Effectiveness of Conservative Therapy and Helmet Therapy for Positional Cranial Deformation

Jordan P. Steinberg, M.D., Ph.D.
Roshni Rawlani, B.A.
Laura S. Humphries, M.D.
Vinay Rawlani, M.D.
Frank A. Vicari, M.D.

Chicago and Park Ridge, Ill.

Background: The authors investigated the effectiveness of conservative (repositioning therapy with or without physical therapy) and helmet therapy, and identified factors associated with treatment failure.

Methods: A total of 4378 patients evaluated for deformational plagiocephaly and/or deformational brachycephaly were assigned to conservative (repositioning therapy, $n = 383$; repositioning therapy plus physical therapy, $n = 2998$) or helmet therapy ($n = 997$). Patients were followed until complete correction (diagonal difference <5 mm and/or cranial ratio <0.85) or 18 months. Rates of correction were calculated, and independent risk factors for failure were identified by multivariate analysis.

Results: Complete correction was achieved in 77.1 percent of conservative treatment patients; 15.8 percent required transition to helmet therapy ($n = 534$), and 7.1 percent ultimately had incomplete correction. Risk factors for failure included poor compliance (relative risk, 2.40; $p = 0.009$), advanced age (relative risk, 1.20 to 2.08; $p = 0.008$), prolonged torticollis (relative risk, 1.12 to 1.74; $p = 0.002$), developmental delay (relative risk, 1.44; $p = 0.042$), and severity of the initial cranial ratio (relative risk, 1.41 to 1.64; $p = 0.044$) and diagonal difference (relative risk, 1.31 to 1.48; $p = 0.027$). Complete correction was achieved in 94.4 percent of patients treated with helmet therapy as first-line therapy and in 96.1 percent of infants who received helmets after failed conservative therapy ($p = 0.375$). Risk factors for helmet failure included poor compliance (relative risk, 2.42; $p = 0.025$) and advanced age (relative risk, 1.13 to 3.08; $p = 0.011$).

Conclusions: Conservative therapy and helmet therapy are effective for positional cranial deformation. Treatment may be guided by patient-specific risk factors. In most infants, delaying helmet therapy for a trial of conservative treatment does not preclude complete correction. (*Plast. Reconstr. Surg.* 135: 833, 2015.)

CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, III.

The prevalence of deformational plagiocephaly and deformational brachycephaly has increased significantly since the adoption of the Back to Sleep campaign in 1992.[1,2] Although the rate of sudden infant death syndrome has decreased by as much as 40 percent,[2] the incidence of positional cranial deformation is estimated to have increased by as much as 600 percent,[3] with a significant increase in the number of case referrals to specialized treatment centers.[4] Current prevalence estimates of positional cranial deformities are as high as 47 to 48 percent.[5,6]

Although various treatments for deformational plagiocephaly/deformational brachycephaly have

From the Ann and Robert H. Lurie Children's Hospital of Chicago; the Division of Plastic Surgery, Northwestern University Feinberg School of Medicine; and the Advocate Medical Group, Lutheran General Hospital.
Received for publication March 25, 2014; accepted September 26, 2014.
Presented in part at the 81st Annual Scientific Meeting of the American Society of Plastic Surgeons, in New Orleans, Louisiana, October 26 through 30, 2012; and at the 92nd Annual Meeting of the American Association of Plastic Surgeons, in New Orleans, Louisiana, April 20 through 23, 2013.

DOI: 10.1097/PRS.0000000000000955

Disclosure: *The authors have no financial interest in any of the products or devices mentioned in this article. There were no sources of funding for this work.*

A Video Discussion by Kant Lin, M.D., accompanies this article. Go to PRSJournal.com and click on "Video Discussions" in the "Videos" tab to watch.

been well described, including repositioning therapy, physical therapy, and helmet therapy, limited evidence exists to guide treatment.[7,8] Previous studies have been limited by small cohorts, inadequate follow-up, lack of reliable objective outcome measures, and influence of commercial interests.[7–10] Moreover, factors associated with treatment failure have not been identified. The purpose of this study was to (1) analyze the effectiveness of conservative therapy (repositioning therapy and repositioning therapy plus physical therapy) and helmet therapy in the treatment of deformational plagiocephaly and deformational brachycephaly and (2) identify independent risk factors for treatment failure in a large patient cohort using objective outcome measures. We hypothesized that although helmet therapy would allow the achievement of corrective endpoints with a high degree of success, conservative treatment alone would be effective in a significant proportion of infants.

PATIENTS AND METHODS

This retrospective cohort study was approved by the Institutional Review Board of Children's Memorial Hospital (presently Ann and Robert H. Lurie Children's Hospital) in Chicago, Illinois. All patients who underwent treatment of nonsynostotic deformational plagiocephaly and/or deformational brachycephaly by a single pediatric craniofacial surgeon (F.A.V.) between 2004 and 2011 were included in the analysis. Patients were excluded from final analysis if they (1) had undergone formal repositioning therapy/physical therapy before initial evaluation, (2) deviated from standardized treatment protocols (e.g., different helmet type because of patient preference), (3) had incomplete STARscanner data, or (4) were lost to follow-up.

Evaluation and Treatment Algorithm

All patients underwent evaluation by the same multidisciplinary team that included a pediatric craniofacial surgeon, physical therapist, nurse practitioner, and orthotist specifically trained in anthropometric cranial vault analysis. As part of the initial evaluation, parents completed a standard birth history and demographic/socioeconomic survey administered by a nurse practitioner. Objective anthropometric measurements of the patient's cranial vault were obtained using a three-dimensional laser surface scanner as detailed below. Patients also underwent a clinical evaluation of their cranial deformity by the surgeon with visual assessment of craniofacial asymmetry from the posterior, vertex, and anterior views. A trained physical therapist assessed motor development, which included evaluation for the presence or absence of torticollis.

