Clinical Outcomes of the Michigan Cranial Reshaping Orthosis: A Retrospective Review of Outcomes Measured by Three-Dimensional Laser Scanning

Ammanath Peethambaran, MS, CO, FAAOP, Alicia Foster, MS, CPO, Kevin Hickey, MSPO, CPO, Rebecca Patterson, MSPO, CO

ABSTRACT

Introduction: Infants treated for positional cranial asymmetry involving plagiocephaly, brachycephaly, and scaphocephaly are often treated with cranial reshaping orthotic helmets to encourage symmetrical cranial growth. The Michigan Cranial Reshaping Orthosis is a bivalve helmet that accommodates overall cranial growth during the therapy period while still directing cranial growth toward the desired areas. This design differs from standard one-piece helmets that allow limited volume for overall cranial growth. This study examines the efficacy and success rate of this low-profile design.

Materials and Methods: Visual inspection and manual measurements taken throughout the helmet therapy period, using a flexible tape measure and an AP-ML gauge, indicate significant cranial asymmetry correction. However, measurement inconsistencies due to soft tissue compression and clinician technique may limit the accuracy of outcome measures. Seventy subjects treated for plagiocephaly and/or brachycephaly with the Michigan Cranial Reshaping Orthosis were identified in this retrospective study. Data were compiled from Omega Tracer (Ohio Willow Wood Company, Mount Sterling, OH, USA) computer-aided design clinical database of three-dimensional cranial scans taken before and after helmet therapy. Cranial helmet therapy treatment timeline was verified through the electronic medical record database. Cranial landmarks were defined on each three-dimensional image. Measurements between defined points were compared on the initial assessment scanned image and the final discharge scanned image for each patient.

Results: Comparison of initial and final three-dimensional scans showed improved symmetry in the relevant measures of cranial vault asymmetry index (CVAI) and cephalic ratio (CR) in 84.3% of subjects. Children in the plagiocephaly-only group showed 28.8% improvement in CVAI. Although sample size was low, children in the brachycephaly-only group showed 4.66% improvement in CR. Children in the combined plagiocephaly/brachycephaly group showed 41.4% improvement in CVAI and 2.60% improvement in CR. Overall, a 33.5% in CVAI and 2.10% improvement in CR were seen. These results are comparable to other studies of remolding helmet efficacy.

Conclusions: The data in the present study, therefore, support the use of the Michigan Cranial Reshaping Orthosis as a viable option in the treatment of plagiocephaly and/or brachycephaly when the primary method of treatment is utilization of a cranial remolding helmet. (*J Prosthet Orthot*. 2015;27:122–131.)

KEY INDEXING TERMS: cranial, reshaping, helmet, plagiocephaly, brachycephaly

While orthotic cranial remolding helmet therapy increased after the start of the "back-to-sleep" program in the early 1990s, cranial shaping has been in use throughout history. Evidence of human skull shape modification has been traced to archeological Neanderthal records and has been discovered on every inhabited continent.[1] Evidence exists of both intentional and unintentional cranial reshaping, the reasoning behind which may have differed between cultures. Nomadic cultures and those that required parents to perform daily tasks with children in tow often used cradle boards, which inadvertently applied pressure on the occipital bone.[1] Other cultures, such as the Arawe of Papua New Guinea, bound infant's skulls to produce an elongated cranial vault, which was considered aesthetically pleasing. Some cultures may have performed cranial shaping as a way of establishing an elite status, group affiliation, and/or to continue the practice of cranial shaping in veneration of ancestors or leaders who displayed cranial shapes consistent with the practice of binding infant skulls.[1]

Reasons for present-day cranial remolding may not be far displaced from our ancestors' motivation. As our lives have become busier and more sedentary, infants tend to spend more time in car seats, infant carriers, and in supine positions. The "safe-to-sleep" program (previously known as the back-to-sleep program), implemented in 1994 to decrease the incidence of sudden infant death syndrome (SIDS), has also greatly increased time spent in a supine position.[2] Supine positioning may place deforming forces on the occipital bone of the developing skull. Although some research is emerging that may show a correlation between

AMMANATH PEETHAMBARAN, MS, CO, FAAOP, and ALICIA FOSTER, MS, CPO, are affiliated with the Department of Physical Medicine and Rehabilitation, University of Michigan Orthotics and Prosthetics Center, Ann Arbor, Michigan.

KEVIN HICKEY, MSPO, CPO, is affiliated with the Hanger Clinic, Denver, Colorado.

REBECCA PATTERSON, MSPO, CO, is affiliated with the Hanger Clinic, Grand Rapids, Michigan.

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The lead author is also the codeveloper of the Michigan Cranial Reshaping Orthosis bivalve helmet design.

Correspondence to: Ammanath Peethambaran, MS, CO, FAAOP, Department of Physical Medicine and Rehabilitation, University of Michigan Orthotics and Prosthetics Center, 2850 S. Industrial Hwy, Suite 400, Ann Arbor, MI 48104; email: peeth@umich.edu

plagiocephaly and altered mandibular development and/or delayed developmental milestone timelines, present-day orthotic cranial reshaping is done primarily for cosmetic purposes.

