

Cranial Growth Unrestricted During DOC® Treatment of Plagiocephaly

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INTRODUCTION

The DOC Band® is a cranial orthosis used to treat deformational plagiocephaly by redirecting symmetrical growth of the head. It works by applying a mild holding pressure to the prominent regions of the skull, while leaving room for growth in the adjacent flattened regions. However, during approval of this device by the U.S. Food and Drug Administration (FDA), concerns were raised about potential restriction of cranial growth.[1,2] The purpose of this investigation was to assess the potential growth restrictions associated with DOC® treatment.

MATERIALS AND METHODS

The subjects for study were retrieved from a pool of 477 non-syndromic, non-synostotic patients treated for deformational plagiocephaly from 1993 through 1995. Only those children meeting the following four criteria were selected for additional analysis: (1) compliant with the DOC treatment protocol; (2) entered treatment prior to 1 year of age; (3) had a complete set of anthropometric measurements at entrance into and exit from the program; and (4) the anthropometric measurements were obtained by a single anthropologist.

The anthropometric assessment included a series of measurements that define the symme-

try or asymmetry of the cranial vault, skull base, and upper face as well as document the growth of the cranium including circumference, cranial breadth, and cranial length. Paired t-tests were used to evaluate the significance of changes in anthropometric measurements with respect to changes in both symmetry and overall growth of the cranium. All statistical analyses were performed using SAS.[3] Differences were considered significant if $p < 0.05$.

RESULTS

The study sample consisted of 190 children meeting the inclusion criteria: 81 females (42.6%) and 109 males (57.4%). All patients presented with significant cranial vault asymmetry with 180 (94.7%) also demonstrating concurrent skull base and orbitotragial asymmetries. Mean age at the start of treatment was 6.5 (± 1.9) months with an average treatment time of 4.1 (± 2.1) months.

Statistical analyses based on paired comparison of pre- to post-treatment measurements (paired t-tests) demonstrated highly significant reductions in asymmetry in all three regions ($p < 0.001$). Mean cranial vault asymmetry was reduced 5.1 mm (8.2 mm to 3.2 mm), mean skull base asymmetry decreased 2.7 mm (5.8 mm to 3.1 mm), and mean orbitotragial depth asymmetry was reduced 1.9 mm (4.3 to 2.4 mm) following orthotic management.

The significance of growth of the head during orthotic management was evaluated by comparing pre- and posttreatment measurements of head circumference, cranial breadth, and cranial length. Statistical analysis of these paired measurements revealed statistically significant increases in all three parameters ($p < 0.001$). Mean head circumference, a measure of the overall size of the head, increased from 434.3 (± 20.1) mm at entrance to 453.5 (± 19.7) mm at exit. Not surprisingly, cranial breadth and length also increased significantly during treatment. Cranial breadth increased from an entrance mean of 119.9 (± 8.2) mm to 125.9 (± 7.2) mm at exit; while mean cranial length increased from 141.8 (± 9.2) mm at entrance to 148.7 (± 9.0) mm at exit. Thus, significant correction of the asymmetries was achieved with synchronous and significant growth of the skull.

Growth of the head may be presented visually by plotting circumference measurements against age- and gender-specific normative data