With the aforementioned assessments taken into consideration, patients were assigned nonrandomly to specific treatment modalities, including (1) conservative therapy, which consisted of repositioning therapy with or without formal physical therapy; and (2) passive cranial orthotic molding (helmet therapy) (Fig. 1). Patients undergoing conservative therapy received either repositioning therapy or a combination of repositioning therapy and physical therapy, with the need for formal physical therapy based on the presence and severity of head position preference, torticollis, and/or neuromuscular developmental delay at the initial consultation. All patients who received helmets also received repositioning therapy with or without physical therapy based on the same criteria. The rationale for concomitant repositioning therapy with or without physical therapy relates not only to the potential for relapse of deformational plagiocephaly/deformational brachycephaly with inattention to factors such as torticollis, but also to the prevention or remediation of significant delays in motor development.

Patients underwent cranial measurement with the three-dimensional laser surface scanner before therapy initiation and at follow-up every 3 months or sooner if progress was not grossly apparent on clinical examination. In a similar fashion to the initial assessment, clinical judgment, rather than strict numeric criteria, was used to determine whether the patient should continue with his or her original treatment protocol or whether a change in therapy was warranted. A subset of patients who failed to achieve correction with initial conservative therapy (i.e., repositioning therapy alone or combined repositioning therapy plus physical therapy) subsequently underwent helmet therapy with continued repositioning therapy with or without physical therapy (crossover group). Compliance was assessed at each follow-up visit by parental questionnaire for repositioning therapy and helmet therapy and by clinical records for physical therapy. All patients were followed until complete cranial deformity correction was achieved, defined by a diagonal difference less than 5 mm for deformational plagiocephaly, a cranial ratio less than 0.85 for deformational brachycephaly, or until 18 months of age. Failure of treatment was defined as failure to achieve a diagonal difference less than 5 mm and/or a cranial ratio less than 0.85 by 18 months of age in either treatment group.

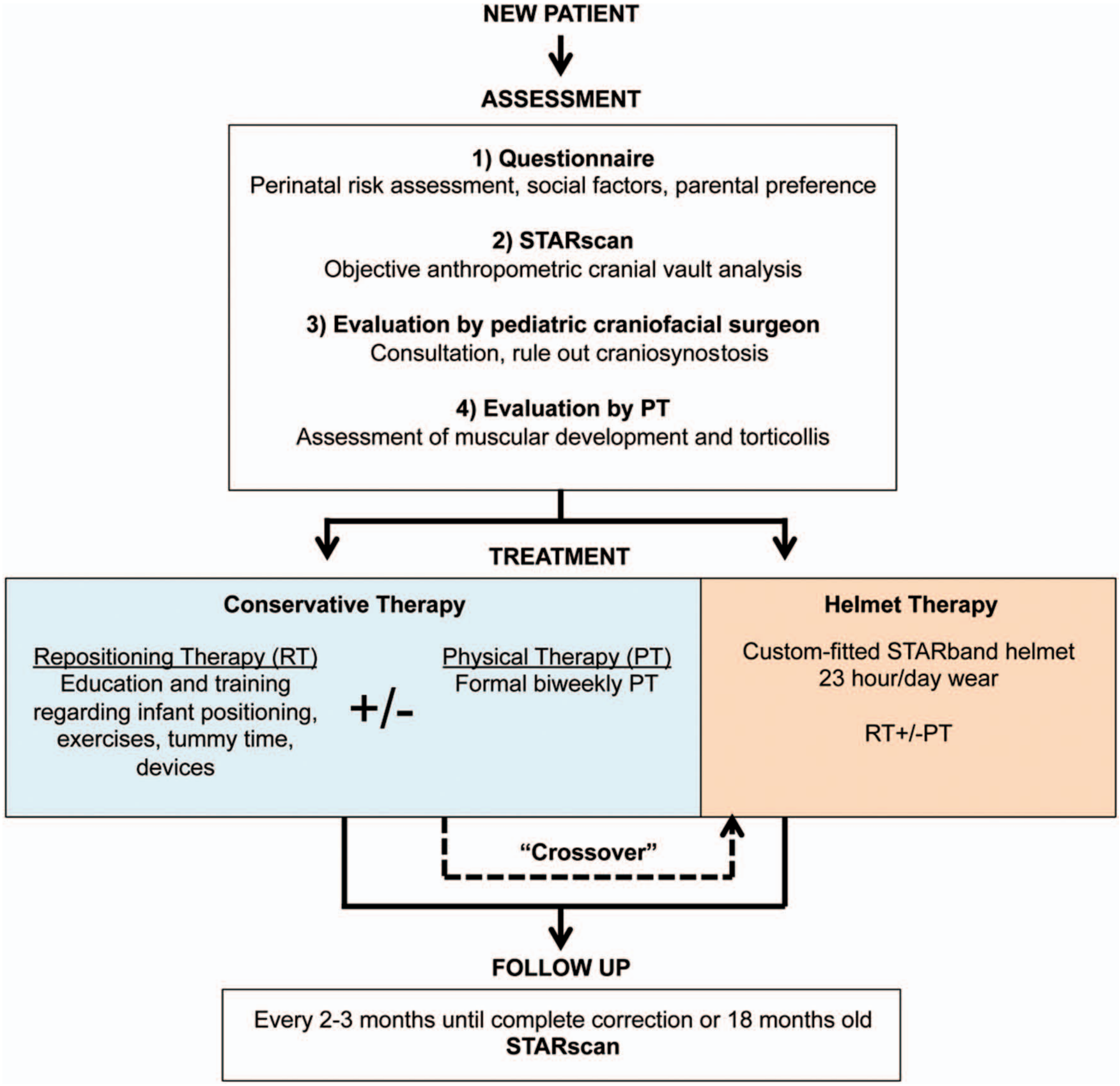

Fig. 1. Initial treatment algorithm and assignments.

