed. For infants who achieved a successful outcome, median time to successful outcome and median treatment duration were calculated and compared using Wilcoxen signed rank test, both overall and by initial corrected age and severity. An ordinary linear regression model was used to evaluate the effect of initial severity and age at initiation on time to successful outcome. A significance level of 0.05 ($P < .05$) was used, as this indicates a less than 5% risk of concluding a difference exists when there is not actually a difference.

RESULTS

The corrected age at initiation of CRO treatment for the 300 infants in the study ranged from 2 weeks to 50 weeks, with a mean of 26.7 weeks. The initial CVA ranged from 6 mm to 28 mm, with a mean of 11.67 mm. The mean follow-up time between visits was 6 weeks (Table 1).

Treatment success was defined as a final CVA of 5 mm or less. Based on this definition, 75% (226/300) of the infants achieved a successful outcome with CRO treatment. Success rates ranged from 24% (8/34) for the most severe group to 92% (91/99) for the least severe group (Table 2).

Of the 226 infants who achieved treatment success, 95% (215/226) reached a successful outcome within 19.4 weeks (4.5 months). For infants with moderate plagiocephaly, 88% (181/206) of them achieved treatment success and 95% (172/181) of those who reached a successful outcome did so within 18.1 weeks (4.2 months). The median time to a successful outcome for all 226 infants was 8.5 weeks (2 months). Time to successful outcome increased significantly with initial severity ($P < .0001$) but was not dependent on age at initiation ($P = .63$). The median time to a successful outcome for the 6–9 mm CVA group was 6 weeks (1.4 months). The median time to a successful outcome for the 10–12 mm CVA group was 9 weeks (2.1 months). The median time to a successful outcome for the 13–16 mm CVA group was 12.9 weeks (3 months). The median time to a successful outcome for the 17+ mm CVA group was 17.5 weeks (4 months) (Figure 2).

For the 226 infants who achieved a successful outcome, treatment duration was also calculated. The median treatment duration for all 226 infants was 13.6 weeks (3.1 months). Treatment duration was dependent on initial severity ($P < .001$) but not on age at initiation ($P = .23$). Median treatment duration for infants who reached a successful outcome ranged from 3–4.2 months, depending on the severity group. The median treatment duration for the 6–9 mm CVA group was 12.6 weeks (3 months). The median treatment duration for the 10–12 mm CVA group was 14 weeks (3.2 months). The median treatment duration for the 13–16 mm CVA group was 15.1 weeks (3.5 months). The median treatment duration for the 17+ mm CVA group was 18.2 weeks (4.2 months). Treatment duration was significantly longer than time to successful outcome for infants with an initial CVA of less than 17 mm ($P < .001$) but not for those with an initial CVA of 17+ mm ($P = .50$) (Figure 2).

DISCUSSION

This study found that the time to reach a successful clinical outcome, defined as a final CVA of 5mm or less, depended on the severity of the initial CVA but did not depend on age at initiation. Time to successful outcome increased significantly as severity increased. Time to successful outcome was significantly shorter than treatment duration for all severity groups except the most severe group (initial CVA of 17+ mm).

The present study is different from previous studies in that it determined the time it took to reach a successful clinical outcome and analyzed how it differed from treatment duration. The time to reach a successful outcome has not been reported previously. Prior studies have reported average treatment durations ranging from 18 to 25 weeks (4.1 to 5.8 months).[5,12,13] Comparatively, this study had a shorter average treatment duration of 14.8 weeks (3.4 months) for the entire cohort (all 300 infants). The reason for the shorter average treatment duration in this cohort compared to other cohorts was not studied. There are a variety of possible reasons for the shorter average treatment duration: the type of provider making the treatment discharge decisions, the providers' level of experience with CRO treatment, the CRO design, the business model for follow up care in CRO treatment at the clinic, the availability of appointments, families' ability to attend follow up visits adhere to treatment protocols.

Because the timing of discharge from CRO treatment can be influenced by family preferences, in addition to clinical criteria, treatment may be discontinued based on the family's satisfaction with the infant's head shape or their dissatisfaction with the challenges of CRO treatment. This may happen before discharge from treatment is clinically indicated. In these cases, a successful clinical outcome is not reached due to the family's desire to discontinue treatment. Conversely, treatment may be continued after an infant has achieved a CVA of less than 5 mm due to the family's desire to obtain further correction, particularly for those infants with moderate plagiocephaly. This extends treatment duration beyond the criteria this study set as achievement of a successful clinical outcome.

