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Helmet Treatment of Infants With Deformational Brachycephaly

Kevin M. Kelly, PhD[1], Edward F. Joganic, MD, FACS[2], Stephen P. Beals, MD, FACS, FAAP[3], Jeff A. Riggs, MA[4], Mary Kay McGuire, OTR/L[4], and Timothy R. Littlefield, MS[4]

Abstract

Deformation of the cranium in infancy represents a spectrum of deformity, ranging from severe asymmetric yet proportional distortion of the skull in plagiocephaly, to nearly symmetric yet disproportional distortion in brachycephaly. As such, the condition is best described as *deformational plagiocephaly-brachycephaly* with isolated plagiocephaly and/or isolated brachycephaly being at either ends of the spectrum. Due to its symmetric appearance, deformational brachycephaly is often incorrectly dismissed as being less concerning, and it has sometimes erroneously been reported that brachycephaly cannot be treated successfully with a cranial orthosis. We prospectively report on 4205 infants with isolated deformational brachycephaly treated with a cranial orthosis from 2013 to 2017. These results demonstrate that the orthosis is successful in the treatment of deformational brachycephaly with an 81.4% improvement toward normal (95.0 to 89.4) in cephalic index. We furthermore demonstrate that entrance age influences treatment results, with younger infants demonstrating both improved outcomes and shorter treatment times.

Keywords

deformational brachycephaly, cranial orthosis, flat head syndrome, cephalic index

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Introduction

Brachycephaly is characterized by symmetric, bilateral flattening of the occiput resulting in a head shape that becomes disproportionately short and wide. While the product of the same external forces that cause deformational plagiocephaly, deformational brachycephaly is often dismissed as less urgent or significant.[1] In particular, the lack of asymmetry often leads to the incorrect assumption that brachycephaly is somehow more "cosmetic" in nature. However, both plagiocephaly and brachycephaly have been shown to deform the skull base, affecting the position and orientation of the temporomandibular joints, and affect occlusal function.[2-7] Specifically, a brachycephalic deformation of the cranial vault results in a posterior tipping of the mid cranial fossa (central skull base) changing the angular orientation of the temporomandibular joints, and potentially resulting in Class III malocclusion (underbite).[8-13] Anterior displacement of the mandible may also affect the soft tissue of the upper airway leading to airway restrictions and obstructive sleep apnea.[14-18]

Moreover, when the back of the head is flattened, the center of mass of the head is displaced anteriorly and superiorly, which, in severe cases, may affect an infant's postural control and postural alignment.[19,20] While the muscular imbalance and restricted range of motion (ie, torticollis, or lateral/rotational imbalance) frequently associated with plagiocephaly is commonly discussed, the muscular imbalance of brachycephaly (what we'll call AP imbalance) has largely gone unrecognized. As the center of mass shifts, the anterior neck muscles become shortened while the extensor neck muscles get lengthened leading to an imbalance of the flexor/extensor muscle groups. This imbalance leads to poor

[1]University of Iowa, Iowa City, IA, USA
[2]Barrow Cleft and Craniofacial Center, Phoenix, AZ, USA
[3]Southwest Craniofacial Center, Phoenix, AZ, USA
[4]Cranial Technologies, Tempe, AZ, USA

Corresponding Author:
Timothy R. Littlefield, Cranial Technologies, Inc, 1395 West Auto Drive, Tempe, AZ 85248, USA.
Email: tlittlefield@cranialtech.com

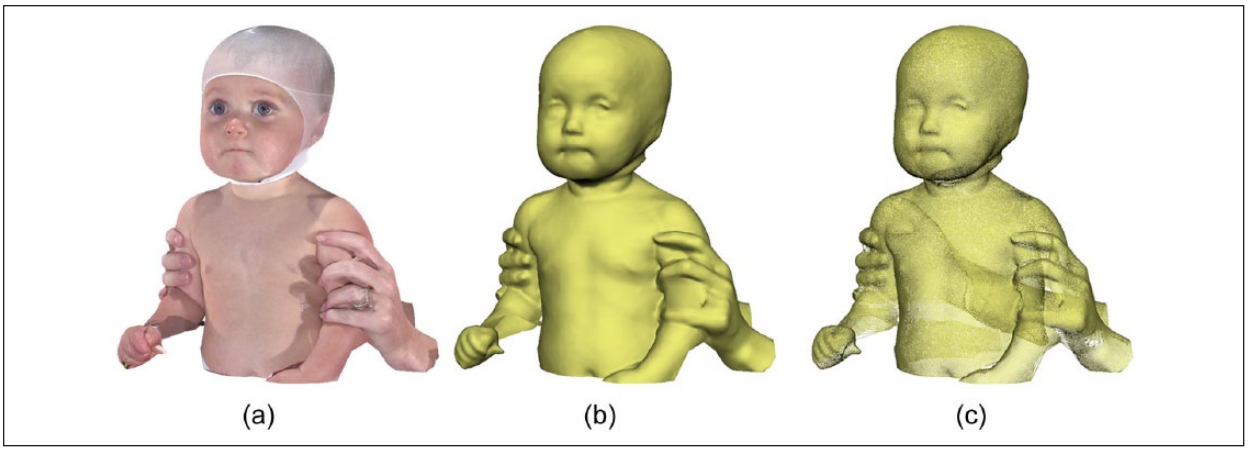

Figure 1. Digital Surface Imaging. Image shown in (a) photographic, (b) solid, and (c) wireframe.

postural stability, with the shorter anterior muscles able to react faster than the lengthened extensor groups. This poor postural stability affects the efficiency of movement, and infants will tend to either posture with the chin flexed and trunk rounded or hyperextend the neck and elevate the shoulders (ie, park the head) in order to stabilize and maintain balance.[19-23] These postures cause less variability in the infant's movement, which limits their interaction with their environment.