Anthropometric Cranial Vault Analysis

Cranial vault anthropometrics were obtained using the STARscanner Laser Data Acquisition System (Orthomerica Products, Inc., Orlando, Fla.) and analyzed using Yeti computer software (Yeti Software LLC, Seattle, Wash.) by a trained orthotist as described previously.[11] Briefly, a stockinet was placed over the infant's head and markers were placed identifying the superior aspect of the tragus (tragion). The sellion and tragion were used to define the base plane. Parallel to the base plane, 10 virtual two-dimensional sections were constructed thorough the cranium up to the vertex. Section 3, which is one-third of the distance from the base plane to the vertex, was used to calculate anthropometric measurements in all patients. Cranial ratio and diagonal difference measurements were calculated in standard fashion as detailed previously (Fig. 2).[11] Diagonal difference was used instead of the cranial vault asymmetry index because of the tendency for ratio measurements to naturally improve with continued head growth.[12]

Therapy Protocols

Repositioning therapy involved parental counseling and training by an in-office physical therapist. Training included discussion of positional preference, repositioning techniques to stretch tightened neck muscles, emphasizing the importance of "tummy time" lasting greater than 50 percent of awake time, carrying techniques to promote independent neck and truncal muscle development, and limiting the use of infant walking devices. Physical therapy involved an initial home program based on age and specific needs determined at the

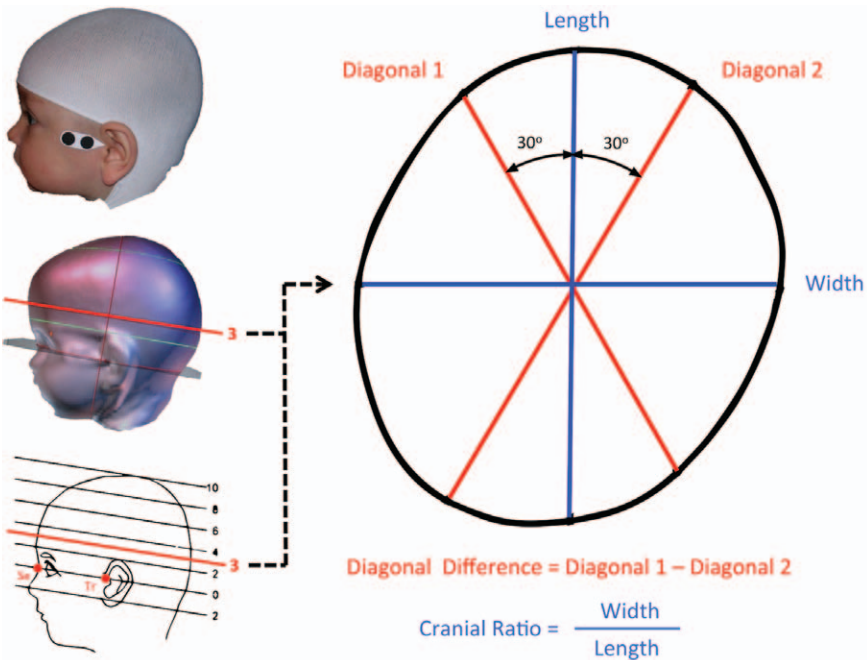

Fig. 2. Cranial measurements obtained with a three-dimensional laser surface scanner. (*Above*, *left*) Photograph of child with stockinet and markers. (*Center*, *left*) Surface rendering illustrating the relative location of the base plane and section 3 used for all standard calculations. (*Below*, *left*) Two-dimensional schematic illustrating the sellion (*Se*) and tragion (*Tr*) landmarks for the base plane and the parallel sections, including the standard Section 3. (*Right*) Computation of cranial ratio as the ratio of biparietal width to anteroposterior length and diagonal difference as the diagonal transcranial difference at 30 degrees.

initial visit followed by continued in-office sessions with regimented exercises. These exercises were designed to address deficiencies in range of motion and extension and general weakness, and also to help in the achievement of motor milestones. Any asymmetry in automatic head righting reflexes[13] was addressed with active rather than passive exercises. The interval for treatment was adjusted at the discretion of the therapist, although children were typically followed until they were walking independently. Helmet therapy involved 23-hour daily wear of a STARband customized cranial orthotic molding helmet (Orthomerica Products, Inc., Orlando, Fla.). Helmets were precisely fabricated by a orthotic specialist using a subtractive process from idealized and actual STARscanner data.[11] Helmets were evaluated at each visit and adjusted by the orthotist as needed.

Statistical Analysis

A multivariate logistic regression statistical analysis using SPSS Version 17.0 (SPSS, Inc., Chicago, Ill.) was performed using a set of predefined clinical factors to identify independent risk factors for treatment failure. Risk factors identified as having a significance of $p < 0.10$ in univariate analysis were included in the multivariate analysis. The relative risk of treatment failure for a range of values within each identified independent clinical factor was calculated.

RESULTS

Between 2004 and 2011, 5152 patients with deformational plagiocephaly and/or deformational brachycephaly were treated with conservative or helmet therapy. A total of 774 patients were excluded: 250 had undergone previous treatment, 318 had incomplete STARscanner data, 157 deviated from standardized treatment protocols, and 49 were lost to follow-up. Ultimately, 4378 patients with a diagnosis of deformational plagiocephaly and/or deformational brachycephaly were included in the study (Fig. 3).

