

Outcome Analysis of Passive, Prefabricated Helmet Therapy for Positional Plagiocephaly as Measured by a Three Dimensional Surface Scanning Laser

J.T. THOMPSON, L.R. DAVID, C. SANGER, B. WOOD and L.C. ARGENTA

Department of Plastic and Reconstructive Surgery, Wake Forest University,
Winston-Salem, North Carolina, USA

SUMMARY

Purpose: A dramatic rise in positional plagiocephaly has been noted over the last decade. We present our results of an inexpensive method of prefabricated helmet molding therapy modified with adjustable foam blocks.

Methodology: 175 infants with positional plagiocephaly were treated at our institution over a 6 month period using prefabricated helmets modified to fit each patient. Results of therapy were measured using a 3-D surface scanning laser. This scan is used to follow the changes in skull shape with therapy. Compliance was also carefully documented.

Results: Improvement in head shape was noted after a mean of 4.9 months of therapy. The scanning laser allowed for objective measurements of symmetry over time.

Conclusions: This method of prefabricated helmet is an affordable and clinically effective tool to treat positional plagiocephaly. Outcome analysis can be reliably measured in a quantifiable way using the 3-D scanning laser.

INTRODUCTION

Since 1992 the incidence of deformational plagiocephaly in the United States has risen dramatically. This is generally attributed to the American Academy of Pediatrics "back to sleep campaign".¹ Parents are instructed to position their babies on their backs to sleep, thus perpetuating posterior pen-natal skull asymmetry.^{2,3} In some studies the incidence of deformational plagiocephaly is up to 15% of otherwise healthy infants.^{2,4,5}

The natural history of this condition has been debated. Some believe that this deformity seen in infants resolves or becomes sufficiently diminished as they grow.⁴ There are several other studies that suggest some of these patients will not return to normal and will retain their craniofacial deformity permanently.^{6,7} Few studies have objectively

followed craniofacial asymmetry in these children into their adult years, therefore the data is limited. In addition, there has been speculation regarding the neurological development of these children. Although not conclusive, several studies have demonstrated abnormal development when compared to age matched controls.³

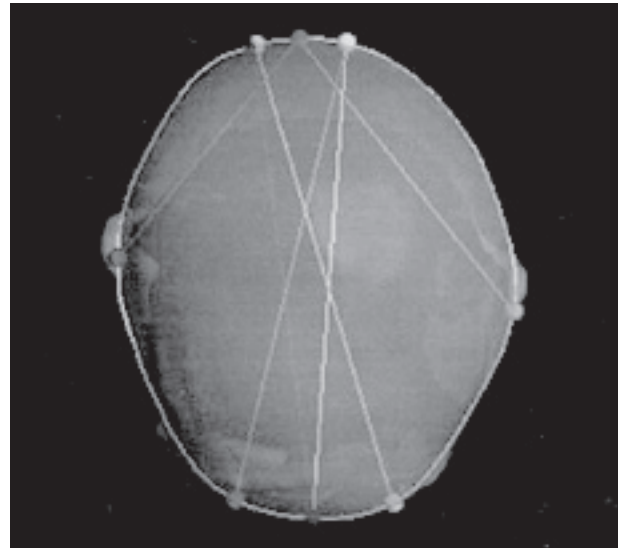


Figure 1 - Vertex view of skull from laser scan. Lines are drawn to reflect symmetry of occiput, forehead and ears.

Given the uncertainty of the natural history, many craniofacial units have chosen to treat this condition rather than observe it. Treatment options include observation, head positioning, helmet therapy, cranial vault remodeling with most centers using either positioning devices or helmets.

At Wake Forest University patients with deformational plagiocephaly have been offered treatment with a prefabricated helmet.^{5,8} The helmet works by functioning as a head positioning device as well as distributing the pressure across the skull when the patient lays on the head. This allows the skull to grow and expand with the underlying brain growth without external pressure being directly applied to the cranial abnormalities.

This study addresses two issues related to helmet therapy for positional plagiocephaly.

First, an objective means of following head shape over time using a surface scanning 3D laser device is established. Second, using this method patients were followed through their treatment to assess success of treatment.

METHODS

Institutional review board approval was obtained prior to commencement of the study. Over a 6 month period 175 patients were enrolled in the study. The diagnosis of positional plagiocephaly was made based on examination by a craniofacial surgeon and radiography was used as necessary. Exclusions from the study were made for patients who failed to show for follow-up appointments, who had a symmetric deformity (deformational brachycephaly), and those with coinciding craniofacial abnormalities other than deformational plagiocephaly.

Each prefabricated helmet [ASEMT, Lewisville NC] was fitted to the patient by applying extra foam padding as necessary. In addition, foam blocks were attached to the posterior surface of the helmet to keep the child from lying on the affected side. Parents were told to keep the child in the helmet as much as possible, especially while sleeping. Follow up appointments were performed every six to eight weeks.