Recently, the potential relationship between severe deformational brachycephaly and hindbrain herniation, due to the reduction in posterior cranial fossa volume, has been discussed,[24,25] although this has not yet been investigated extensively. Additionally, one of the immediate concerns of deformational brachycephaly is its impact on the fit of protective equipment. In brachycephaly, the head is disproportionally wider, shorter, and often taller than the average head for that age. It is not uncommon for parents to report having to purchase adult-sized helmets in an attempt to accommodate for the increased width of their child's or adolescent's head, but then discovering that the helmet tends to tip into the child's face. When considering the number of athletic and recreational activities that now require the use of protective helmets, this is no small consideration and affects not only the child's participation, but also how well they are protected during the activity.

While the treatment of plagiocephaly has received considerable attention (see Flannery et al[26] for a recent review), only 2 studies[27,28] have specifically addressed the treatment of brachycephaly. This study was undertaken to prospectively examine the effects of helmet treatment of isolated deformational brachycephaly and to investigate the role of 3 key treatment factors (entrance age, treatment time, and initial severity) on treatment outcome.

Materials and Methods

Study subjects were identified from among a cohort of infants who have been registered in a central clinical research database since January 2013. Briefly, the database contains information on all infants referred by their primary physician for consultation at any of 30 clinic locations through the Unites States. This cohort includes infants with abnormal head shape diagnoses of all types (synostotic and nonsynostotic), forms (plagiocephaly, brachycephaly, dolichocephaly), and severity levels (mild to severe). Data include demographic and assessment information as well as a detailed medical history regarding the well-established risk factors previously reported.[29-31] Quantifiable information regarding the infant's cranial shape is obtained using a 3-dimensional (3D) imaging system previously documented elsewhere[32,33] (Figure 1). The accuracy of both the 3D image acquisition, as well as software measurement functions, have been previously validated to be within ± 0.5 mm.[32-34]

Subject Identification

Patient data from the period January 2013 through December 2017 (5 years; 128 014 patients) were evaluated. The study population comprised 4205 infants (3.2% of the total patient population) treated for isolated deformational brachycephaly. Study subjects had complete records at entry into and exit from treatment, moderate to severe brachycephaly as previously described[27,28] (ie, a cephalic index [(Cranial Width/Cranial Length) $\times$ 100] $\geqslant$ 90), normal or minimal asymmetry (specifically, cranial vault asymmetry, midface asymmetry, skull base asymmetry $\leqslant$3 mm), and had entered into treatment between 3 and 12 months of age. All infants began treatment within 3

Table 1. Relevant Treatment Parameters by Age of Entry Into Treatment[a].

Parameter	All, N = 4205	⩾3 to <6, n = 2485	⩾6 to <9, n = 1531	⩾9 to ⩽12, n = 189
Consult age (months)***	5.4 (±1.5)	4.4 (±0.6)	6.5 (±0.7)	9.6 (±0.8)
Entry age (months)***	5.8 (±1.5)	4.8 (±0.6)	6.9 (±0.7)	10.0 (±0.8)
Treatment time (weeks)***	13.5 (±5.7)	11.9 (±5.4)	15.8 (±5.3)	17.4 (±4.3)
% Male not significant	62.8%	63.3%[#]	62.7%[#]	57.7%[#]
Initial cranial index (CI)**	95.0 (±3.2)	95.1 (±3.3)	95.0 (±3.0)	94.3 (±3.1)
Exit CI***	89.4 (±2.8)	89.3 (±2.9)	89.6 (±2.8)	90.0 (±2.7)
Change in CI***	−5.6 (±2.3)	−5.8 (±2.3)	−5.4 (±2.2)	−4.3 (±1.8)
Initial circumference (mm)***	433.6 (±18.3)	426.1 (±15.3)[c]	443.1 (±16.2)[c]	455.7 (±17.2)
Exit circumference (mm)***	452.3 (±17.9)	446.6 (±16.5)[c]	459.7 (±16.2)[c]	468.2 (±17.0)
Change circumference (mm)***	18.7 (±7.6)	20.4 (±7.9)	16.6 (±6.4)	12.6 (±5.8)
Initial cranial width (mm)***	130.7 (±6.1)	128.3 (±5.2)	133.7 (±5.5)	136.5 (±5.9)
Exit cranial width (mm)***	132.5 (±6.2)	130.6 (±5.7)	134.9 (±5.7)	137.7 (±5.8)
Change cranial width (mm)***	1.8 (±2.7)	2.2 (±2.7)	1.2 (±2.5)	0.1 (±2.3)
Initial cranial length (mm)***	137.6 (±6.4)	135.0 (±5.2)	140.8 (±5.5)	146.0 (±5.9)
Exit cranial length (mm)***	148.2 (±5.9)	146.3 (±5.5)	150.6 (±5.5)	153.0 (±5.7)
Change cranial length (mm)***	10.5 (± 3.5)	11.3 (±3.5)	9.8 (±3.0)	7.0 (±2.7)