Treatment was initiated with conservative measures in 3381 infants (repositioning therapy, $n = 383$; repositioning therapy plus physical therapy; $n = 2998$) and with helmet therapy in 997 infants. Baseline characteristics of both groups are shown in Table 1. Starting ages differed

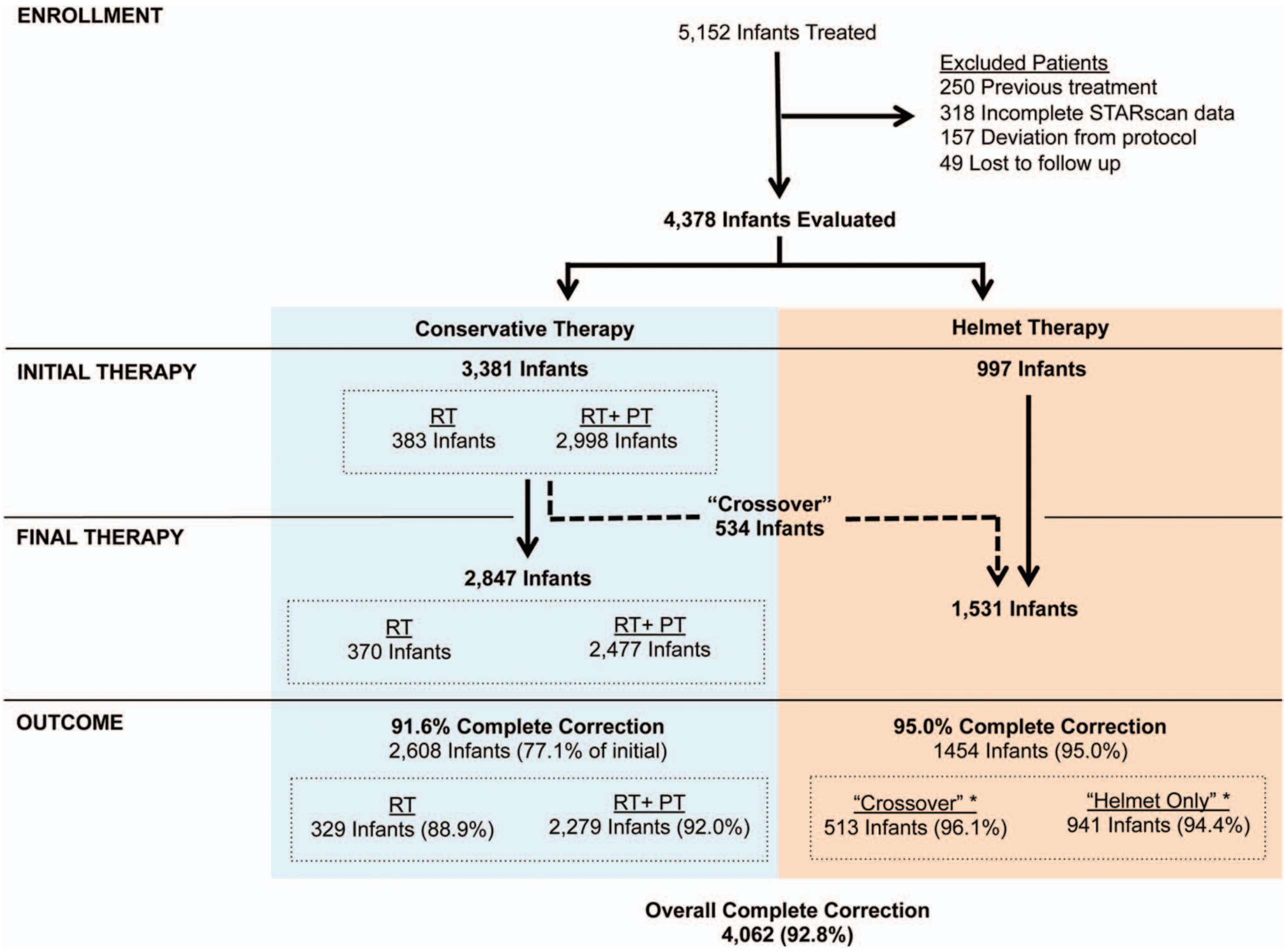

Fig. 3. Flow diagram of treatment groups and outcomes. *Crossover versus helmet only, $p = 0.17$. *RT*, repositioning therapy; *PT*, physical therapy.

significantly between the groups (7.1 ± 3.8 months for helmet therapy versus 5.1 ± 2.1 months for conservative therapy; $p < 0.001$), as did diagnoses. Deformational plagiocephaly was more frequent than deformational brachycephaly in those initiated on helmet therapy (41 percent versus 25 percent). Torticollis (49 percent versus 40 percent; $p < 0.001$) and developmental delay (20 percent versus 9 percent; $p < 0.001$) were also more prevalent in the helmet therapy group. Furthermore, cranial ratio (0.99 ± 0.28 versus 0.92 ± 0.25; $p < 0.001$) and diagonal difference (12.8 ± 4.7 versus 9.2 ± 3.8; $p < 0.001$) were significantly more abnormal in these infants. The presence of multiple gestation, method of delivery, and age at delivery did not differ between the groups.

Overall, complete correction was achieved in 4062 of 4378 patients (92.8 percent). A total of 77.1 percent of the 3381 conservatively treated patients (repositioning therapy, $n = 329$; repositioning therapy plus physical therapy, $n = 2279$) achieved complete correction with repositioning therapy with or without physical therapy alone. A subset of patients (15.8 percent of the initial cohort; repositioning therapy, $n = 13$; repositioning therapy plus physical therapy, $n = 521$) were transitioned to helmets (crossover group) because they failed to improve. The remaining 7.1 percent (repositioning therapy, $n = 41$; repositioning therapy plus physical therapy, $n = 198$) ultimately failed to achieve complete correction with continued conservative therapy. In total, 1531 infants underwent cranial orthotic molding, including 997 patients who were initially assigned to helmet therapy and the 534 patients transitioned to helmets after having failed initial conservative treatment. Complete correction was achieved in 95.0 percent of these 1531 total patients who underwent helmet therapy (Fig. 3). There was no difference in outcome between crossover patients who transitioned to helmet therapy after a mean 4.1 ± 1.4 months of conservative therapy and those who received helmet therapy as first-line treatment (96.1 percent versus 94.4 percent; $p = 0.375$).