Cranial deformity arises from three factors: 1) abnormalities in brain shape or development; 2) abnormalities in bone or suture development; and 3) prenatal and postnatal deforming forces.[3] The majority of patients treated with orthotic cranial remolding helmet therapy develop asymmetry due to prenatal and postnatal forces on the cranium. Increased intrauterine pressures due to multiples, large fetus size, abnormal positioning, and forces from vaginal births may cause cranial asymmetry.[3] Supine postnatal positioning may also contribute to cranial asymmetry through deforming forces on the occipital bone. Torticollis is also a common concomitant finding. Limited range of motion from torticollis may cause the child to spend more time lying on one side of his/her head, creating more deformational forces in the affected area.

LITERATURE REVIEW

TREATMENT OPTIONS, EFFECTIVENESS, AND TIMELINES

The two most prevalent treatment options for plagiocephaly are repositioning and helmet therapy. Helmet therapy has proven to be an effective treatment for plagiocephaly in those who adhere to wearing instructions. However, the effectiveness of helmet therapy, in comparison to repositioning, is still disputed.[4,5] Cranial remolding helmet therapy can be a difficult decision for parents. Child comfort, parental time commitment, cost, potential social stigma of a helmeted child, and the effectiveness of helmet therapy are all factors that weigh into the decision to utilize helmet therapy.

Both treatment methods have proven to be effective; however, studies have found that helmet therapy attains desired outcomes more quickly. Loveday and de Chalain[6] found the management time for repositioning was approximately three times longer than the management time for helmet therapy. The findings of Lipira et al.[7] also demonstrated that the symmetry gains were reached in a significantly shorter time frame: 3.1 months in comparison to 5.2 months for those who were repositioned.

Loveday and de Chalain[6] also found that, of the infants treated with helmet therapy, CVAI outcomes were more favorable for nonbrachycephalic infants. Brachycephalic infants may have attained less desirable results due to helmet fitting difficulty associated with the flat occipital region in brachycephalic infants, which often leads to lower compliance rates.

Initiation of helmet treatment at 36 weeks of age or later may have been more successful in comparison to repositioning due to the ability to take advantage of the faster helmet treatment timeline during the rapidly closing treatment window as the subjects' cranial growth was slowing.[6] However, due to rapid cranial growth in the first 6 months of life, optimal initiation of helmet therapy may be significantly earlier.[8] In a study by Kluba et al.,[9] helmet therapy was found to be most effective and requiring shorter helmet therapy duration when initiated in months 5 to 6 of life. Only infants with 12 mm or greater difference in cranial diagonals were included in the study of Kluba et al.,[9] possibly indicating treatment initiation in the fifth or sixth month of life as being most critical for those with severe asymmetry. Thompson et al.[4] also supported this treatment initiation time frame.

Traditional remolding helmets consist of a plastic shell lined with a thick layer of foam material. As the child grows, the foam is gradually removed to encourage additional growth in the flattened areas of their skull. The Michigan Cranial Reshaping Orthosis is a low-profile helmet, designed and developed by Ammanath Peethambaran, MS, CO, FAAOP, that allows accommodation for growth through anteroposterior expansion at a bivalve joint rather than foam removal. This design differs from many on the market due to a bivalve design of 3/16″ copolymer plastic shell with 1/4″ Aliplast foam inner lining. Growth accommodation is made through the addition of spacers at the bivalve joint to increase anteroposterior length. This allows the desired shape of the helmet to remain consistent throughout the process, eliminating the need to remove helmet padding to accommodate growth throughout the therapy process. The low-profile design is anecdotally well accepted by parents, and the growth expansion joint provides for improved adjustability with regard to growth modification. This adjustability may reduce the need for additional helmets as the child grows.

MEASUREMENT METHODS

Several anthropometric measurements are used to quantify cranial asymmetry, each of which indicates a level of symmetry in a certain region of the cranium (Table 1).[3] Based on the nature of the asymmetry, the most appropriate measure is selected. For example, some of the more commonly used measures include cephalic ratio (CR) and cranial vault asymmetry index (CVAI). Cephalic ratio is used as a measure of cranial width versus length for infants with brachycephaly, whereas cranial vault asymmetry index is used to measure asymmetry of diagonal length from frontozygomaticus to the contralateral eurion in infants with plagiocephaly.[3] Anthropometric indices and ratios allow comparison of cranial asymmetry between children with different cranial size.

Many studies have been conducted to quantify effectiveness of helmet therapy using varied measurement techniques. Difficulty in attaining accurate, repeatable measurements creates a challenge for the healthcare professional when diagnosing plagiocephaly, identifying severity, and quantifying outcomes, and as such, there is little consistency between research methodologies. Various measurement methods are utilized for assessing cranial shape asymmetry. Evaluation of infants with plagiocephaly is often performed by caliper measurement. Caliper measurement creates conceivable limitations in accuracy and repeatability due to clinician technique, soft tissue compression, patient cooperation, and instrument variability. Computed tomography scans have been used to assess cranial anomalies; however, this exposes infants to radiation, which is not recommended for the purposes of measurement.[10]