[a]For overall group differences: ***$P < .0001$; **$P < .001$. For group-wise comparisons: means with "#" are not significantly different. Other pairwise comparisons (ie, unmarked group statistics) are significant at the .05 level.

weeks of their initial treatment consultation for a cranial remodeling orthosis described elsewhere.[35-37] Patients with confounding medical conditions (≈ 0.9%; eg, synostosis, syndromic conditions, surgical shunt) were excluded from the analyses. The study protocol was approved by an external independent review board (Argus IRB, Tucson, AZ). Informed consent was obtained for all participants.

Statistical Analysis

To more easily visualize the effects of treatment age on treatment outcome, the study population was divided into 3 groups based on entrance age into treatment. Group 1 entered treatment between ⩾3 months and <6 months of age, Group 2 entered treatment between ⩾6 months and <9 months, and Group 3 entered treatment between ⩾9 months and ⩽12 months of age. These groups were selected based on popular thresholds established in the literature, and for the purpose of allowing comparison to other previously published studies.[27,28] Descriptive statistics for all treatment variables in aggregate and by treatment group are reported in Table 1.

All statistical analyses were performed using SAS software.[38] Group differences in sex ratio were evaluated using χ^2 test (SAS PROC FREQ[38]). Analysis of variance (SAS PROC GLM using the DUNCAN MEANS option to assess differences among group means[38]) was performed to evaluate differences among groups with regard to parametric variables as well as to identify how key treatment parameters (age of treatment, treatment time, and initial cephalic index) contributed to treatment outcome.

Results

A total of 4205 infants were studied in this investigation (Table 1). Mean entrance age was 5.8 months with a mean treatment time of 13.5 (±5.7) weeks. Over the treatment period, circumference increased an average of 18.7 mm (±7.6), from 433.6 mm to 452.3 mm. Mean cranial width began at 130.7 mm (±6.1) and increased marginally to 132.5 mm (±6.2), a change of only 1.8 mm (±2.7) indicating that biparietal width was held as intended. Conversely, the cranial length increased from 137.6 mm (±6.4) to 148.2 mm (±5.9), a change of 10.5 mm (±3.5). The result was a mean overall cephalic index reduction of 5.6% (95.0% at treatment entry to 89.4% at treatment exit, representing an 81.4% improvement toward normal; Table 1).

Moreover, by cross-classifying the infants by their initial and final severities (Table 2), we can examine how the infants responded to treatment. Of the 4205 infants in this investigation, 2921 (69.5%) infants began treatment initially classified as having severe brachycephaly. Of those, 17.4% (509/2921) finished treatment in the normal category; 27.3% (799/2921) finished as mild; 39.6% (1156/2921) were moderate; with only 15.6% (457/2921) remaining in the severe category. Another way of reporting this is that, of the 2921 infants initially classified as having a severe deformity at the initiation of treatment, 84.4% (2464/2921) were no

Table 2. Pretreatment Versus Posttreatment Classification of Severity.

Pretreatment Classification		Posttreatment Classification			
	Total	Normal (⩽88)	Mild (>88 to ⩽90)	Moderate (>90 to ⩽93)	Severe (>93)
Mild (=90)	26 (0.6%)	22 (0.5%)	4 (0.1%)	0 (0.0%)	0 (0.0%)
Moderate (>90 to ⩽93)	1258 (29.9%)	868 (20.6%)	335 (8.0%)	557 (1.3%)	0 (0.0%)
Severe (>93)	2921 (69.5%)	509 (12.1%)	799 (19.0%)	1156 (27.5%)	457 (10.9%)
Total	4205 (100.0%)	1399 (33.3%)	1138 (27.1%)	1211 (28.8%)	457 (10.9%)

