Outcome analysis after helmet therapy using 3D photogrammetry in patients with deformational plagiocephaly: The role of root mean square

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Summary Deformational plagiocephaly (DP) is a multifactorial non-synostotic cranial deformity with a reported incidence as high as 1 in 7 infants in North America. Treatment options have focused on non-operative interventions including head repositioning and the use of an orthotic helmet device. Previous studies have used linear and two dimensional outcome measures to assess changes in cranial symmetry after helmet therapy. Our objective was to demonstrate improvement in head shape after treatment with a cranial molding helmet by using Root Mean Square (RMS), a measure unique to 3D photogrammetry, which takes into account both changes in volume and shape over time. Three dimensional photographs were obtained before and after molding helmet treatment in 40 infants (4–10 months old) with deformational plagiocephaly. Anatomical reference planes and measurements were recorded using the 3dMD Vultus analysis software. RMS was used to quantify symmetry by superimposing left and right quadrants and calculating the mean value of aggregate distances between surfaces. Over 95% of the patients demonstrated an improvement in symmetry with helmet therapy. Furthermore, when the sample of infants was divided into two treatment subgroups, a statistically significant correlation was found between the age at the beginning of treatment and the change in the RMS value. When helmet therapy was started before 7 months of age a...
greater improvement in symmetry was seen. This work represents application of the technique of RMS analysis to demonstrate the efficacy of treatment of deformational plagiocephaly with a cranial molding helmet.

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Introduction

Deformational plagiocephaly (DP) is a non-synostotic cranial deformity described as flattening of an infant's head as a result of extrinsic factors such as intrauterine constraint, multiple births, preferential head positioning and congenital muscular torticollis. Since the advocacy of supine sleep positioning for infants to reduce the incidence of Sudden Infant Death Syndrome (SIDS), the incidence and prevalence of DP are on the rise: in 2003 Persing et al. reported that the prevalence of deformational plagiocephaly was in the range of 5%–48% of healthy newborns.1 More recently in 2005 Losee et al. reported an incidence of 1 in 7, noting that the true incidence of DP at an early age is probably still underestimated.2

Treatment options for DP have focused on non-operative interventions including head repositioning and the use of an orthotic helmet device. Numerous non-randomized cohort and single group studies suggest a significant improvement in shape and symmetry with the use of an orthotic helmet device3–5; however, systematic reviews of the literature have shown many pitfalls in the methodology of these studies. Reviewed case series lacked a comparison group and comparative studies lacked randomization of participants to intervention groups. Considerable biases were also present. For example, outcome measures were neither standardized nor validated; conflicts of interest with orthotic companies were not disclosed, sample size was not justified, and substantial information was often not provided by the authors of these studies. Documentation of the effectiveness of treatment requires a durable, reproducible and rapid method to quantify head shape and asymmetry. To date, a reliable standardized outcome measurement for DP is lacking.6–8

Plagiocephalometry and spreading calipers use differences in linear measurements to provide documentation regarding changes in cranial shape but they are limited to the transverse plane and do not take into account asymmetry relative to circumference, volume or overall shape of the cranium. In order to overcome these limitations, measuring techniques have been developed that take into account the three dimensional nature of cranial deformities and the change in head shape over time. Recent technologies such as laser surface scanning and 3D photogrammetry have provided a potential solution to these difficulties. Digital data sets can be acquired rapidly and non-invasively, while simultaneously being archived for future analysis. Improvements in head shape after treatment with an orthotic device have been verified using a three dimensional non-invasive laser scanner3–10 and 3D photogrammetry is capable of greater precision when compared with direct anthropometry.11–14

Our study aims to analyze the effect of helmet therapy with 3D photogrammetry by looking at changes in both volume and overall shape of the cranium over the duration of treatment. Root mean square (RMS) is a measurement unique to 3D photogrammetry, which takes into account both changes in volume and shape. It is the statistical measure of the magnitude of a varying quantity; the mean value of aggregate distances between surfaces (measured in millimeters). In our study, we used the root mean square value to quantify symmetry before and after helmet treatment in children with deformational plagiocephaly.

Materials and methods

In a retrospective analysis, 40 infants (23 males, 17 females) with DP referred to our institution were included in this study. Subjects were between four and 10 months of age at the time of referral. All patients in this study underwent treatment with an orthotic helmet device. Infants were classified into two groups: right posterior plagiocephaly and left posterior plagiocephaly. Patients with brachycephaly (posterior symmetrical flattening of the cranium and/or a cephalic index equal or greater than 95%) were excluded from the analysis.