Outcomes were measured by both traditional subjective assessment of head shape using a clinical scoring system, and by objective measurement of asymmetry performed using a 3-D laser scanning device. The subjective clinical scoring system has been published previously and is a simple way of classifying deformation plagiocephaly based on an anatomic progression of deformity.⁹

The objective scoring system was designed to assess the asymmetry of the occiput, forehead, and ear position by

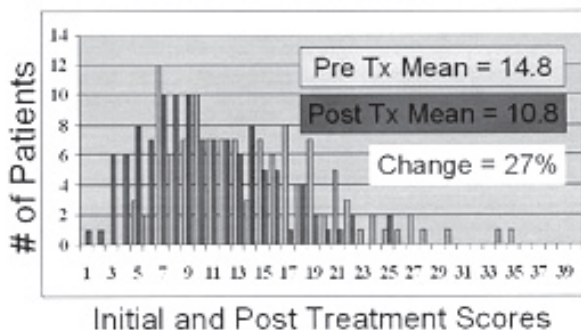


Figure 2 - Initial v. Post-treatment composite scores showing an overall 27% improvement.

drawing a pair lines for each point to be measured. (See Figure 1) The length of these lines was then taken as a ratio.

From this the absolute difference from 1 was obtained. This gives a score measuring the asymmetry of the two lines since in perfect symmetry the ratio would be one, which would give a score of zero. The larger the score, the more asymmetric the lines would be. This measurement was performed for all three lines and then a composite score was calculated. A score was calculated on each clinic visit.

Compliance with helmet therapy was also followed. Parents were asked how many hours per day on average their child was wearing the helmet. The responses were then scored as poor (<6hrs/day), fair (6-12 hrs/day), good (12-18 hrs/day), and excellent (>18 hrs/day).

RESULTS

Of the initial 175 patients, 44 (25%) were excluded due to failure to follow up. Six were excluded for symmetric deformational brachycephaly, and three others were excluded for coexisting craniofacial conditions. Of the remaining 117 patients, the average the age at initial

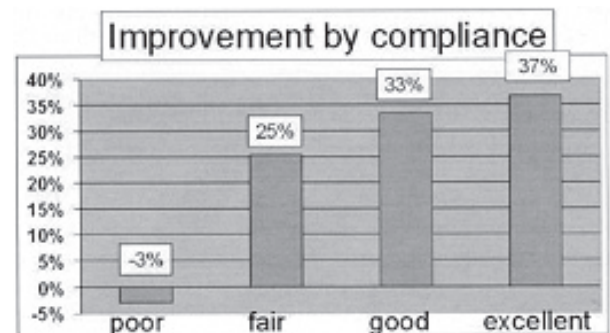


Figure 3 -Change in composite score by compliance.

treatment was 6.1 months and mean treatment length was 4.9 months. Seventy-two percent of the patients were male and 28% female.

Compliance with the helmet therapy was as follows: Poor 16%, Fair 30%, Good 41%, and Excellent 13%.

The initial and post treatment scores were calculated and are shown in Figure 2. The initial mean score was 14.8 (range 5.3 - 35.8). Following treatment the mean score was 10.8 (range 1.6 —25.7) which was a 27% improvement. When comparing outcome and compliance, it was found that patients in the better compliance categories obtained better results. (Figure 3) In addition, it was found that

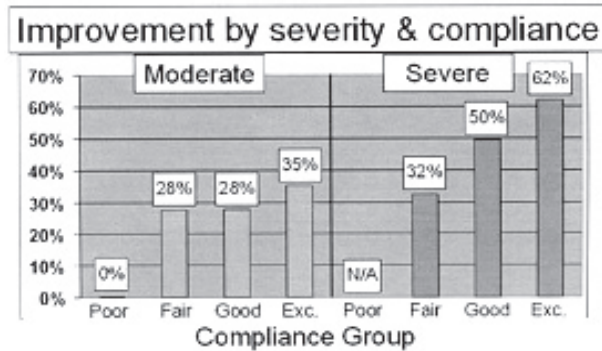


Figure 4 - Improvement by compliance and severity.

patients with more severe deformities obtained better results and this also corresponded to compliance. (Figure 4)

CONCLUSION

Deformational or positional plagiocephaly has been an increasing problem for infants as a result of supine positioning. The debate about the natural history of this condition continues. While some have demonstrated persistence of the skull asymmetry into adulthood, others have shown spontaneous resolution in some children. In addition the nature of how skull deformity without synostosis affects neurological development is currently a subject of ongoing research.

Treatment options are varied, but at our institution these patients are offered prefabricated helmet therapy.

The helmets offered in this study were prefabricated helmets that are purchased in bulk in generic sizes. This allows for reduced cost (\$500.00 USD) as the helmets are not tailor-made for each child. In addition, the helmets are adjustable and do not exert pressure on the patient thus avoiding any pressure related complications. Patients were primarily treated between ages 6 and 12 months as it is generally felt that the skull is too firm to improve with this technique once the anterior fontanelle closes.

Our results demonstrated several important points. The improvement in skull shape over the course of treatment was measurable using the laser scanning system. In

addition we were able to correlate improvement in skull shape with compliance. While the non-compliant patients do not offer a true control, we are able to determine that the helmets do have a positive effect on those patients who wear them especially >12 hrs/day. Also, we noted that patients with more severe deformities obtained the best results. From this we can conclude that the patients most likely to benefit from this type of helmet therapy are those that have moderate to severe deformities and wear the helmets >12 hrs/day. Patients with less severe deformities can expect less dramatic improvement especially with poor compliance.

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