Table 1. Anthropometric measurements

Anthropometric measurements	Cranial landmarks
Cranial circumference	Taken at the equator
Cranial width	Eu-eu
Cranial length	G-op
Cranial vault, right and left	Frontozygomaticus to contralateral eurion
Orbitotragial depth (upper face), right and left	Ex-t
Cranial base (lower face), right and left	Sn-t
Additional Measures	**Calculations**
CI	CI = cranial width/cranial length
CVA	CVA = cranial vault (R) – cranial vault (L)
CVAI	CVAI = [cranial vault (R) – cranial vault (L)]/cranial vault (R)
OTDA	OTDA = orbitotragial depth (R) – orbitotragial depth (L)
CBA	CBA = cranial base (R) – cranial base (L)

Adapted from Fish and Dulcey.[3]

Eu-eu, eurion to eurion; G-op, glabella to opisthocranion; Ex-t, exocanthion to tragion; Sn-t, subnasion to tragion; CI, cephalic index; CVA, cranial vault asymmetry; CVAI, cranial vault asymmetry index; OTDA, orbitotragial depth asymmetry; CBA, cranial base asymmetry.

Öhman[11] analyzed the interrater and intrarater reliability of a modified "severity scale for assessment of plagiocephaly among physical therapists." The severity scale, developed by Cranial Technologies, Inc (Tempe, AZ, USA), uses photographs of the child in comparison to five measures: posterior flattening, ear misalignment, forehead asymmetry, neck involvement, and facial asymmetry. Öhman[11] found that the scale has satisfying statistical agreement; however, the number of years of experience of the therapists did affect reliability. Though severity scale assessment is a useful, low-cost tool, variability may be present due to practitioner experience and the subjective nature of the process.[11]

Plank et al.[12] reported the benefits of cranial vault asymmetry indices and identified the limitations of single cross-section measures. Cranial vault asymmetry indices calculate differences in cranial measurements as a percentage of the individual's skull circumference, allowing for more meaningful comparisons between subjects with differing head sizes.[13] Accommodation for skull growth is also an important factor when assessing the skull asymmetry of a growing child. Use of the three-dimensional scanner allows for repeatable measures of the maximum, anteroposterior, mediolateral, oblique linear measures, and quadrant volumes.[13]

The present study utilized three-dimensional scanning with Omega Tracer scanner (Ohio Willow Wood Company, Mount Sterling, OH, USA). This method is safe for the child and minimizes the length of the appointment while still improving accuracy by eliminating variances due to soft tissue compression. It is our hypothesis that the Michigan Cranial Reshaping Orthosis produces improvements in infants' cranial asymmetry comparable to published results for one-piece designs.

MATERIALS AND METHODS

University of Michigan institutional review board approval was attained for a secondary use of existing data study involving the review of patient chart notes and three-dimensional scans taken with the Omega Tracer scanner. Quantification of asymmetry correction using the Michigan Cranial Reshaping Orthosis was attained through the use of three-dimensional imaging and Omega Tracer software.

SUBJECTS

Seventy-one subjects 18 months old and younger at age of helmet therapy initiation who were identified in the Omega Tracer database had undergone an initial scan at the time of evaluation and a final scan at the completion of cranial remolding helmet therapy between January 2009 and March 2012. One subject was excluded due to a diagnosis of scaphocephaly, leaving 70 subjects included in the study. Subject demographics showed a total of 47 male subjects and 23 female subjects (Table 2). The average age at onset of helmet therapy was 5.89 months (177 days), and the average duration of helmet therapy was 4.99 months (150 days). Subjects who exhibited nonsynostotic plagiocephaly and/or brachycephaly and who met the compliance requirement of full-time helmet use were selected. Subjects who discontinued helmet use before clinician recommendation were excluded from the study. Treatment timelines and compliance were verified through review of practitioner treatment notes in CareWeb patient management database. No

Table 2. Demographics

	Plagiocephaly	Brachycephaly	Combined (P/B)	Total
No. subjects	43	5	22	70
Males	29	4	14	47
Females	14	1	8	23
Average age, mo	5.48 (range, 3–7)	6.25 (range, 3–7)	6.62 (range, 3–10)	5.89

P/B, plagiocephaly/brachycephaly.