The cranial molding orthosis used at the Hospital for Sick Children facilitates the development of normal cranial symmetry by inducing prominent areas of the skull to be retained passively while flattened areas grow into the hollow spaces of the device. The device is made of a hard outer shell with a foam lining. Each helmet is custom made based on anthropometric measurements and a plaster moulage of the infant’s head. Adjustments to each cranial molding device were carried out based on established departmental guidelines, on a monthly basis, to maintain consistency in fit criteria.

All patients underwent 3D photography at the beginning and at the completion of molding helmet treatment. All images were captured between January 2010 and November 2011. A 3D photograph of each infant was acquired using a multicamera system (3dMD; Cranial System, Atlanta, GA). The full 360-degree 3D photograph was generated with the 3dMD system using a 5 pod, 20 camera configuration and a capture speed of 1.5 ms, which allows errors arising from the movement of infants to be avoided. All children were wearing a one-ply open face stockinet over their head to eliminate extraneous data. Markers were placed on the sellion and each tragion of the reconstructed image to define the anatomical reference planes, which were then used for quadrant placement and volume calculations. Standard anthropometric parameters for head length, width and head diagonals were collected, using the 3dMD Vultus® analysis software, according to landmark

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an anthropometric literature. All of the pre-treatment and post treatment measurements were performed by the same investigator (TB).

The standardized orientation of each image was determined by placing the origin of the three coordinates at the midpoint between the tragion landmarks. The horizontal Y-axis was defined at the supraorbital ridge. The Z-axis was perpendicular to the Y-axis on the reference plane, bisecting the tragions, separating anterior quadrants from posterior quadrants. The X-axis was projected superiorly and inferiorly perpendicular to the zero reference plane, separating left from right quadrants. Images were transferred to the Canfield Mirror Suite software (Canfield Imaging Systems, Fairfield, NJ) for calculation of the RMS measures.

RMS and statistical analysis

The RMS is a measure unique to 3D photogrammetry that takes into account changes in cranial volume and shape over time. It does not measure volume per se, but it is an indicator of volume change as it calculates the absolute difference between the three dimensional space occupied by two distinct surfaces. Root mean square was derived by superimposing left and right quadrants and by calculating the mean value of aggregate distances between these surfaces (measured in millimeters). In other words, Root Mean Square is the area under the curve in three dimensions. Occipital RMS was calculated by superimposing left and right posterior quadrants and frontal RMS was calculated in similar fashion by superimposing left and right anterior quadrants. Measures were obtained before and after treatment with a cranial molding orthosis. The mathematical equation used for RMS calculation is as follows:

\[ \text{RMS} = \sqrt{\frac{x_1^2 + x_2^2 + \ldots + x_N^2}{N}} \]

X represents the orthogonal distance between two points and N represents the total number of reference points between the two compared surfaces. The number of points (N) is determined by the number of points captured by the 3D camera image for the selected region. These points are used as vertices to create the wireframe for the surface. Shapiro–Wilks's test of normality indicated normal distribution of the occipital RMS values, however the frontal RMS values were not normally distributed. Accordingly, paired T-tests and the Wilcoxon Signed Rank Test were computed on the respective data sets using SPSS v.20 statistical software. Mixed-design Analysis of Variance (ANOVA) was computed to compare the treatment effects helmet therapy on infants who began treatment at a younger versus older age, demonstrated that the data for the occipital measures was normally distributed (\( p = 0.485 \)); however the data on the frontal measures was not normally distributed. Therefore, the data for the frontal measures were analyzed with the Wilcoxon Signed Rank Test. Non-parametric testing was used to analyze the patients that did not demonstrate an improvement with helmet therapy due to small sample size.

Patients were also divided into two groups based on age at which treatment was initiated (group 1: 0–6 months and group 2: 7–10 months). Allocation of infants to each group was based on age at clinical presentation. Confidence intervals were set at 95% (\( p < 0.05 \)) for all statistical calculations. The Wilcoxon Signed Rank test was used to analyze the patients that did not demonstrate an improvement with helmet therapy due to small sample size.

Results

Forty patients (17 females; 23 males) underwent molding helmet treatment for DP (26 right sided, 14 left sided) for a mean length of 4 +/− 1.5 months (2–8 months). All patients tolerated the molding helmets and there were no issues related to treatment (Table 1).

RMS was applied to the frontal and occipital regions. Mean occipital RMS reduced from 4.73 to 3.52 (\( p < 0.001 \)) during the treatment period, indicating a significant improvement in posterior skull asymmetry. Mean frontal RMS was also significantly improved with a reduction from 2.02 (pre-treatment) to 1.59 (post treatment) in all patients (Table 2). One patient showed no improvement in occipital RMS and six patients showed no change in frontal RMS during the treatment period.

