Cranial Remolding Helmet Treatment of Plagiocephaly: Comparison of Results and Treatment Length in Younger Versus Older Infant Populations

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ABSTRACT

It is well known throughout the medical community that children's heads grow most rapidly during the first 12 months of life, followed by continued growth at a much slower rate. This fact is very important in the timing of the application of cranial remolding orthosis therapy for children with plagiocephaly. Most of the reviewed literature mentions the need to exploit this rapid growth period, but evidence is lacking that compares the degree of correction and length of treatment in children who undergo cranial remolding orthotic therapy before and after the critical 12-month-old time point. The purpose of this study was to determine whether there is a difference between results of orthotic treatment and length of treatment for children with plagiocephaly who complete at least half of cranial remolding helmet therapy earlier than 12 months of age (young group) and those who complete at least half of treatment at or after 12 months of age (old group). The "beginning of therapy" is defined as the date of casting. The study was conducted by retrospective chart review of patients seen at Atlantic Prosthetics and Orthotics at the University of North Carolina Hospitals, tracking the changes in asymmetry and amount of correction through the course of treatment, as well as the overall length of treatment and comparing the results between the two groups. Ninety-eight charts were reviewed; 58 subjects met inclusion criteria, with 48 in the young group and 10 in the old group. A major excluding factor was parents choosing not to complete helmet therapy. The results of this study showed that cranial remolding treatment is effective for patients in the old group and that similar amounts of asymmetry correction can be obtained as with patients in the young group (asymmetry correction comparison, $p = 0.95$). However, a significant difference in treatment length exists with treatment length almost doubling to obtain similar amounts of correction in the old group compared with the young group ($p = 2.85 \times 10^{-5}$). Educating physicians on the importance of encouraging parents to start treatment as early as possible may help to increase effectiveness by increasing parental compliance as treatment length is almost halved when starting a few months earlier. (*J Prosthet Orthot*. 2009;21:55–63.)

KEY INDEXING TERMS: plagiocephaly, cranial remolding orthosis, helmet, helmet therapy

The number of children diagnosed with plagiocephaly has increased dramatically since the early 1990s. Depending on the criteria used to make the diagnosis of plagiocephaly, estimates of incidence range from 0.33% to as much as 48% of live births.[1,2] Many studies, and common thought within the medical field, theorize that this increase is associated with the initiation of the Back to Sleep program in 1992, which has increased the amount of children who sleep in a supine position.[3] One study tracked the incidence of plagiocephaly for 2 years before and after the Back to Sleep program was initiated, with the later time frame having an incidence five times greater than the time frame before the Back to Sleep program was initiated.[2] The Back to Sleep program, backed by the American Academy of Pediatricians, is reported to have lowered the incidence of Sudden Infant Death Syndrome (SIDS) by 40%. The success of the Back to Sleep program for SIDS prevention may come at the cost of increased incidence of plagiocephaly, but the benefits far outweigh the risks.

There are many factors prenatally, perinatally, and postnatally, which can cause plagiocephaly. Prenatal uterine constraint, which is a more common problem in multiple child pregnancies, is a risk factor, and perinatal birth injury can cause cranial malformation. Both of these etiologies of plagiocephaly tend to be associated with spontaneous correction of the asymmetry providing no further risk factors are present.[1] Postnatal risk factors for plagiocephaly are static supine position (both during sleep and awake hours) and the presence of torticollis (one-sided neck tightness).[1] More recently, the advent and use of multifunction infant carriers, which no longer require repositioning from car seat to carrier to stroller have been found to be a risk factor as the child remains in the same position far longer than before their advent.[3] The postnatal causes of plagiocephaly often require some means of treatment to obtain correction.[1]

The diagnosis of plagiocephaly involves observation by following the infant's cranial shape from birth. Pediatricians visually inspect the infant's face and cranial shape and symmetry at the newborn examination and at mandatory infant

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checkups. If plagiocephaly is suspected, radiograph, computed tomographic, or magnetic resonance imaging scans or a combination may be used to rule out a more serious condition called craniosynostosis that requires surgery for correction.[1,3]