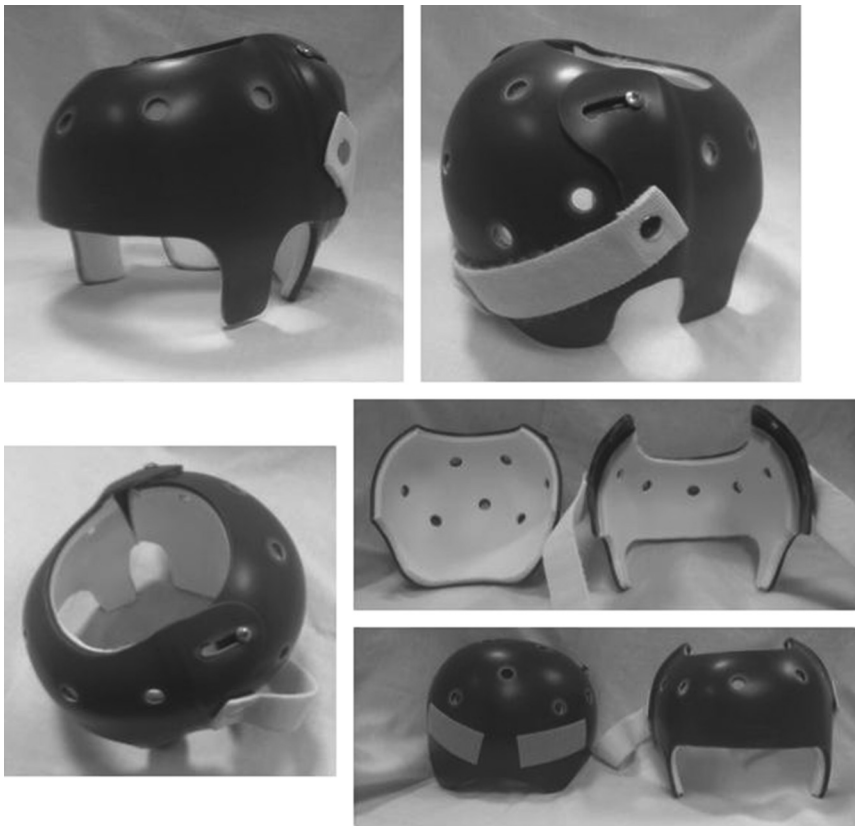

Figure 1. Michigan cranial remolding orthosis.

other data sources were used, and data do not contain patient identifiers or links to patient identifiers.

PROCEDURE

Helmet use of 23 hours per day was recommended, allowing 1 hour out of the helmet for infant bathing and helmet cleaning. All participants were treated with the Michigan Cranial Reshaping Orthosis (Figure 1).

A single practitioner evaluated and measured each subject and modified the initial scan. During the initial assessment, circumferential, diagonal, width, and length cranial measurements were taken using a flexible tape measure and AP-ML gauge. Patients were considered candidates for cranial reshaping therapy if they had unsuccessfully attempted repositioning and displayed a 6-mm or greater difference in diagonals and/or a cephalic index greater than two standard deviations from the mean based on age- and sex-matched mean (Tables 3, 4).[3] After a review of findings and an explanation of the cranial remolding helmet therapy, scanning was initiated. A nylon stocking cap was donned on the infant's head and reflective dots applied on the pinnas of the ears, each tragus, each cheek, each exocanthion, each eurion, each frontotemporale, the glabella, the tip of the nose, the opisthocranion, and otherwise applied in a random pattern over the remainder of the child's cranium.

Scanning was conducted using the Ohio Willow Wood three-dimensional Omega Tracer CAD/CAM scanner (Figure 2). Upon attaining a successful scan, a single clinician modified the scan using the Omega Tracer CAD/CAM software to attain the desired

Table 3. Criteria for helmet therapy

Sex	Age	−2 SD	−1 SD	Mean	+1 SD	+2 SD
Male	16 d to 6 mo	63.7	68.7	73.7	78.7	83.7
	6–12 mo	64.8	71.4	78.0	84.6	91.2
Female	16 d to 6 mo	63.9	68.6	73.3	78.0	82.7
	6–12 mo	69.5	74.0	78.5	83.0	87.5

Adapted from Fish and Dulcey.[3] Cephalic Indices for infants up to age 6 months. −SD is below the standard deviation mean. +SD is above the standard deviation mean.

Table 4. Criteria for helmet therapy

Plagiocephaly grading guide

Take the measurement of A-B. For children that produce a difference in symmetry, follow guide below

Mild, <6 mm
Moderate, 6–10 mm
Severe, >10 mm

Moderate and severe asymmetry warrants coverage for cranial molding helmet therapy.
Age, 3–12 mo
Clinical grading (general rule)
– (Negative): Cranium is normal or has minimal asymmetry.
+ (Positive): A layperson can recognize the deformity when a healthcare professional points out.
++ (Severe): Any layperson can easily recognize the cranial deformity.

University of Michigan Orthotics and Prosthetics Center based on Aetna medical policy.

cranial shape (Figures 3, 4). A positive model of the desired cranial shape was carved from foam blocks and sent to Danmar Products (Ann Arbor, MI, USA) for helmet fabrication. Parents and subjects returned 2 weeks after the initial evaluation and scanning for the fitting and final delivery of the helmet. Fitting appointments included helmet use and care, donning and doffing instructions, and a discussion regarding signs of an ill-fitting helmet. Parents were instructed to contact us immediately if they felt the helmet was not fitting appropriately. In the event adjustments were needed, appointments were made as soon as possible to promote compliance. A 4-day to 5-day break-in period was recommended to facilitate skin accommodation and inspection before overnight use and to allow the infant to become accustomed to the helmet. After the break-in period, full-time use of 21 to 23 hours per day was attained for those who were included in the study. Compliance was determined by patient parent report only and was not an objectively quantifiable outcome measure for the current study. Completion of therapy was recommended by the clinician when the subject's asymmetry was corrected to less than a 6-mm difference in diagonal measurements and/or the cephalic index fell within two standard deviations from their age- and sex-matched mean (Figure 1).[3] Discontinuation of helmet use was ultimately based on parental discretion, and final scans were performed at the final orthosis visit. The recommendation of discontinuation of helmet use included a 2-week period of weaning out