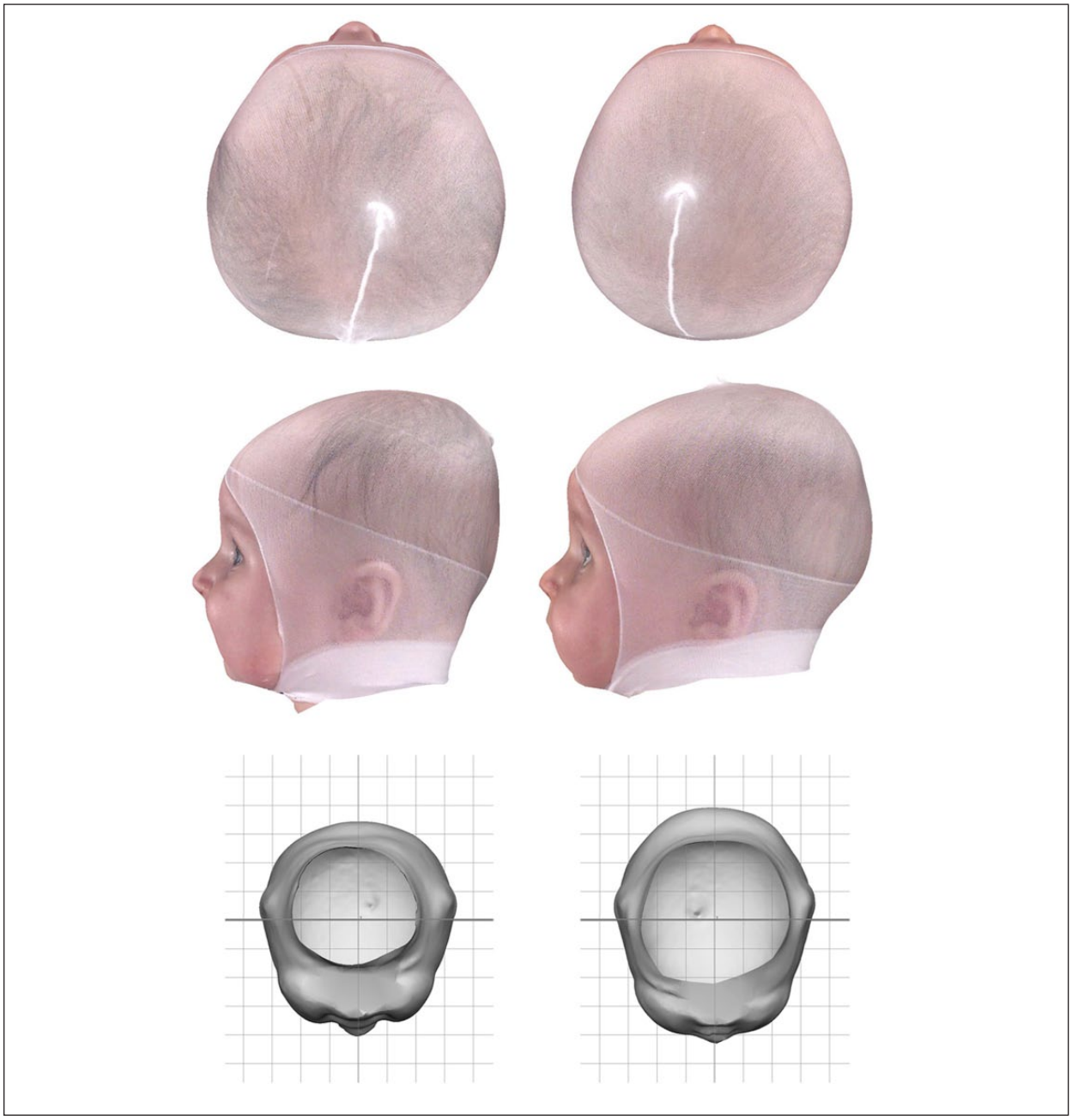

Figure 2. Female infant starting treatment at 4 months of age; initial cephalic index: 98.5; exit cephalic index: 89.3; treatment time 2¾ months (*grid units 20 mm*).

Table 3. Results of Analysis of Variance for Treatment Variables Showing Differences by Treatment Group[a].

Parameter	3 to <6 Months of Age	6 to <9 Months of Age	9 to 12 Months of Age	*F*	*P*
Initial cephalic index (CI)	95.1[#]	95.0[#]	94.3	5.34	.0048
Treatment time	11.9	15.8	17.4	300.34	<.0001
Change in CI	−5.8	−5.4	−4.3	48.85	<.0001

[a]For groupwise comparison: means with "#" are not significantly different. Other pairwise comparisons are significant at the .05 level.