The characteristics of infant cranial growth, as well as the natural progression of plagiocephaly, are factors that influence the course of treatment. Eighty-five percent of postnatal cranial growth occurs in the first year of life, and bone stiffness and load bearing capacities of the skull bones increase as children age.[2,4] The skull grows through the process started by brain growth, which pushes the skull bones apart, then new bone is formed along the suture lines to fill in the space created by the brain growth. If growth in one area is restricted, whether by constant contact from static positioning or by the application of a cranial remolding orthosis, the skull will grow in all nonrestricted directions to make up for the lack of growth in the restricted direction. Deformed skulls have been shown to have the same internal volume to accommodate the brain as those considered to be normal shaped, so brain growth is not restricted by a reshaping process providing some areas have no growth restriction.[5] The natural progression of plagiocephaly left untreated has been studied by Hutchison et al.[6] They found that regardless of the etiology of plagiocephaly, the deformity tends to increase at 4 months of age, then begins to spontaneously correct in most cases. Hutchison et al.'s[6] data showed a prevalence of 19.7% in their study population at 4 months of age, which decreased to 3.3% by 2 years of age (90.5% of the patients were followed up to 2 years).

Many complications have been found to occur in untreated patients with plagiocephaly in whom the plagiocephaly does not self-correct. Despite the finding by Tubbs et al.[5] that skull volume is the same whether the skull is deformed or normal shaped, Panchal et al.[7] found that before treatment children in their study population diagnosed with plagiocephaly had significantly different from normal distribution mental developmental index (MDI) and psychomotor developmental index (PDI) scores obtained by Bayley Scales of Infant Development-II (BSID-II) testing, which are accepted as indicators of developmental delays.[7] This group did not retest subjects after treatment, so there is no data on whether treatment can correct the developmental delays. They also noted that it is not known whether cortical problems lead to the skull deformation or whether skull deformation leads to cortical problems. In the first case, treatment would have no effect on correcting the delays, whereas if the latter were true, treatment may have an effect.[7] The facial asymmetries associated with plagiocephaly have also been found to lead to long-term physical maladies. Mandibular dysmorphology, a common facial asymmetry associated with plagiocephaly, has been tracked and found to lead to dentoskeletal complications and temporomandibular joint dysfunction (TMJ) if left untreated.[8,3] Asymmetries in the boney anatomy around the orbits may lead to visual field development problems; although when studied, the problematic part of the visual field and side of occipital flatness did not correlate in laterality or severity.[9] The existence of mental and physical problems in association with the diagnosis of plagiocephaly substantiates the use of treatment to correct the involved deformity.

There has been much debate and study to determine whether positioning or orthotic intervention is more effective and to determine what time each treatment regime is most appropriate and beneficial. The general consensus is that positioning techniques are most appropriate early on, with one study recommending it for the first 2–3 months of life. These techniques include initiating crib position changes to encourage lying on the uninvolved side of the head, increasing tummy time during awake hours, and performing torticollis stretching exercises during diaper changes if applicable.[1] Another study came to the conclusion that positioning was only effective up to the first 3–4 months of life and that older children should be treated with more aggressive procedures.[3] Different measurement techniques used in studies comparing orthotic treatment and conservative stretching/positioning effectiveness prevent the ability to draw conclusions.[10]

The guideline according to current common thought for orthotic management of plagiocephaly is that "the younger the better," referring to capturing the most rapid cranial growth that occurs up to1 year of age. A study by Graham et al.[11] concluded that earlier treatment is most effective and that treatment must take place while "enough residual cranial growth" is available to capture for correction. These conclusions were based on their study population with results of the group beginning orthotic therapy older than 8 months of age having a 51% decrease in diagonal difference (DD), whereas the group starting treatment at less than 8 months of age had a 65% decrease in DD. This group also stated, although with providing no data, that there is no evidence that orthotic treatment can provide a "significant benefit" to patients older than 12 months old.[11] Another study stated that "less modification to cranial configuration when [orthotic treatment is] used after 12 months of age" and they found that the best outcome is when treatment occurred between 4 and 12 months of age.[1] A clinical review by Lima and Fish[3] stated that orthotic therapy is not effective after 18 months of age. Cranial growth charts distributed by the Centers for Disease Control and Prevention used in every pediatric office show marked drop off in the growth rate once children reach 12 months of age.[12] The length of treatment can also be affected by the child's age at the beginning of treatment. Of the reviewed literature only one study reported data on treatment lengths between different age groups of subjects and found that in their study population younger patients (patients starting treatment at age less than 8 months) had longer treatment times.[11]

Twelve months of age is widely mentioned as the end date for orthotic treatment in literature involving the treatment of plagiocephaly, yet little evidence is available to substantiate finishing treatment before 1 year of age. Graham et al.[11] stated that no evidence is available that proves any benefit can be obtained from orthotic treatment for plagiocephaly in patients older than 12 months of age. The purpose of this study was to determine whether there is a difference in results and treatment length between children who are less than 12 months of age for at least half their treatment time (young group) and those who are 12 months or older for at least half their treatment time in cranial remolding orthoses (old group).