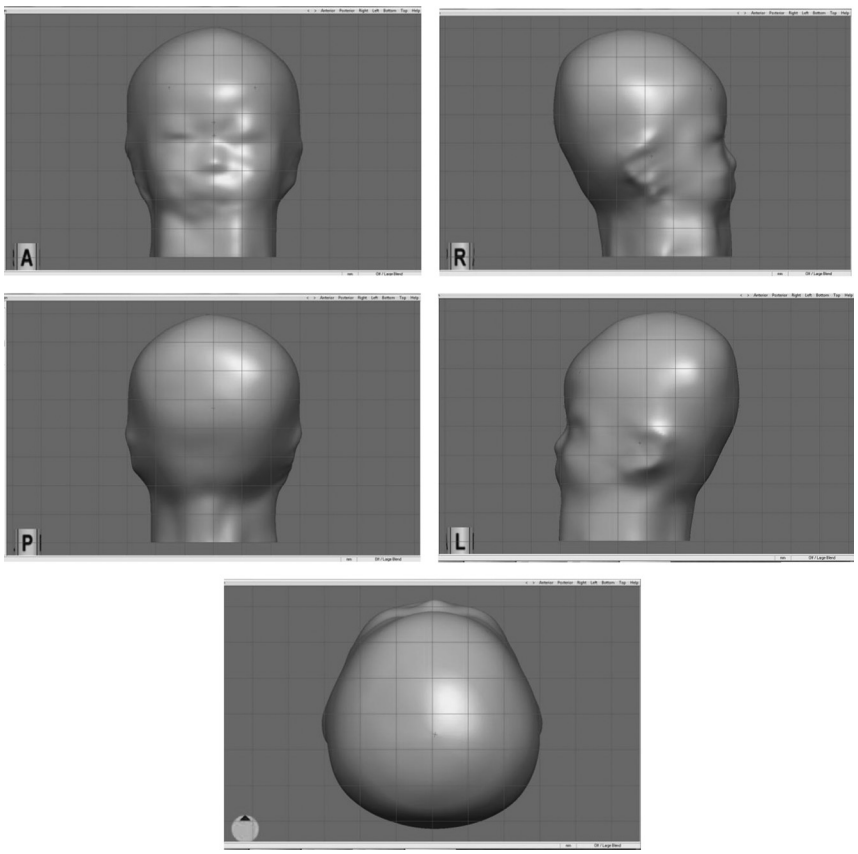

Figure 2. Images of smoothed cranial scans with landmarks.

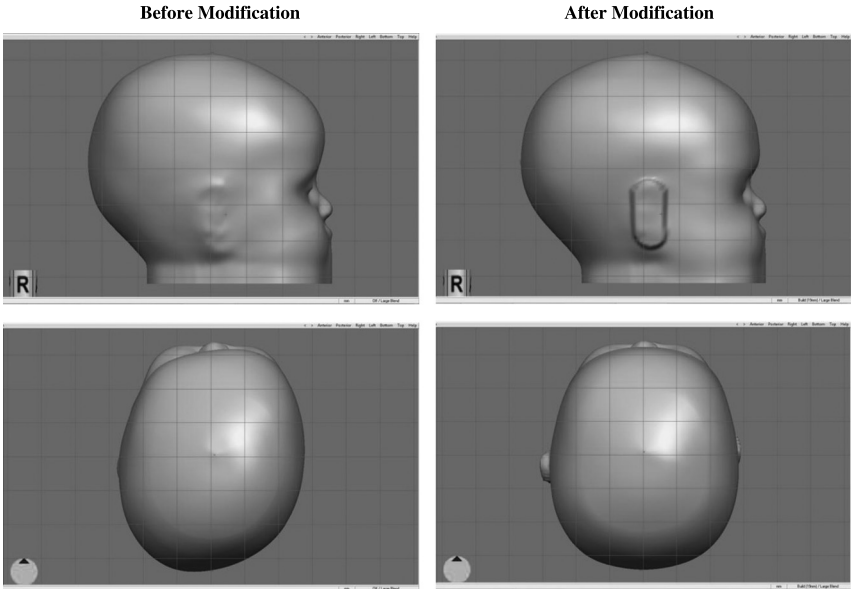

Figure 3. Initial scanned image compared with modified scanned image (plagiocephaly).

of helmet wear, during which only nighttime and naptime use was recommended.

OUTCOME MEASURES

Ohio Willow Wood's Omega Tracer software version 12.0 and Cranial Asymmetry Report (Figure 5)[14] were utilized to compare initial scans and final scans. A combination of the Loveday method setting and manual data retrieval using the "mini-assistant" option were used. The Loveday method allows the identification of landmarks as a starting point for measurement to the Tracer-searched longest point on the contralateral side that lies within a predetermined region. The Loveday method removes some variability in the identification of the Tracer-searched furthest contralateral point within the predetermined region. Diagonals were measured using the clinician-identified most prominent point on each frontal tuberosity in relation to the furthest Tracer-searched point in the shaded region on the posterior contralateral side. Frontal tuberosity landmarks were used in diagonal measurements to more closely replicate caliper measurements used in clinical practice and were identified by one person to ensure consistency.

The cranial length was determined through measurement of the longest distance along the *z* axis between two points, one from each shaded frontal and occipital region through the use of the Loveday setting.[14] The two regions are identified by the Omega Tracer software and are defined in relation to the clinician-identified glabella and opisthocranion.