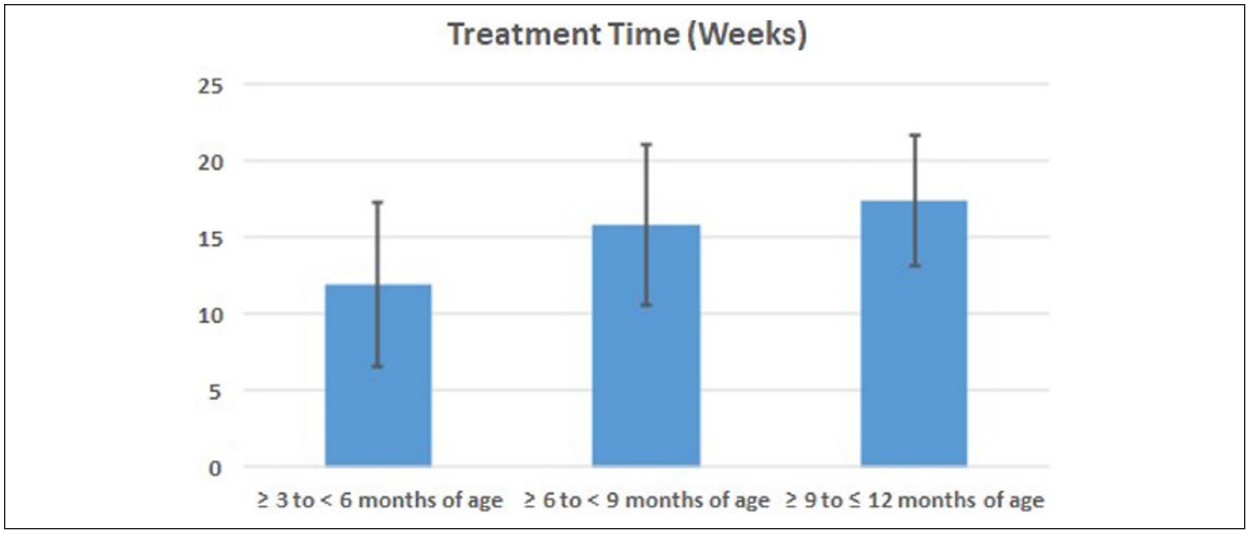

Figure 3. Mean treatment time by group (with 1 standard deviation bars).

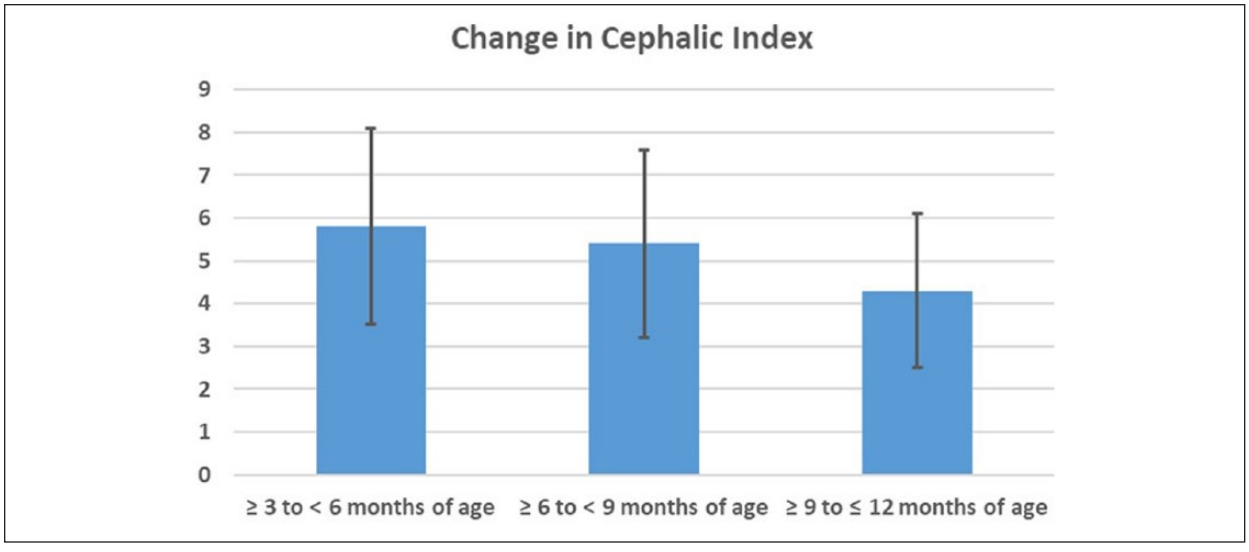

Figure 4. Mean change in cephalic index by group (with 1 standard deviation bars).

longer in that category at the end of treatment, with nearly half, 44.8% (1308/2921), having been returned to a "normal-to-mild" classification. In totality, 60.3% (2537/4205) ended treatment with a "normal-to-mild" classification (Figure 2). Overall, 87.7% of the infants (3689/4205) demonstrated improvement in cephalic index following treatment with a cranial orthosis; 3948 infants (92.9%) having been treated with only one