The finding that time to successful outcome was significantly shorter than treatment duration for all severity groups, except for the most severe group, suggests that CRO treatment may be longer than necessary for some infants. The most notable differences in median time to successful outcome and median treatment duration were in the two moderate groups, where the difference was 6.6 weeks in the 6–9 mm CVA group and 5 weeks in the 10–12 mm CVA group. The explanation for treatment durations that are significantly longer than time to successful outcome is likely that treatment durations reflect both time to successful outcome and more ambiguous factors such as parental desire for further correction, concern over potential regression post-treatment, scheduled follow-up appointment intervals and/or appointment availability. Thus, it is not expected that the time to successful outcome and the treatment duration should always be equal. However, the results of this study challenge current treatment durations for infants with moderate plagiocephaly given the significant disparities between time to successful outcome and treatment duration. Given the results of this study, it may be worthwhile for clinicians to schedule follow up visits closer together

once an infant is nearing a successful clinical outcome to potentially shorten the treatment duration.

Previous studies have reported that treatment duration depends on age at initiation and severity of initial asymmetry.[5,8–10,12] Kunz *et al* reported that treatment duration increased with age at initiation and that, in older infants, a higher initial asymmetry significantly increased the treatment duration.[5] Graham *et al* found that treatment duration was significantly associated with severity of initial asymmetry and age at initiation.[9] Yoo *et al* reported that treatment duration increased significantly with the severity of initial asymmetry.[8] The present study confirmed that treatment duration is dependent on initial severity but found that it is not dependent on age at initiation.

A substantial difference between this study and prior literature is the use of the CVA rather than the cranial vault asymmetry index (CVAI).[2,7–10,12–16,21] The CVAI is a measure of the proportion of cranial asymmetry compared to the overall head size, not a direct measurement of asymmetry. Head circumference increases substantially during the first year of life and is strongly correlated with age,[22] so a change in CVAI is reflective of growth as well as a possible change in cranial asymmetry. An infant's CVAI will decrease as the head grows even if the asymmetry remains the same. This can be seen as improvement in the asymmetry when it is may only be improvement in the deformity relative to the size of the head. The CVAI is useful for comparing the severity of deformity among different infants, as it is important to compare their asymmetry to one another relative to their head size. However, when assessing the effectiveness of plagiocephaly treatment over time, the authors prefer the use of CVA as a measure of successful clinical outcome, as it only decreases if the asymmetry decreases. If discharge decisions are based on CVAI, a measure dependent on age, this may explain why many studies find that treatment duration is dependent on age, while the current study did not. Future studies looking at the effect of using CVA versus CVAI when making discharge decisions may help explain the potential confounding effects of the relationship between age and reported outcome measures.

LIMITATIONS

The retrospective nature of this study creates some inherent limitations. The primary limitation of this study was that CVA was only measured at approximately 6-week intervals, thus limiting the specificity of reported time to successful outcome and treatment duration. Infants who reached a successful outcome (CVA of 5 mm or less) may have reached that successful outcome between their 6-week follow-up visits. For example, infants with an initial CVA of 6–9 mm had a median time to a successful outcome of 6 weeks; however, since they often were not seen before 6 weeks, they may have achieved this outcome before their first follow-up. Thus, reported times to successful outcomes are likely inflated. Few studies analyze measurements of head deformity at intervals more frequent than 6 weeks throughout treatment.[8] Future studies measuring head deformity on a weekly or biweekly basis would help further ascertain the precise amount of time required to achieve a successful outcome.

The method of taking cranial measurements is an additional limitation. Due to the retrospective nature of the study and the involvement of multiple certified orthotists,

the technique for taking the diagonal measurements could not be controlled. Further, measurements were obtained on moving infants using hand tools. This introduces a margin of error in CVA measurements. However, a previous study has found that the inter-observer and intra-observer reliability of standard cranial measurement methods have low variability and are highly reproducible.[23]

CONCLUSION

This study provides median times to reach a successful outcome categorized by the infant's initial severity of deformity. The times to successful outcome were significantly shorter than the treatment duration in all but the most severe group of infants. Times to successful outcomes are useful in aiding orthotists in appropriately guiding families' expectations for CRO treatment duration. Discussions of expectations for CRO treatment duration should be tailored to each individual infant based on the initial severity of their deformity.