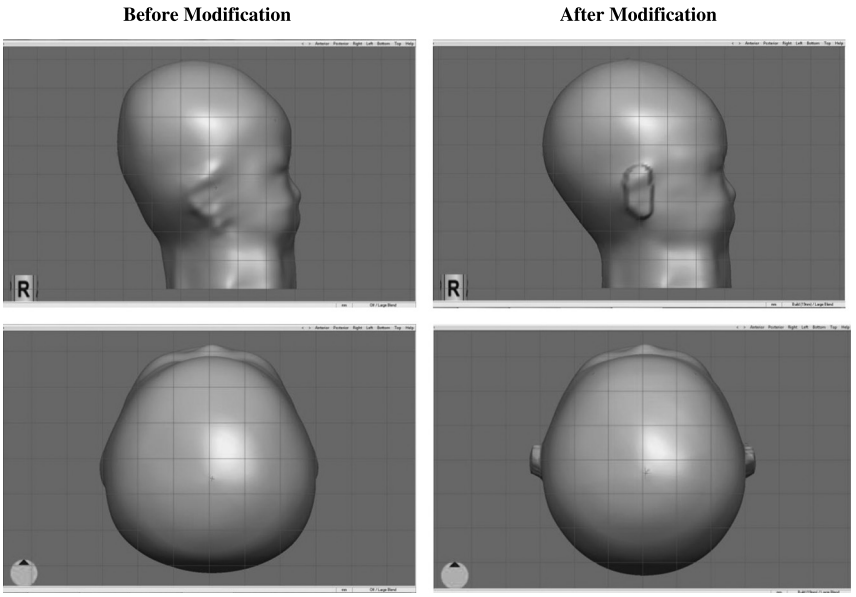

Figure 4. Initial scanned image compared to modified scanned image (brachycephaly).

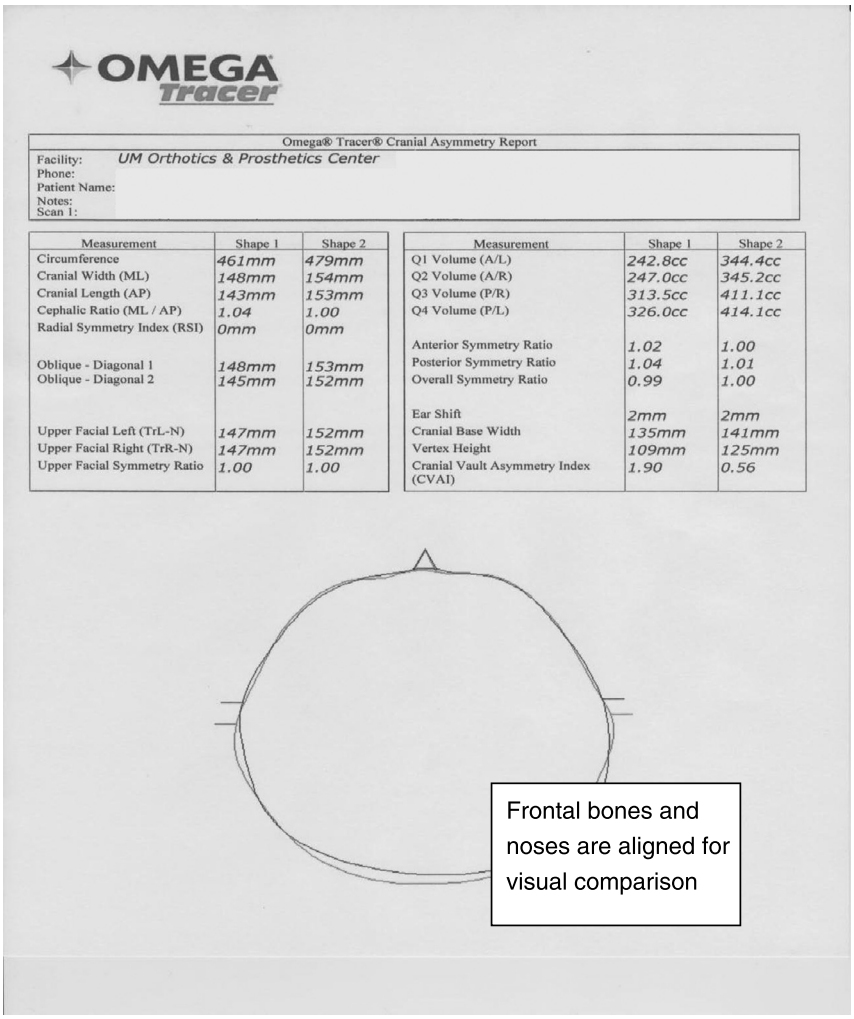

Figure 5. Ohio Willow Wood's Omega Tracer Cranial Asymmetry Report.

Through trial and evaluation, it was noted that the cranial width using the Loveday method occasionally searched too far caudally and included the width of the ears. For consistency purposes and to ensure our measurements closely reflected standard clinical practice, the mini-assistant option was used to manually identify cranial width at the level of the glabella.

Cranial circumference was also measured through the Loveday method as the largest circumference in a region at the level of the glabella and opisthocranion landmarks. Both landmarks were identified by the clinician. For landmark identification consistency purposes, the opisthocranion was identified as the most prominent point at the *y* axis midline of the occipital region at the level of the glabella.