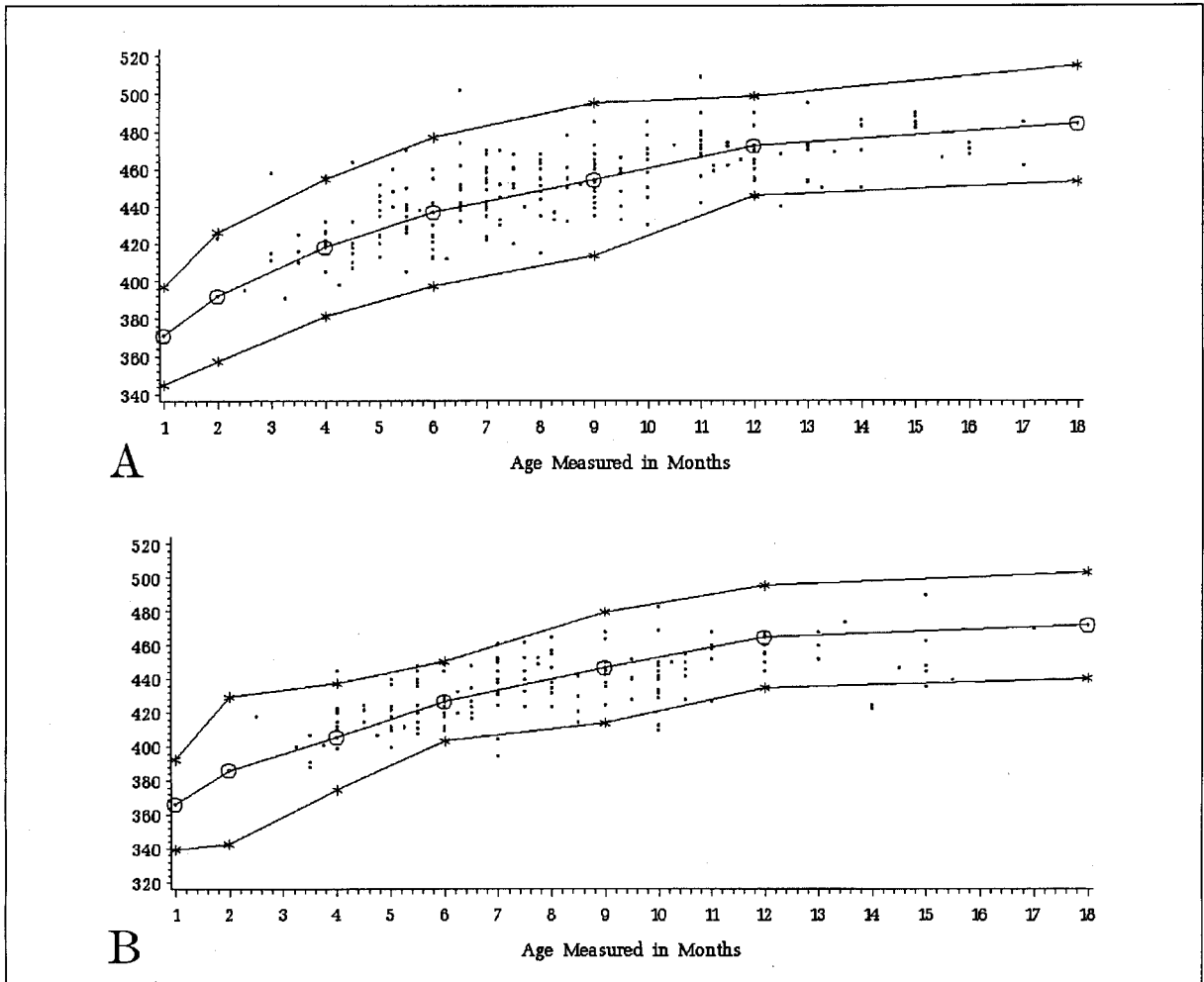


Figure 1: Head circumference. Head circumference is plotted against age at measurement. The plots are overlaid with data from age- and gender-specific norms provided by Dekaban [3] showing means and ± 2 SD. Norms are represented by connected data points; patient data by individual data points. (a) Plot of entrance and exit head circumference measurements of 109 male patients. (b) Plot of entrance and exit head circumference measurements of 81 female patients.

provided by Dekaban [4]. Showing means and ± 2 SD. (Figure 1). From this figure, it can be seen that infants being treated orthotically exhibit normal growth trajectories when compared against their age and gender specific norms. Normal growth trajectories are also observed for both cranial breadth and cranial width [5].

CONCLUSIONS

Three observations are evident from the anthropometric data: (1) patients exhibit statistically significant reductions in craniofacial

asymmetry following orthotic management; (2) patients demonstrate statistically significant increases in circumference, cranial breadth, and cranial length during treatment; and (3) infants being treated exhibit growth trajectories similar to normals. In short, these findings demonstrate that DOC treatment results in significant reduction of craniofacial asymmetry, while more importantly documenting that this correction is achieved with concomitant, statistically significant growth of the skull.

In this investigation, we have documented the ability of our orthosis to reshape the head without restricting overall growth of the skull. However, we recognize that any cranial ortho-

sis has the potential to restrict cranial growth. For that reason, our treatment program incorporates special controls to minimize this risk while assuring effectiveness. This includes that patients return for weekly or biweekly visits to allow us to monitor the correction being achieved as well as ensure proper growth.

DISCLOSURE

Ms. Pomatto has a financial interest in the product discussed in this article.

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