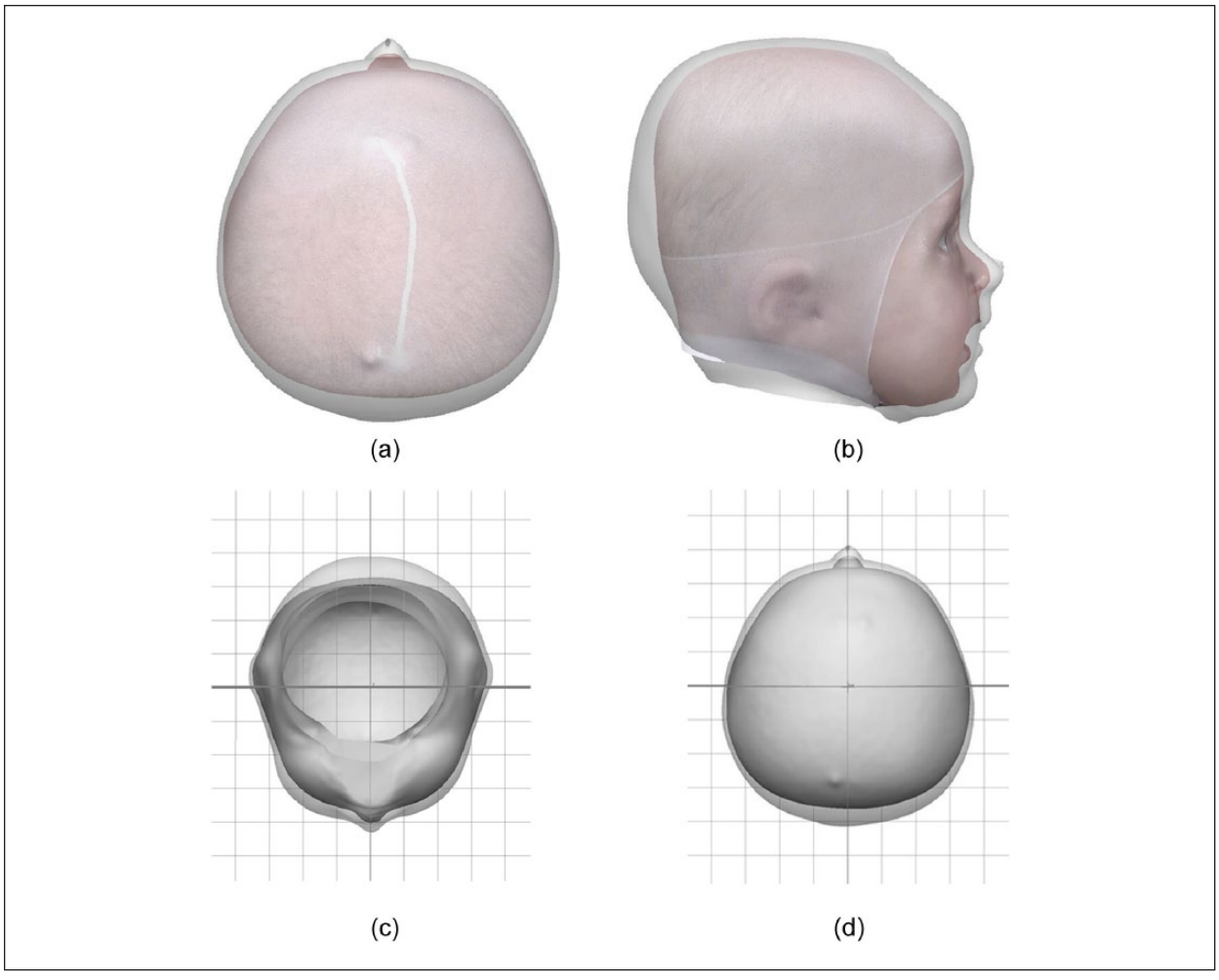

Figure 5. Male infant entering treatment at 3¾ months of age; initial cephalic index: 102.3; exit cephalic index: 90.5; treatment time 3.25 months.

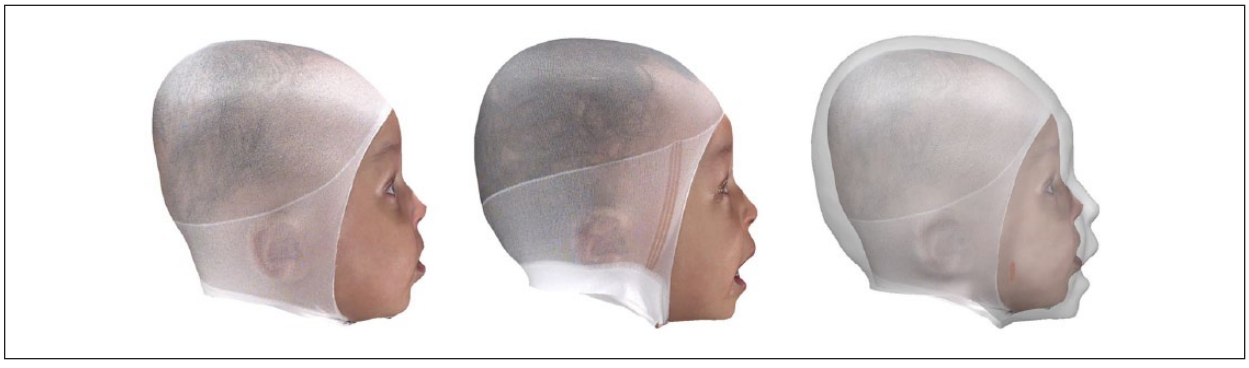

Figure 6. Male infant entering treatment at 8 months of age; initial cephalic index: 102.9; exit cephalic index: 91.1; treatment time 9.5 months.

cranial orthosis. In no case did the condition worsen. With the exception of a low incidence (0.91%) of skin irritation (red spots, skin breakdown, heat rash), no significant issues were reported.

To explore the effects of age on treatment, the sample was stratified into 3 equal interval treatment ranges ($\geq$3 to $<$6 months; $\geq$6 to $<$9 months; $\geq$9 to $\leq$12 months; Tables 1 and 2). Although the mean entrance

Table 4. Results of Analysis of Variance for the Effects of Treatment Variables on "Change in Cephalic Index" Using the Type III Sum of Squares to Partition Their Contribution.

Parameter	Type III Sum of Squares	*F*	*P*
Initial cephalic index	3729.31	1038.54	<.0001
Treatment time	747.90	208.28	<.0001
Entry age	886.27	246.81	<.0001

Table 5. Deformational Brachycephaly Study Comparisons.