Changes in occipital RMS were greater (\( F = 11.580, p = 0.002 \)) in the younger age group (<7 months of age), but this difference was not seen in frontal RMS (\( F = 0.108, p = 0.745 \)) (Figures 3 and 4).

Discussion

In this study, we demonstrated significant (\( p < 0.0001 \)) improvement in head shape after treatment with a cranial molding helmet by using root mean square to measure both changes in cranial volume and shape over time. Previous studies have documented an improvement in head shape after helmet therapy by looking at anthropometric measurements, head tracings, clinical experience and parental assessment; however, most of these tools are time consuming, observer dependent and limited to linear measures affected by subjective variability. The introduction of more advanced technology such as 3D computed tomography (CT); 3D surface scanning lasers and 3D photogrammetry has overcome some of these limitations by

<table>
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<th>Table 1 Patient Characteristics.</th>
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<td>Gender</td>
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<tr>
<td>Male</td>
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<tr>
<td>Female</td>
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<tr>
<td>Plagiocephaly</td>
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<td>Right Posterior</td>
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<td>Left Posterior</td>
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<td>Pre-treatment age (months)</td>
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<td>Minimum</td>
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<td>Maximum</td>
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<td>Mean</td>
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<td>Length of treatment (months)</td>
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<td>Mean</td>
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providing objective measures of symmetry and volume for the assessment of efficacy of treatment.\textsuperscript{8,9,27–31} Three dimensional imaging modalities overcome errors caused by patient movement, they limit inter-observer variability, and provide the opportunity for unlimited repetition of measurements and the option to archive results for long term follow up.

In 2004, Bruner et al. reported a decrease in cranial asymmetry with the use of helmet therapy by measuring overall changes in intracranial volume derived from reformatted three dimensional CT scans.\textsuperscript{28} Although this was the first study to use intracranial volume to assess the efficacy of treatment of DP, increasing concerns regarding radiation exposure from CT scans in childhood and the subsequent potential increased risk of cancer limit the indications for the use of CT scans in infants with cranial vault asymmetry.\textsuperscript{32} In 2009, Thompson et al. used a hand held 3D surface scanning laser to report a significant improvement in head shape in 116 patients who were compliant with helmet therapy. Treatment was assessed by a severity and compliance score; however, their outcome analysis was limited to linear anthropometric measures.\textsuperscript{8}

Plank et al. used the STARscanner (Orthomerica, Orlando, FL), a digital surface laser scanner, to document changes in 3D head shape after helmet therapy. Their analysis of 25 independent variables led to the identification of five variables as the best predictors of asymmetry: the Posterior Symmetry Ratio (PSR), Overall Symmetry Ratio (OSR), Cranial Vault Asymmetry Index (CVAI), Radial Symmetry Index (RSI) and the Cephalic Index (CI).\textsuperscript{12} Over 96% of the treatment group showed an improvement in each of these variables after treatment with a cranial molding orthosis. In 2010, Schaaf et al. also documented an improvement in symmetry after helmet therapy by comparing pre and post treatment CVAI measures obtained with 3D photographic analysis.\textsuperscript{27}

Although most of these symmetry indices (PSR, OSR, CVAI) are reproducible from one subject to another because they do not depend on age or head circumference, they are 2D measures that do not take into account the multi-planar changes in DP which affect both changes in cranial volume and shape over time. The RSI and RMS are measures unique to 3D imaging systems: RSI provides morphological data by vector analysis at 15° increments, while RMS is the only measure that is an indicator of volumetric change by calculating the mean value of aggregate distances between surfaces. While RSI is a 2D surface measure, RMS is an axial measure that accounts for changes in volume and shape over time.

Using RMS as an indicator of asymmetry, there was a significant ($p < 0.0001$) improvement in both occipital and frontal values with helmet therapy. The average improvement in occipital RMS (1.21 mm) was greater than the average improvement in frontal RMS (0.43 mm). The difference in mean occipital and frontal RMS measures can be explained by the fact that in treated DP, most of the skull remodeling occurs in the occipital region (Figure 1). For the single subject whose occipital RMS failed to improve with treatment: the patient was older, started treatment later, and had a shorter duration of treatment than the rest of the study group. Lack of improvement in this case may also be secondary to poor compliance with the 23 h/day helmet wearing time during treatment, which was not closely monitored. For the six patients who failed to show an improvement in frontal RMS with treatment, the differences were not as great ($D = 0.18$, $p < 0.001$). Pre and post treatment photographs of these infants did show a clinical improvement in occipital symmetry as also demonstrated by an improvement in occipital RMS values. However, very little frontal skull remodeling was seen with treatment. The significance of these findings warrants further investigation.