Table 1. Baseline Patient Characteristics

	Conservative Therapy (%)	Helmet Therapy (%)	p
No. of patients	3381	997	
Sex			0.365
Male	1860 (55)	565 (57)	
Female	1521 (45)	432 (43)	
Age, mo	5.1 ± 2.1	7.1 ± 3.8	<0.001
Diagnosis			<0.001
Brachycephaly	839 (25)	186 (20)	
Plagiocephaly	861 (25)	412 (41)	
Combination	1681 (50)	389 (39)	
Cranial ratio	0.92 ± 0.25	0.99 ± 0.28	<0.001
Diagonal difference	9.2 ± 3.8	12.8 ± 4.7	<0.001
Torticollis			<0.001
Present	1352 (40)	493 (49)	
Absent	2029 (60)	504 (51)	
Developmental delay			<0.001
Present	300 (9)	198 (20)	
Absent	3081 (91)	799 (80)	
Gestation			0.741
Single	3110 (98)	914 (92)	
Multiple	271 (2)	83 (8)	
Method of delivery			0.451
Cesarean	839 (25)	235 (24)	
Vaginal	2542 (75)	762 (76)	
Prematurity			0.5325
Premature	465 (14)	145 (15)	
Full-term	2916 (86)	852 (85)	

Table 2. Crossover Patient Characteristics

	RT ± PT Only (%)	Crossover (%)	p
No. of patients	2847	534	
Sex			0.4204
Male	1575 (55)	285 (53)	
Female	1272 (45)	249 (47)	
Age, mo	5.1 ± 1.9	5.7 ± 2.6	<0.001
Diagnosis			
Brachycephaly	708 (25)	131 (25)	0.946
Plagiocephaly	722 (25)	139 (26)	
Combination	1417 (50)	264 (49)	
Cranial ratio	0.91 ± 0.23	0.94 ± 0.35	0.012
Diagonal difference	9.0 ± 3.8	10.3 ± 4.1	<0.001
Torticollis			0.004
Present	1108 (39)	244 (46)	
Absent	1739 (61)	290 (54)	
Developmental delay			<0.001
Present	225 (8)	75 (14)	
Absent	2622 (92)	459 (86)	
Gestation			0.099
Single	2609 (92)	501 (94)	
Multiple	238 (8)	33 (6)	
Method of delivery			<0.001
Cesarean	634 (22)	205 (38)	
Vaginal	2213 (78)	329 (62)	
Prematurity			0.951
Premature	392 (14)	73 (14)	
Full-term	2455 (86)	461 (86)	
Compliance			0.043
Conservative therapy	2488 (87)	449 (84)	
Helmet therapy	—	513 (96)	

RT, repositioning therapy; PT, physical therapy.

Characteristics of crossover patients were compared with those who received only conservative therapy (Table 2). These patients were significantly older (5.7 ± 2.6 months versus 5.1 ± 1.9 months; $p < 0.001$) at the start of therapy and had significantly greater deformity, as demonstrated by their increased cranial ratio (0.94 ± 0.35 versus 0.91 ± 0.23; $p = 0.012$) and diagonal difference (10.3 ± 4.1 versus 9.0 ± 3.8; $p < 0.001$). Torticollis (46 percent versus 39 percent; $p = 0.004$) and developmental delay (14 percent versus 8 percent; $p < 0.001$) were also more prevalent, as was cesarean delivery (38 percent versus 22 percent; $p < 0.001$). Compliance was significantly lower in crossover patients (84 percent versus 87 percent; $p = 0.043$); however, this improved after transitioning to helmet therapy (84 percent versus 96 percent; $p < 0.001$). Overall compliance for helmet treatment was significantly better than for conservative treatment (94 percent versus 87 percent; $p = 0.001$).

Independent risk factors for conservative and helmet therapy failure were identified using a multivariate logistic regression statistical analysis (Table 3). For this analysis, crossover patients were included as a part of both groups because of their potential to fail conservative therapy and helmet therapy independently. Risk factors for failure of conservative treatment included poor compliance (relative risk, 2.4; $p = 0.009$), advanced age at the time of therapy initiation (relative risk, 1.76 to 2.08; $p = 0.008$), the presence of torticollis (relative risk, 1.12 to 1.74; $p = 0.002$), the presence of developmental delay (relative risk, 1.44; $p = 0.042$), and increased severity of cranial deformity at the time of therapy initiation as measured by the cranial ratio (relative risk, 1.08 to 1.11; $p = 0.044$) and diagonal difference (relative risk, 1.07 to 1.13; $p = 0.027$). Prematurity and male sex were not risk factors, whereas multiple gestation and vaginal delivery were protective.

Independent risk factors for helmet therapy failure included only advanced age and poor treatment compliance. Older patients at the time of helmet therapy initiation ($p = 0.011$), particularly age 9 to 12 months and older than 12 months, were 1.93 and 3.08 times more likely to fail helmet therapy than their 3- to 6-month-old counterparts, respectively. Noncompliant patients were 2.4 times more likely to fail helmet therapy ($p = 0.025$) compared with their compliant counterparts. However, cranial deformity severity (diagonal difference and cranial ratio) at therapy initiation, and the presence of torticollis and developmental delay, were not risk factors for helmet therapy failure.