Parameter	Teichgraeber (2004)[27]	Graham (2005)[28]	Kelly (Current)
Sample size (n)	64	92	4205
Mean initial cephalic index	93.7%	96.1%	95.0%
Mean end cephalic index	90.9%	91.9%	89.4%
Mean change in cephalic index	2.8%	4.2%	5.6%
Treatment time	4.5 months	3.7 months	3.4 months

cephalic index was not statistically significant different between the groups (95.1, 95.0, 94.3; Table 3), treatment time was significantly longer (11.9 weeks, 15.8 weeks, 17.4 weeks; Table 3 and Figure 3) and treatment changes significantly smaller (5.8, 5.4, 4.3; Table 3 and Figure 4) moving up in age cohort. As would be anticipated from the pediatric cranial growth charts, mean change in circumferential growth also decreased with entrance age (20.4 mm, 16.6 mm, 12.6 mm; Table 1), and this despite the longer treatment times documented for the older groups. Therefore, although the initial deformity was not significantly different across the age groups, infants treated prior to 9 months of age received significantly greater improvements than children treated at 9 months of age or later. Moreover, children treated at earlier ages had significantly shorter treatment times than those in subsequent treatment groups (Figures 5 and 6).

Analysis of variance was also used to partition the variation observed among set observations into portions associated with certain factors. For example, variation in improvement in cephalic index can be partitioned into factors associated with "initial cephalic index," "treatment time," and "age at entry into treatment" (Table 4). The 2 intuitively obvious findings were that greatest change in cephalic index could be achieved (*a*) in those infants who initially *presented with the most severe deformities* (ie, had the largest initial cephalic index), and (*b*) by treating any infant (regardless of severity) for a *longer period of time*. However, the more interesting and clinically meaningful findings were that the younger the infant entered treatment (*c*) the *shorter their treatment duration*, and (*d*) the *greater their reduction in cephalic index*.

Discussion

Although the American Academy of Pediatrics' "Back to Sleep (BTS)" campaign is frequently cited as the reason for the recent increase in cranial deformities, other factors—*most notably, devices of convenience*—also contribute. Today infants spend extended periods of time in devices including infant swings, bouncy seats, carriers, and car seats.[39] Although not always appreciated, these devices result in cranial deformation that are similar to those produced by the cradle boards used by several Native American Indian tribes.[40,41] In fact, Davis et al[42] have documented that infants from the ages of 0 to 3 months (a critical age in the development of plagiocephaly/brachycephaly) spent ~23 hours/day in a supine-like position. Today the American Academy of Pediatrics, as well as many other organizations, now advise parents to limit the time infants spend in car seats and other devices of convenience.[43]

Correction of Deformational Brachycephaly

While the treatment of deformation brachycephaly has received limited attention, both previously published studies[27,28] reported significant correction of the deformation (Table 5). In particular, in the only other treatment study to have focused exclusively on deformational brachycephaly, Graham and colleagues[28] report significant correction of deformational brachycephaly. Among a subgroup of infants who—in common with the current study—initiated treatment with a cephalic index ⩾90% (n = 92), Graham and associates observed a mean reduction in cephalic index of 4.2% (from 96.1% to 91.9%).

Table 6. Deformational Brachycephaly Study Change Comparisons by Age Group.

Age at Treatment Initiation	Teichgraeber (2004)[27]	Graham (2005)[28]	Kelly (Current)	
3.0 to 4.5 months	2.8%	5.1%	5.8%	5.8%
4.5 to 6.0 months		3.2%		5.8%
⩾6.0 to <9.0	2.6%	2.9 %	5.2%	5.4%

Teichgraeber et al[27] reported that helmet treatment produced favorable outcomes for infants with both deformational brachycephaly as well as deformational plagiocephaly; however, they noted that "the head shapes of the children with positional brachycephaly did not normalize despite statistically significant improvement in their cephalic index . . . ," concluding that ". . . helmet therapy is more effective in children with posterior positional plagiocephaly than in children with positional brachycephaly."

However, it should be noted that the challenge of returning a brachycephalic head to within normal limits lies in the observation that once an infant's head has obtained a certain width, there is no way to reduce this dimension. By design, cranial orthotic devices do not compress the head and therefore cannot make a head any narrower; all that can be achieved is to redirect future growth in the anteroposterior dimension. Additionally, in severe cases, where the occipital bone has been allowed to become nearly perfectly flat, it is difficult to restore the natural occipital curve. Instead, increased posterior growth will often result in lengthening to the cranium and improved cephalic index, yet from a lateral perspective, the occipital profile may still appear flat. Hence, an argument could be made that intervention prior to this level of deformity is warranted, both from a treatment outcome as well as a preservation of posterior cranial volume perspective.

Influence of Entrance Age on Outcome

Although Teichgraeber et al[27] found that "the age at which therapy was begun did not have an impact on the final results," they further note that "these results do not correlate with what is seen clinically . . . ," suspecting that the "discrepancy between the data and the authors' clinical experience may be a result of having arbitrarily divided the children into 2 subgroups and the small numbers of children in both of these subgroups."[27]

Consistent with our findings, Graham et al[28] found an inverse correlation between entrance age and outcome. For infants beginning treatment between 3.0 and 4.5 months of age, reduction in cephalic index was 5.1%; for infants 4.5 to 6.0 months of age, it was 3.2%; and for infants entering treatment later than 6 months, reduction in cephalic index was 2.9%. These results mirror the findings of other investigators who have previously reported on the positive impact of early entrance age on the effectiveness of the cranial orthosis[37,44-52] (Table 6).