METHODS

The subject population was gathered by chart review of cranial remolding helmet patients seen at the research facility (Atlantic Prosthetics and Orthotics at the University of North Carolina Hospitals). The Starband™ cranial remolding helmet orthosis with side opening is used for all plagiocephaly patients at this facility. Patients are casted at the facility, then the cast is sent to Orthomerica for helmet fabrication. Helmets are fit 2 weeks after casting. Patients were followed-up 1 week after fitting, then every 2–3 weeks depending on the child's growth rate (slower growing = 3 week intervals). Pictures and measurements are taken and any necessary adjustments are made at each visit. Measurements include cranial length, width, both diagonals, and circumference. Full-time therapy is ended when a consensus between physician, practitioner, and parents is reached. Patients then continue night and nap time wear for 2–4 weeks or until the child grows out of the helmet, whichever comes first, but no follow-up appointments occur during this time. The standard protocol after a child completes helmet therapy at the facility is to move the patient's computer file containing digital pictures from each visit into the "completed helmets" folder. At the time the subject population was created patients in the completed helmets folder were those who had completed the cranial remolding treatment at the facility beginning with the earliest available records on our computer in 2005 and ending treatment by January 18, 2008. The completed helmets folder was used to create a list of patient names whose charts were then reviewed to determine whether the patients met inclusion criteria for this study.

Patients were included in the subject population if they met all of the following inclusion criteria:

- Any age child who began and ended cranial remolding helmet therapy at the facility;
- End of treatment was agreed upon by the practitioner, parents, and referring physician;
- Diagnosis of plagiocephaly;
- Plagiocephaly was the main cranial asymmetry to correct with therapy.

Patients were excluded from the subject population if they met any of the following exclusion criteria:

- History of craniosynostosis;
- History of a syndrome with a characteristic cranial shape;
- Simultaneous diagnosis of brachycephaly and plagiocephaly, where brachycephaly is the main cranial asymmetry to correct (determined if initial diagonal symmetry was greater than or equal to 93%);
- Patient lost to follow-up;
- Parents happy with results and opted to stop therapy before practitioner's recommended end date;
- Parents not happy with treatment and opted to stop treatment;
- Patients whose charts were not readily available.

Charts were reviewed for diagnosis, start date, end date, follow-up visit dates, and diagonal measurements from all appointments. Start date was defined as the date of casting, although orthotic treatment was not initiated for another 2 weeks. Measurements were not taken on the day of the helmet fittings (2 weeks after casting) per the facility's protocol; therefore, treatment start date could not be defined as the actual start date of orthotic intervention. The UNC Hospital Webcis system was used to find date of birth.

Microsoft Excel was used for data input and data treatment. The date function fx=DAYS360 was used to calculate the number of days between date of birth (DOB) and start date to determine start age in days, which was then divided by 7 for age in weeks, then by 30 for age in months rounded to two decimal places (hundredths). The same procedure was used to find the end age data using DOB and end date, and the treatment length data using the start date and end date. The function fx = AVG was used by inputting the end age and start age in months, which output the age in months of each patient at the treatment halfway point. Patients were assigned to the "old" subject group if their age halfway through treatment was more than or equal to 12 months. Patients were assigned to the "young" subject group if their age halfway through treatment was less than 12 months. The function fx = IF ([cell containing age at halfway point] > = 12,"Old," "Young") was used to assign patients to the old or young group.

For each treatment date for each subject, the function fx = DAYS360 was used to calculate the days into treatment that the visit took place using the start date and visit date. The diagonal measurements taken at each visit (right anterior to left posterior and left anterior to right posterior) were used to calculate the DD, percent of symmetry, and percent correction at each follow-up appointment. DD = large diagonal-small diagonal. Percent of symmetry = (small diagonal/large diagonal) × 100. Percent of correction = [(start DD − current DD)/start DD] × 100.

The significance of the data was analyzed using independent two-tailed *t*-tests for treatment length and asymmetry correction percentage. The function fx = TTEST (young group treatment length array, old group treatment length array, 2, 2) was used to perform a two-tailed *t*-test with a two-sample, equal variance data set to determine the *p* value for a treatment length comparison of the two groups. The function fx = TTEST(young group asymmetry correction array, old group asymmetry correction array, 2, 2) was used to perform a two-tailed *t*-test with a two-sample, equal variance data set to determine the *p* value for an asymmetry correction comparison between the two groups.