Table 3. Analysis of Risk Factors for Treatment Failure

	Conservative Therapy*			Helmet Therapy†		
	Failure Rate (%)	RR	*p*	Failure Rate (%)	RR	*p*
Therapy compliance						
Compliant	19.41	1.00 (Ref)	0.009	4.59	1.00 (Ref)	0.025
Noncompliant	46.58	2.40		11.11	2.42	
Age						
<3 mo	17.10	1.00 (Ref)	0.008	—	—	—
3–6 mo	20.51	1.20		4.22	1.00 (Ref)	0.011
6–9 mo	24.62	1.44		4.77	1.13	
9–12 mo	30.09	1.76		8.14	1.93	
>12 mo	35.55	2.08		13.00	3.08	
Torticollis						
Absent	19.39	1.00 (Ref)	0.002	4.88	1.00 (Ref)	0.587
<6 mo	21.72	1.12		5.22	1.07	
>6 mo	33.74	1.74		5.47	1.12	
Cranial ratio						
<0.95	17.71	1.00 (Ref)	0.044	4.63	1.00 (Ref)	0.313
0.96–1.05	24.97	1.41		5.01	1.08	
>1.05	29.04	1.64		5.13	1.11	
Diagonal difference						
<10	18.00	1.00 (Ref)	0.027	4.76	1.00 (Ref)	0.377
11–16	23.58	1.31		5.10	1.07	
>16	27.81	1.48		5.38	1.13	
Developmental delay						
Absent	22.14	1.00 (Ref)	0.042	4.9	1.00 (Ref)	0.353
Present	31.88	1.44		5.4	1.10	
Gestation						
Single	23.66	1.00 (Ref)	0.034	5.01	1.00 (Ref)	0.443
Multiple	15.42	0.65		4.92	0.98	
Method of delivery						
Cesarean	26.00	1.00 (Ref)	0.032	4.89	1.00 (Ref)	0.493
Vaginal	22.01	0.85		5.04	1.03	

RT, repositioning therapy; PT, physical therapy; RR, relative risk; Ref, reference.
*RT ± PT only and crossover ($n = 3381$).
†Crossover and helmet only ($n = 1531$).

DISCUSSION

The results of this study demonstrate that conservative treatment (repositioning therapy with or without physical therapy) and helmet therapy are each effective in correcting positional cranial deformation. Overall in this study, the largest to date, successful treatment endpoints were achieved for 4062 of 4378 infants (92.8 percent). Among those who were initiated on repositioning therapy with or without physical therapy alone, 77.1 percent achieved complete correction. An additional 15.2 percent of these patients achieved complete correction after transitioning to helmet therapy. Cranial orthotic molding helmets achieved complete correction in 95.0 percent of patients, with no difference in outcomes between patients who received helmet therapy after failed conservative therapy compared with those who received them as initial treatment.

Although many groups have identified general risk factors for the development of deformational plagiocephaly/deformational brachycephaly, no previous reports have focused on risk factors for failure of differing treatment modalities. The results of the present study show that the risk factors for treatment failure were distinct for conservative and helmet therapy. For conservative therapy, the severity of deformity (as measured by cranial ratio and diagonal difference), the persistence of torticollis beyond 6 months of age, and neuromuscular developmental delay were risk factors in addition to age and compliance. Multiple gestation and vaginal delivery were found to be protective against conservative treatment failure, whereas prematurity and male sex, two previously cited risk factors for deformational plagiocephaly/deformational brachycephaly,[14–17] were not found to be associated with outcomes. By contrast, for helmet therapy, the age at initiation of therapy and patient compliance were the only risk factors for failure.

Our identification of specific independent risk factors for treatment failure provides insight into the pathogenesis and treatment of deformational plagiocephaly/deformational brachycephaly. Current literature suggests the influence of both static and dynamic forces on the cranium that ultimately affect symmetry. Static forces include in utero position and neonatal activities that may influence head turns to a particular side (e.g., the adoption of a preferred breastfeeding position).[14,18,19] Dynamic forces include brain growth and the asymmetric pull from tightened or contracted muscles (or lack of pull from weak muscles).[12,16,17,20] As discussed by Rogers et al.,[17] these forces may be interdependent, in that intrauterine positioning gives rise to a congenital muscular torticollis, which then continually drives head turning to a particular side. This, in turn, fuels a vicious cycle of asymmetric occipital flattening (deformational plagiocephaly) and a tendency of the infant to rest comfortably on the flat spot. A similar cycle may fuel the development of deformational plagiocephaly, in which muscles are symmetrically weak. Our confirmation of torticollis as an independent risk factor for conservative treatment failure is consistent with its hypothesized pathogenic role. Specifically, our findings suggest that if torticollis persists beyond 6 months age, it is more likely to lead to prolonged cranial deformation with an increased risk for conservative treatment failure compared with torticollis that improves with normal neck muscular development at approximately 4 to 6 months of age. Our finding that neuromuscular developmental delay significantly increased the risk of conservative treatment failure is also consistent with the proposed etiopathogenesis of deformational plagiocephaly/deformational brachycephaly. Delays in muscular development may preclude these infants from overcoming deforming forces. Finally, we found both vaginal delivery and multiple gestation to be independently protective against conservative treatment failure. Both represent static forces from intrauterine life or the birth process that may influence head shape. We hypothesize that when not associated with torticollis development, these factors may be markers for improved outcomes because the deforming forces cease after birth.

With regard to risk factors, it is interesting to note that the failure of helmet therapy in this analysis was affected only by compliance and the age at therapy initiation. The severity of the initial cranial deformity and the presence of external deforming forces, such as torticollis and developmental delay, were not found to be associated with treatment failure. Based on these results, one can consider the helmet to provide a passive environment of fixed shape into which the brain can drive skull growth, isolating out external deforming forces. Therefore, although the continued presence of deforming forces may prompt the initiation of helmet therapy, the forces may be irrelevant to the outcome, provided that patients are compliant and therapy is commenced by the appropriate age. Of note, patients treated with helmets were more compliant in this study than those treated conservatively, likely because compliance with helmet therapy (assessed strictly on the basis of helmet wear) demanded less time and work by parents than the intensive home activities and weekly therapist visits required for repositioning therapy and physical therapy alone.