The key message from these observations is that brachycephaly, just like plagiocephaly, should not be allowed to progress to a severe classification before intervention is started. Conservative efforts such as supervised tummy time, repositioning, and limiting time in devices of convenience should be initiated as soon as a widening of the head is observed. If after 6 to 8 weeks of these efforts the head is continuing to become more brachycephalic, use of a cranial orthosis may be warranted in order to leverage—as we have demonstrated here—the benefits of early intervention that include improved outcomes and shorter treatment times.

As with all studies, it is important to acknowledge the limitations of the work presented so that future investigators may be aware, and critically review the content in light of these weaknesses. The most immediate limitation is that this is not, nor was it designed to be, a randomized control trial. While many authors have previously discussed why execution of a randomized control trial may be difficult or even ethically questionable,[52-54] it was simply not within our scope to be able to perform. As a medical treatment provider, patients are sent by physicians who have diagnosed and monitored their patients and have prescribed treatment based on their dissatisfaction with the progression of head shape.

The use of linear anthropometric measurements to describe changes in a complex 3D head shape is also a limitation of this study. Although there is a high degree of confidence in the repeatability and reliability of these measurements, linear measurements can only convey so much information.[55] This was why we chose to provide so many figures illustrating the correction that may be achieved, as these figures demonstrate the clinically significant change in curvature, volume, and shape that are sometimes difficult to appreciate with just a few percentage point changes in cephalic index. Several studies have now reported on the use of 3D data in the form of root mean square calculations, and we applaud the authors in those efforts and feel this is the direction that future investigations must go.[56,57] However, in the case of studies on proportionality,

such as in deformational brachycephaly, the root mean square measure is a less useful measurement. Furthermore, the cephalic index is a well-established, reproducible value that is well understood by the medical community, and in using this measure, it allowed us to make direct comparisons to other previously published studies on this subject.

Conclusions

As discussed, deformation of the cranium in infancy represents a spectrum of deformity, ranging from severe asymmetric yet proportional distortion of the skull in plagiocephaly, to nearly symmetric yet disproportional distortion in brachycephaly. As such, the condition is best described as *deformational plagiocephaly-brachycephaly* with isolated plagiocephaly and/or isolated brachycephaly being at either ends of the spectrum.[58,59]

This investigation demonstrates that the cranial orthosis is successful in the treatment of deformational brachycephaly. These findings are consistent with the only other 2 published studies specifically looking at deformational brachycephaly as a separate entity from deformational plagiocephaly. It has also been demonstrated that entrance age is a critical variable in the overall effectiveness of treatment with younger infants demonstrating both improved outcomes and shorter treatment times, regardless of the severity of the presenting deformity.

When considering the mechanics of how a cranial orthosis works (ie, holding the prominences and redirecting brain growth into the adjacent flattened areas), as well as a basic understanding of normal craniofacial growth patterns of the infants from birth to 12 months of age, it may be recognized that the treatment of deformational brachycephaly in many ways is no different than the treatment of deformational plagiocephaly. All that has changed is the direction in which the corrective forces are applied, from a contralateral pattern in plagiocephaly to a lateral pattern in brachycephaly. The rest is accomplished by growth of the brain and proper adjustment of the product by the treating clinician.

Authors' Note

A preliminary portion of these data were included in the book *Smith's Recognizable Patterns of Human Deformation*, 4th edition, by Graham JM and Sanchez-Lara P, and cited as unpublished data (eBook ISBN: 9780323295383; Hardcover ISBN: 9780323294942).

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Author Contributions

KMK participated in the conceptualization and design of the study, performed all statistical analysis, and reviewed, revised and approved the final manuscript as submitted.
JAR developed the DSi Analysis reports; developed, programmed and maintained the Excel/SQL databases; and reviewed and approved the final manuscript as submitted.
EFJ reviewed the design of the study and, reviewed and approved the final manuscript as submitted.
SPB reviewed the design of the study and, reviewed and approved the final manuscript as submitted.
MKM provided insight into the developmental impact of brachycephaly and concerns being raised in the physical and occupational therapy communities, and reviewed and approved the final manuscript as submitted.
TRL conceptualized and designed the study, submitted the IRB approval, trained the individuals and verified the accuracy of the anthropometric measurements, and approved the final manuscript as submitted.

Ethical Approval

The study protocol was approved by an external independent review board (Argus IRB, Tucson, AZ; CF#02_01).

Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Mr Littlefield, Mr Riggs, and Ms McGuire are employees of Cranial Technologies, Inc. The remaining authors have no financial or commercial interest.

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Informed Consent

Informed consent was obtained for all participants.

ORCID iDs

Kevin M. Kelly https://orcid.org/0000-0002-9177-1454
Timothy R. Littlefield https://orcid.org/0000-0002-8262-5519

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