The data was then compared through averaged results listed in tables, in scatter plots using best fit lines, and with a box and whisker plot.

RESULTS

A list of 98 names was compiled containing all the patients who were in the completed helmets file. Ninety-eight charts were reviewed with the breakdown of group assignment listed in Table 1. Table 2 lists the major points of interest with the averages calculated for each subject group. Table 1 deciphers how 40 patients were excluded, with the majority of exclusions because of noncompletion of treatment or brachycephaly being the major cranial asymmetry to correct. Fifty-eight patients were found to fit inclusion criteria: 48 fit the young subject group criteria, 10 fit the old subject group criteria.

Table 2 shows that the old group average start age was just barely younger than the young group's end of treatment age. The old group started and ended about two percentage points less symmetrical than the young group, but both groups had nearly equal asymmetry correction. The young group had almost a 20% greater amount of correction than the old group. The old group's average treatment length was 1.8 times the length of the young group (6.51 months vs. 3.62 months respectively). The significance of the data calculated by independent *t*-tests is also listed in Table 2. There is not a significant difference in the amount of asymmetry correction attained through orthotic therapy between the young and old groups as $p = 0.95$, which is much greater than the standard significance indicator $\alpha = 0.05$. There was found to be a significant difference in the treatment lengths of the two groups, with $p = 2.85 \times 10^{-5}$, which is much smaller than $\alpha = 0.05$.

Table 1. Chart review breakdown into included and excluded groups. A total of 98 charts were reviewed

Breakdown of reviewed charts	
Excluded	40
Brachycephaly > plagiocephaly	15
Not finish	14
Associated syndrome	4
Moved before finishing	2
Scaphocephaly	2
Started at another facility	2
Chart not available	1
Included	58
Young group	48
Old group	10

Table 2. Averages of main data interest points for both subject groups

Basic Data Statistics		
	Subject Group	
Averages	Young	Old
Start age (mos)	7.08	10.05
End age (mos)	10.70	16.56
Start % symmetry	90.71	88.68
End % symmetry	97.32	95.24
Change in symmetry %	6.61	6.56
End % correction	72.13	53.03
Treatment length (mos)	3.62	6.51
p value for change in symmetry comparison	$p = 0.95$	
p value for treatment length comparison	$p = 2.85 \times 10^{-5}$	

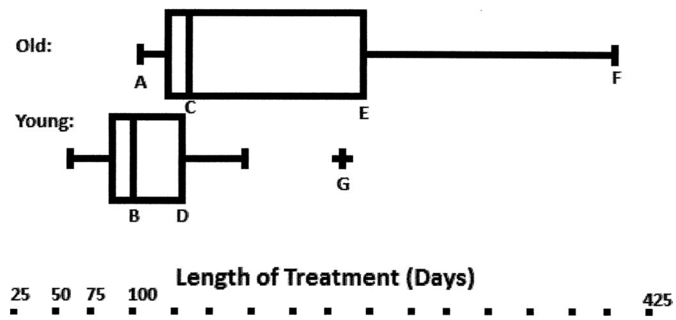

Figure 1. The old subject group's treatment lengths are plotted in the upper box, and whisker plot and the young subject group is plotted in the lower one. The data show that the majority of treatment lengths for the old group are longer than those for the young group, and that the range of treatment length is larger for the old group than the young group.

Figure 1 is a box and whisker representation of the treatment lengths for the children in each group. The shortest treatment of a young patient is almost 50 days less than the shortest treatment for an old patient. Figure 1 shows that there are no outliers in the old group, but there is one outlier on the long end of treatment length for the young group. More than half of the young group's treatment lengths were shorter than the shortest treatment length of patients in the old group (compare points A and B). More than half of the old group's treatment lengths were longer than or equal to the treatment lengths of the longest 25% of the young group's (compare points C and D). The young group's long treatment outlier fits in the 50% to 75% range of the long group's treatment lengths (compare G with E and F).

Figures 2–4 compare the results obtained throughout the course of treatment between the young and old groups. Figure 2 shows the symmetry percentage throughout the course of each patient's treatment in both groups. Figure 3 shows the correction percentage as treatment progresses for each group. Figure 4 compares the starting symmetry percentage with the final correction percentage. Trend lines for each group are also included to help interpret the many plotted points.