The age at which to initiate helmet therapy in infants with positional cranial deformities has been the subject of considerable debate.[12,21–27] Although some studies have reported no correlation between age and treatment outcomes,[24,25] others have shown significantly improved correction with earlier treatment.[22,23] In a recently published report, Kluba et al.[23] found that patients whose helmet therapy was initiated earlier than 6 months of age had shorter treatment time and greater improvement in absolute and relative cranial asymmetry measurements. Although Seruya et al.[12] confirmed a faster and more complete rate of correction in infants treated with helmets from an earlier age, they challenge the concepts espoused by Kluba et al.[23] in terms of a specific cutoff age after which it may "too late" to start helmet therapy. They instead suggest that helmets can be effective provided that there is still brain growth; in older children, helmets would be required for longer durations because of decelerated growth.[12] Our results in a significantly larger cohort of infants build on these findings. We have shown that (1) a significant proportion (77.1 percent) of patients initially treated with conservative measures alone will achieve complete correction in head shape without the need for helmet therapy, and (2) delaying helmet therapy for a trial of initial conservative management does not increase the risk of helmet failure. We believe this is applicable throughout a "critical period" of infancy during which brain growth is ongoing and consequent volumetric changes in head shape can be directed. The "critical age" after which helmet therapy initiation is likely to be unsuccessful can theoretically be computed for each infant based on standardized volumetric head growth curves constructed from STARscanner population data.[28]

In comparison with previous reports, our study has several unique strengths. First, the data were derived from the largest cohort of patients heretofore described in the literature with long-term follow-up. Second, all patients were evaluated and treated by a uniform team, including a single pediatric craniofacial plastic surgeon, a cohesive group of trained pediatric physical therapists, and licensed orthotists specifically trained on the STARscanner system. In contrast to other centers that have come to rely on nurse practitioner screening for head shape anomalies,[29] all patients at our center were initially evaluated by the surgeon and plans of care were then communicated back to the patient's referring pediatrician. Finally, rather than relying on imprecise recordings with hand-held calipers, this study used objective, volumetric cranial measurements obtained with a safe, reliable, and validated instrument (STARscanner).[11]

An important limitation of our work is that the treatment modalities were not randomized, and the analysis cannot therefore be used to comment on the superiority of one method over another. We reemphasize that the primary purpose of this study was not to determine which is *more* effective. Rather, we aimed to retrospectively analyze the *overall* effectiveness of our treatment paradigm for infants with positional cranial deformation. As depicted in Figure 1, our paradigm was based on clinical judgment and social factors, including parent preference. Consistent with this, a majority of patients (3381 of 4378) were initially assigned to a trial of conservative treatment. Older infants and those with more severe cranial deformation (deformational plagiocephaly with a higher diagonal difference, and deformational brachycephaly with a higher cranial ratio) tended to proceed directly to helmet therapy. We believe the paradigm to be successful in that 77.1 percent of infants assigned to conservative therapy alone obtained complete head shape correction. A majority of those who did not (534 of 773) were successfully transitioned to helmet therapy (crossover patients), for which the rate of complete correction was 96.1 percent. This proved to be similar to the rate of complete correction of those patients assigned to helmets at the outset (94.4 percent). Moreover, it again supports the contention that delaying helmet therapy for an early trial of repositioning therapy with or without physical therapy does not preclude eventual complete correction.

The effectiveness of orthotic helmets for passive cranial molding is clear. In keeping with our stated purpose, however, the practical import of this work is not to emphasize helmet therapy as the criterion standard because of a higher (i.e., 95 percent) overall correction rate, but instead to clarify to the broader pediatric community when a helmet should be recommended. For patients with minimal risk factors (e.g., age younger than 6 months, cranial ratio <0.95, diagonal difference <10 mm, absence of neuromuscular developmental delay, or persistent torticollis), we strongly favor an initial trial of conservative therapy because of the high potential for success with these techniques alone. For patients with significant risk factor profiles (e.g., age older than 7 to 8 months, cranial ratio >1.0, diagonal difference >15 mm, presence of developmental delay, or persistent torticollis), we favor counseling families on the increased likelihood of conservative treatment failure and the option of proceeding straight to helmet therapy. For patients with some combination of the above factors and a more "moderate" risk factor profile, we do not believe any ultimate progress is lost with an initial trial of repositioning therapy with or without physical therapy alone. Future studies will help optimize care recommendations by (1) enabling pediatric practitioners to easily calculate the "critical age" after which helmet therapy can no longer achieve complete correction because of decelerated brain growth, and (2) establishing a more comprehensive normative data set of infants to better define indices of deformational plagiocephaly and deformational brachycephaly severity.

CONCLUSIONS

Conservative treatment and helmet therapy were found to be effective for correcting positional cranial deformation in 92.8 percent of infants. Treatment may be guided by patient-specific risk factors. Helmet therapy appears to isolate out external factors that increase the risk of conservative treatment failure and thus may be preferable at the outset when these factors are present. Delaying the initiation of helmet therapy for a trial of conservative treatment does not preclude complete correction, provided that the helmet therapy is begun while brain growth is ongoing and patients are compliant.

Frank A. Vicari, M.D.
Advocate Medical Group
Lutheran General Hospital
1675 Dempster Street, 3rd Floor
Park Ridge, Ill. 60068
frank@vicari.com

REFERENCES

1. American Academy of Pediatrics AAP Task Force on Infant Positioning and SIDS: Positioning and SIDS. *Pediatrics* 1992;89:1120–1126.
2. Changing concepts of sudden infant death syndrome: Implications for infant sleeping environment and sleep position. American Academy of Pediatrics. Task Force on Infant Sleep Position and Sudden Infant Death Syndrome. *Pediatrics* 2000;105:650–656.