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<tr>
<th>Table 2</th>
<th>Changes in RMS Before and After Treatment.</th>
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<td></td>
<td>Pre</td>
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<tr>
<td>Occipital RMS (mm)</td>
<td>4.73</td>
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<tr>
<td>Frontal RMS (mm)</td>
<td>2.02</td>
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<tr>
<td>0–6 months ($N = 19$)</td>
<td>5.2</td>
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<tr>
<td>Frontal</td>
<td>1.98</td>
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<tr>
<td>7–10 months ($N = 21$)</td>
<td>4.3</td>
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<tr>
<td>Occipital RMS (mm)</td>
<td>2.1</td>
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Figure 1 Pre and post treatment 3D images superimposed in a patient with left DP demonstrating an improvement in overall symmetry.
with a larger patient cohort and comparison with a control group (Figure 2).

In the current literature there is overall consensus that the effectiveness of helmet therapy is dependent on the remaining growth potential of the infant skull. However, differences in opinion exist with regard to timing and treatment regimens.\(^8,33–36\) When the sample of infants in this study was divided into two treatment subgroups for further analysis (group 1: 0–6 months and group 2: 7–10 months old), a statistically significant \((p = 0.002)\) correlation was found between the age at the beginning of treatment and the change in the RMS value (Figure 3). When helmet therapy was started before 7 months of age a greater improvement in symmetry was seen. Delaying the start of helmet therapy to age 7 months or later resulted in a less favorable outcome as manifested by the smaller change in the root mean square value (Figure 4). Previous studies have shown that due to rapid natural cranial growth, skull thickness and pliability, spontaneous correction of skull asymmetry may be possible up to 4 months of age.\(^19\) Our data support previous findings by Thompson et al.\(^8\) and Kluba et al., which showed that optimal outcomes can be achieved when helmet therapy is started between 4 and 6 months of age.

The main limitations of this study are the lack of a control group, selection bias in the study population, no comparison with normative data and the absence of a classification system for deformational plagiocephaly. The lack of a randomly selected control group is the main limitation in most studies looking at treatment outcomes in DP. In our retrospective analysis we were unable to identify an adequate control group for comparison. Only nine patients

![Figure 2](image2.png)

**Figure 2** Change in RMS over the treatment period in a patient with left DP.

![Figure 3](image3.png)

**Figure 3** Changes in occipital RMS values based on treatment age. A greater improvement in occipital symmetry was achieved when helmet therapy was started before 6 months of age.
with DP did not receive helmet therapy. This sample was self selected, comprised of patients with mild DP whose families declined helmet therapy. The sample also included patients with brachycephaly. As the purpose of this study was to quantity changes in skull asymmetry before and after helmeting, the application of RMS is not useful in symmetric cases of plagiocephaly. This retrospective study demonstrates an improvement in cranial asymmetry with molding helmet therapy; however, without a comparison to a randomized control group where the patients did not receive treatment, we cannot say with certainty how much of the change in head shape was attributable to the molding helmet as opposed to the natural history of the condition itself.

Further attempts at standardizing an outcome measure are also limited by the fact that there is no agreed upon classification system for non-synostotic plagiocephaly. Various classification systems have been suggested based on either clinical exam\(^1\) or anthropometric measurements.\(^{17,37}\) However, currently available clinical classification systems are only moderately reliable at best\(^2\) and it is unclear whether anthropometric measurements correlate with clinical impression of severity.\(^{27}\) Designing a classification system for non-synostotic plagiocephaly based on objective measurements that correlate with clinical severity and that are reliable, valid and easy to use is the challenge of future studies.

Since this is the first study to use Root Mean Square as an outcome measure for helmet therapy in DP, no normative data exist for comparison. Work is underway to establish a database of normative values using the Root Mean Square. Although the database is still in its infancy, preliminary data suggests that there is a range of normal age-based values, which may take into account variations in head shape due to ethnic diversity and cultural practices. Theoretically, three dimensional changes in head morphology could be monitored with the RMS value in a variety of conditions with cranial asymmetry including synostotic and non-synostotic plagiocephaly, metopic, coronal and sagittal synostosis, as well as fibrous dysplasia and hemifacial microsomia.

Conflict of interest
The authors have no conflicts of interest and no sources of funding to declare.

References