To fully utilize Omega Tracer's Cranial Asymmetry Report, the following landmarks were also identified by the practitioner: frontotemporale, nasion, and vertex. Outcomes were measured by comparison of the Omega Tracer Cranial Asymmetry Report for each subject's initial and final scans. The two scanned images were aligned with respect to the glabella to allow a meaningful visual comparison of the two cranial shapes (Figure 5).[14] A difference in diagonal measurements of 0 mm or a CVAI of 0% will indicate perfect symmetry. Indices were used to allow meaningful outcome comparisons between infants with varied cranial size.

STATISTICAL ANALYSIS

Mean differences between before-helmet and after-helmet therapy CVAI and CR values were analyzed using repeated measures, two-tailed *t*-tests. Correlations were determined using a Pearson product-moment correlation with bivariate correlation for initial versus final asymmetry, total change in CVAI and CR throughout course of therapy, and the age at initiation of therapy and duration of helmet therapy. Significance values were further verified by visual inspection of the plotted data. The confidence interval was used to determine success rate of helmet therapy, with confidence interval set at 95%. The interval was quite wide for all groups; therefore, only general comparisons could be made. All statistical analysis was performed on SPSS 21.0 statistical software (International Business Machines Corp, Armonk, NY, USA) using a significance level of 0.05.

Based on methods and findings from previous studies, a CVAI of less than or equal to 3.5% was used as an indication of successful therapy for those treated for plagiocephaly.[6,15] Percent change in CVAI was reported and compared based on age at

initiation of helmet therapy, sex, and duration of helmet therapy. For brachycephalic subjects, a final cephalic index within two standard deviations of the age- and sex-matched mean was considered a successful outcome (Figure 1).[3,13]

RESULTS

Overall, 84.3% of patients improved in the relevant outcome measure. For improved discrimination of data, subjects were divided into three groups and compared separately in addition to total subject pool comparison. The three groups were plagiocephaly-only (P) with 43 subjects, brachycephaly-only (B) with 5 subjects, and subjects who exhibited a combination of plagiocephaly and brachycephaly (C) with a total of 22 patients. Subject data were also analyzed based on age at helmet initiation and sex.

The plagiocephaly-only group showed a 28.8% improvement in CVAI on average. The average duration of treatment in this group was 5.24 months (157 days). This change in CVAI, from helmet initiation to final scan, was statistically significant ($P < 0.000$).

In the brachycephaly-only group, there was an average cranial ratio improvement of 4.66%. Average duration of treatment for the brachycephaly-only group was 4.39 months (132 days). This change was not found to be statistically significant ($P = 0.542$).

The combined plagiocephaly and brachycephaly group showed a 41.4% improvement in CVAI ($P < 0.000$) and a 2.60% improvement in CR on average ($P < 0.000$). These changes from helmet initiation to final scan were statistically significant ($P < 0.05$). In this group, the average duration of treatment was 4.61 months (138 days).

For all patients, there was a 33.5% improvement in CVAI, a 2.10% improvement in cranial ratio, and an average duration of treatment of 4.98 months (149 days). Change in CR and CVAI were found to be statistically significant. These results are summarized in Tables 5 and 6.

All groups had a higher improvement in CVAI than in CR. Of the 27 subjects in the brachycephaly-only and combined groups, all but four showed improvement in cranial ratio values. However, none improved in CR enough to fall within two standard deviations of the age- and sex-matched means.

Table 5. Treatment results by diagnosis

	Average % improvement		Duration	
	CR	CVAI	Days	Months
Plagiocephaly	1.54	28.75	157	5.24
Brachycephaly	4.66	40.04	132	4.39
Combined (P/B)	2.6	41.41	138	4.61
Total	2.1	33.54	149	4.98

CR, cephalic ratio; CVAI, cranial vault asymmetry index; P/B, plagiocephaly/brachycephaly.

Table 6. Treatment results by age

Average % improvement			Duration	
Starting age	CR	CVAI	Days	Months
<6 mo	2.09	33.73	159	5.31
>6 mo	2.12	33.24	135	4.49

CR, cephalic ratio; CVAI, cranial vault asymmetry index.

No data were discernible for differences in improvement in CVAI or CR between sexes. A positive correlation was found between initial asymmetry and final asymmetry, as well as the total amount of change seen in both CVAI and CR. While not conclusive, this indicates that subjects with higher initial cranial asymmetries tended to exhibit higher levels of improvement, but also tended to complete treatment with higher final asymmetries than children with lower initial asymmetries. There was a very slight negative correlation between age at initiation of helmet therapy and the duration of helmet therapy, but only for patients who were considered successful cases within the plagiocephaly-only group (final CVAI <3.5%). No correlation was found between the duration of helmet therapy and treatment outcomes. There were no significant correlations found between age, initial severity, correction achieved, or final asymmetry.

Of the 70 patients included in this study, 18 (26%) required fabrication of a second helmet. The use of a second helmet was largely related to clinician preference.

DISCUSSION

Overall, there was comparable improvement in CVAI to previous literature. In the present study, the percent improvement of 28.8% in the plagiocephaly-only group and 33.5% for all groups is comparable to the results of Katzel et al.,[5] where 33% improvement in CVAI was reported. Our values showed greater improvements when compared with the reported values from the study by Kluba et al.[9] who reported 10.5% improvement in CVAI for infants 6 months and younger and 8.60% improvement for infants 6 months and older. Lipira et al.[7] and Moss[13] each reported on improvement in CVAI measurements, and both saw a 4.50-mm improvement in asymmetry after treatment. Our values were slightly lower than these studies at 1.54-mm improvement in the plagiocephaly-only group and 1.83-mm improvement overall.