3. Argenta LC, David LR, Wilson JA, Bell WO. An increase in infant cranial deformity with supine sleeping position. *J Craniofac Surg.* 1996;7:5–11.
4. Kane AA, Mitchell LE, Craven KP, Marsh JL. Observations on a recent increase in plagiocephaly without synostosis. *Pediatrics* 1996;97:877–885.
5. Rogers GF, Miller J, Mulliken JB. Comparison of a modifiable cranial cup versus repositioning and cervical stretching for the early correction of deformational posterior plagiocephaly. *Plast Reconstr Surg.* 2008;121:941–947.
6. Mawji A, Vollman AR, Hatfield J, McNeil DA, Sauvé R. The incidence of positional plagiocephaly: A cohort study. *Pediatrics* 2013;132:298–304.
7. Bialocerkowski AE, Vladusic SL, Howell SM. Conservative interventions for positional plagiocephaly: A systematic review. *Dev Med Child Neurol.* 2005;47:563–570.
8. Robinson S, Proctor M. Diagnosis and management of deformational plagiocephaly. *J Neurosurg Pediatr.* 2009;3:284–295.
9. McGarry A, Dixon MT, Greig RJ, et al. Head shape measurement standards and cranial orthoses in the treatment of infants with deformational plagiocephaly. *Dev Med Child Neurol.* 2008;50:568–576.
10. Rogers GF. Deformational plagiocephaly, brachycephaly, and scaphocephaly. Part II: Prevention and treatment. *J Craniofac Surg.* 2011;22:17–23.
11. Plank LH, Giavedoni B, Lombardo JR, Geil MD, Reisner A. Comparison of infant head shape changes in deformational plagiocephaly following treatment with a cranial remolding orthosis using a noninvasive laser shape digitizer. *J Craniofac Surg.* 2006;17:1084–1091.
12. Seruya M, Oh AK, Taylor JH, Sauerhammer TM, Rogers GF. Helmet treatment of deformational plagiocephaly: The relationship between age at initiation and rate of correction. *Plast Reconstr Surg.* 2013;131:55e–61e.
13. Nandi R, Luxon LM. Development and assessment of the vestibular system. *Int J Audiol.* 2008;47:566–577.
14. Hutchison BL, Thompson JM, Mitchell EA. Determinants of nonsynostotic plagiocephaly: A case-control study. *Pediatrics* 2003;112:e316.
15. McKinney CM, Cunningham ML, Holt VL, Leroux B, Starr JR. A case-control study of infant, maternal and perinatal characteristics associated with deformational plagiocephaly. *Paediatr Perinat Epidemiol.* 2009;23:332–345.
16. Oh AK, Hoy EA, Rogers GF. Predictors of severity in deformational plagiocephaly. *J Craniofac Surg.* 2009;20 (Suppl 1):685–689.
17. Rogers GF, Oh AK, Mulliken JB. The role of congenital muscular torticollis in the development of deformational plagiocephaly. *Plast Reconstr Surg.* 2009;123:643–652.
18. Rogers GF. Deformational plagiocephaly, brachycephaly, and scaphocephaly. Part I: Terminology, diagnosis, and etiopathogenesis. *J Craniofac Surg.* 2011;22:9–16.
19. van Vlimmeren LA, van der Graaf Y, Boere-Boonekamp MM, et al. Risk factors for deformational plagiocephaly at birth and at 7 weeks of age: A prospective cohort study. *Pediatrics* 2007;119:e408–418.
20. Golden KA, Beals SP, Littlefield TR, Pomatto JK. Sternocleidomastoid imbalance versus congenital muscular torticollis: Their relationship to positional plagiocephaly. *Cleft Palate Craniofac J.* 1999;36:256–261.
21. Graham JM Jr, Gomez M, Halberg A, et al. Management of deformational plagiocephaly: Repositioning versus orthotic therapy. *J Pediatr.* 2005;146:258–262.
22. Kelly KM, Littlefield TR, Pomatto JK, et al. Importance of early recognition and treatment of deformational plagiocephaly with orthotic cranioplasty. *Cleft Palate Craniofac J.* 1999;36:127–130.
23. Kluba S, Kraut W, Reinert S, Krimmel M. What is the optimal time to start helmet therapy in positional plagiocephaly? *Plast Reconstr Surg.* 2011;128:492–498.
24. Mulliken JB, Vander Woude DL, Hansen M, LaBrie RA, Scott RM. Analysis of posterior plagiocephaly: Deformational versus synostotic. *Plast Reconstr Surg.* 1999;103:371–380.
25. Teichgraeber JF, Seymour-Dempsey K, Baumgartner JE, et al. Molding helmet therapy in the treatment of brachycephaly and plagiocephaly. *J Craniofac Surg.* 2004;15:118–123.
26. Vles JS, Colla C, Weber JW, et al. Helmet versus nonhelmet treatment in nonsynostotic positional posterior plagiocephaly. *J Craniofac Surg.* 2000;11:572–574.
27. Thompson JT, David LR, Wood B, et al. Outcome analysis of helmet therapy for positional plagiocephaly using a three-dimensional surface scanning laser. *J Craniofac Surg.* 2009;20:362–365.
28. Steinberg JP, Rawlani V, Rawlani R, Dumanian GA, Vicari FA. The "critical age:" Objective, patient-specific timing of helmet therapy in treatment of deformational plagiocephaly and brachycephaly. Poster presented at: 92nd Annual Meeting of the American Association of Plastic Surgeons; April 20–23, 2013; New Orleans, La.
29. Kuang AA, Bergquist C, Crupi L, Oliverio M, Selden NR. Effectiveness and safety of independent pediatric nurse practitioners in evaluating plagiocephaly. *Plast Reconstr Surg.* 2013;132:414–418.