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Figure 1.
Michigan Cranial Reshaping Orthosis.

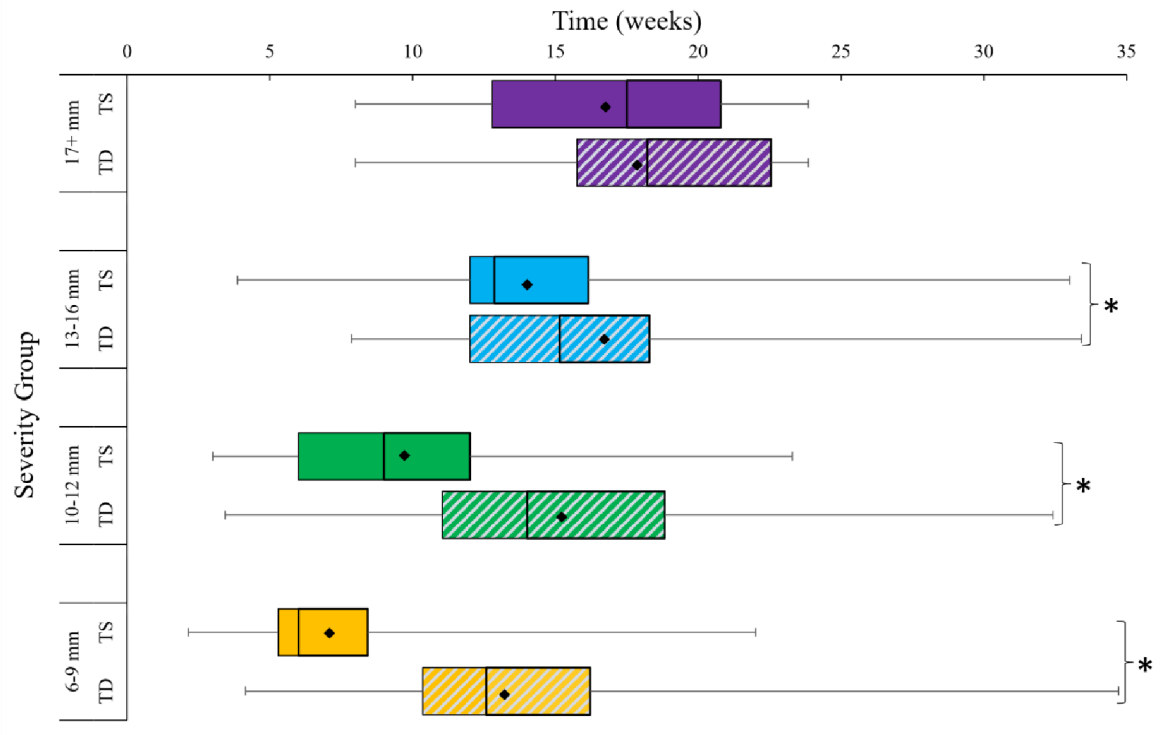

Figure 2.

Box and whisker plot of time to successful outcome (TS, final CVA ≤ 5 mm) versus treatment duration (TD) for initial severity groups.

*Statistically significant difference, $p < .05$

Table 1:

Study subject characteristics.

Subject Characteristics		
Total Infants in Study, N	300	
Infants Born Preterm, n	77	
Total Infants Reaching Successful Outcome, n	226	
Initial Presentation	**Mean (SD)**	**Min/Max**
Initial CVA (mm)	11.6 (4.1)	6/28
Corrected Age at Initiation (weeks)	26.7 (7.3)	2/50
Follow Up Frequency (weeks)	6 (2)	2/22

Table 2:

Infants reaching a successful outcome (final CVA ≤ 5mm).

Infants Reaching Successful Outcome by Severity Group, n			
6–9 mm	***10–12 mm***	***13–16 mm***	***17+ mm***
91/99	90/107	37/60	8/34