Our study did not find statistically significant improvement in CR in the brachycephaly-only group. This particular group was quite small with only five patients. Perhaps with a larger sample size for this group, statistical significance could be achieved. In the combined group, significant improvements were found in CR and CVAI, possibly due to the larger group size of 22 patients in this group. When compared with the results reported by Katzel et al.[5] who showed a 4% improvement in average CR (from 90% to 86%), the results obtained in the present study are comparable, finding average improvement of 4.66% in the

Table 7. Results from previous studies

	UM CRO						
	Plagiocephaly	Total	Bruner et al[16] (P)	Katzel et al[5] (P)	Kluba et al[9] (P)	Lipira et al[7] (P)	Moss[13](P)
CVAI% Δ	28.75%	33.54%	—	33%	10.50% 8.60%	—	—
CVA Δ, mm	–1.54	–1.83	—	—	—	–4.5	–4.5
Quadrant volume	—	—	36% to 58%	—	—	—	—

brachycephaly-only group. These results are summarized in Table 7.

The data in the present study support the use of the Michigan Cranial Reshaping Orthosis as a viable option in the treatment of cranial asymmetry, specifically in treatment of plagiocephaly, when that treatment's primary method is utilization of a cranial remolding helmet. The Michigan Cranial Reshaping Orthosis is unique to other helmets on the market in improved modifiability and ease of donning and doffing due to the bivalve nature of the design. This helmet can be relieved as needed and expanded circumferentially and in the anteroposterior dimension with the use of foam spacers cut to the appropriate thickness. The low-profile aspect of the design may potentially improve compliance and helmet acceptance, although this was not qualitatively analyzed in the present study. In addition, the increased modifiability decreases necessity for multiple helmets throughout the duration of therapy, possibly decreasing overall cost of treatment.

STUDY LIMITATIONS

There are some limitations to the current study that need to be discussed. The use of Omega Tracer scanner and software may have improved outcome measurement accuracy and consistency; however, software measurements rely on clinician identification of certain landmarks for alignment of the scanned images. Consistent identification of the frontotemporale, glabella, nasion, opisthocranion, and vertex were necessary and were identified by the practitioner on both the initial and final scan. Inconsistency in landmark placement may have caused errors in outcome measures; however, model alignment and landmark identification by a single clinician decreased interclinician variability.

The decision to end helmet therapy may be somewhat subjective. Ultimately, it is the parents' decision regarding satisfaction with the results or weighing the potential for further correction to the onus of continuing with full-time helmet wear. If a more stringent protocol were used to determine discharge from helmet therapy, trends in the length of wear may become discernible.

While only subjects whose parents reported helmet use of 21 to 23 hours per day were included in the study, there remains the possibility of compliance misreporting by subjects' parents. If this occurred, effectiveness of cranial remolding therapy may have been misrepresented in the data. This study also did not quantify complication rates, which may have affected helmet wear.

The retrospective nature of this study and the lack of a control group for comparison purposes limit our insight regarding the effectiveness of the Michigan Cranial Reshaping Orthosis in relation to repositioning. A control group was not a viable option due to ethical concerns regarding withholding treatment from infants with plagiocephaly. The results of this study were compared with those of previous studies to establish a comparison; however, accurate comparisons are difficult to make between studies on helmet therapy due to differences in measurement techniques and variable selection.

FUTURE DIRECTIONS

While many of our research questions were satisfied, still others remain to be answered. Typically, initiation of helmet therapy does not occur until the child is old enough to support his or her head independently, usually around 3 months of age. However, no age limit has been described for an age after, which point initiation of helmet therapy is not indicated. This might be beneficial information for future patients being treated for cranial asymmetry.

In the present study, we did not find any distinguishable trends in rate of correction with regard to age at therapy initiation or with regard to sex. Clinically, there does seem to be a correlation between rate of correction and age at initiation of therapy where both improved correction and increased rate of correction are evident when starting helmet therapy between 3 and 6 months of age. In future research, perhaps a larger subject pool would be needed to determine such possible correlations. It may also be beneficial to include more frequent measurement scans in addition to pretreatment and posttreatment. The decision to discontinue helmet therapy can be somewhat subjective. More frequent measurements would better quantify the actual rate of correction based on the child's age.

The present study also showed higher correction rates for nonbrachycephalic children than for brachycephalic children. One clinical question that may be worth further research is whether or not complications are greater for patients with brachycephaly than for those with plagiocephaly or a combination of the two. It may be beneficial to investigate what improvements might be made to improve outcomes for brachycephalic children or if another type of treatment may produce improved results for this population.

Lastly, it would be highly beneficial to determine a standard for measurement across facilities. Currently, there is no set standard placement of calipers that has been widely accepted, and therefore several different measurement methods are in place and represented throughout the literature. This makes accurate comparison of data across studies very difficult. In order for different styles of helmets to be compared, standardized measures of cranial asymmetry are necessary.

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