The trend lines in Figure 2 show that the symmetry percentage corrected toward normal in both groups throughout treatment. However, the slope of the young group's trend line is slightly greater than that of the old group's, showing

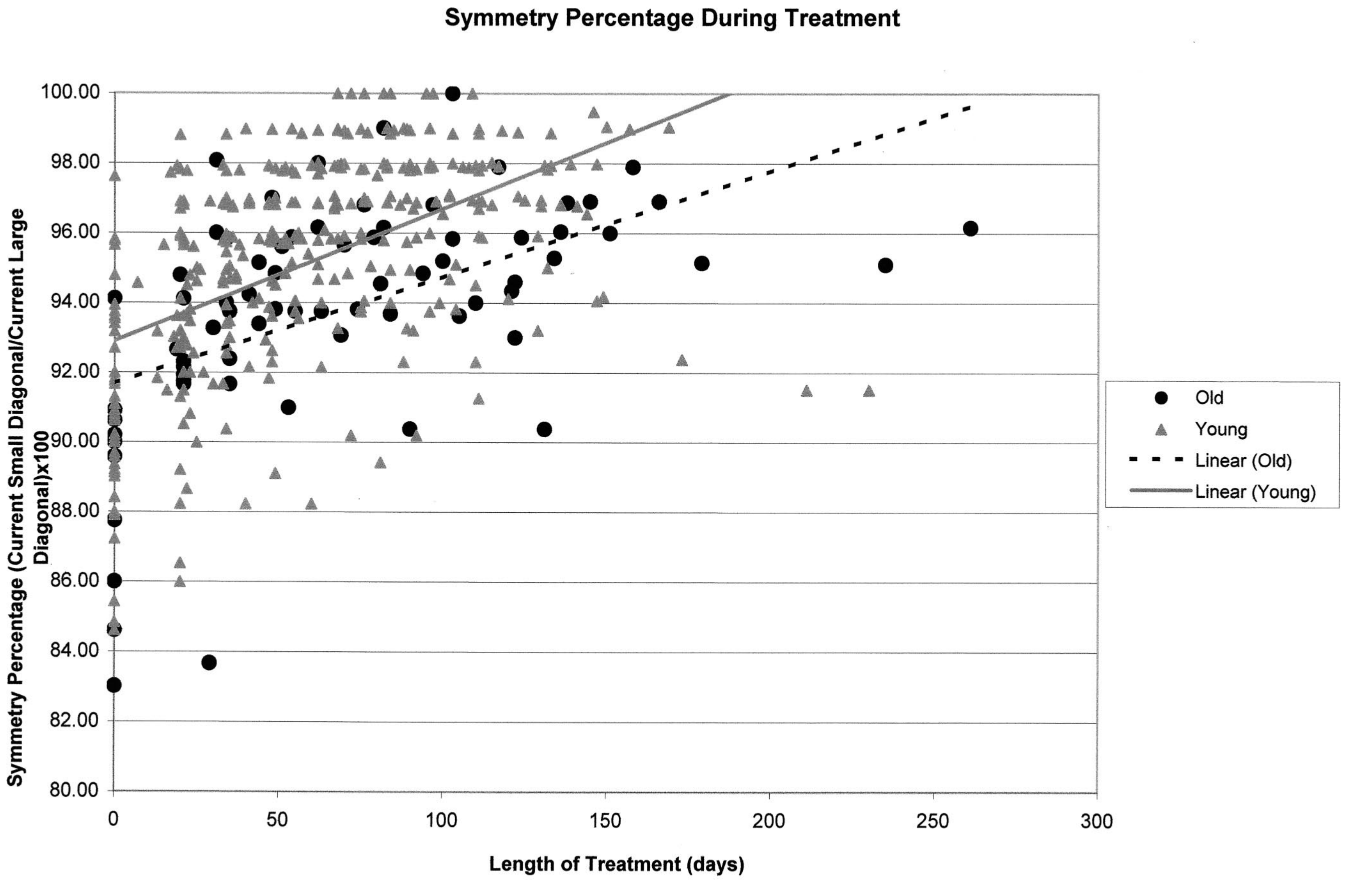

Figure 2. Each plotted point represents the symmetry percentage of a single subject's cranial measurements at one visit during the course of treatment. Each subject has multiple points plotted that follow the symmetry change throughout the cranial remolding therapy. The data demonstrate that the young group's symmetry improved more quickly than the old group's symmetry, but that both groups did see improvement.

slightly quicker correction in the young group. As noted in Table 2, you can also see in Figure 2 that the old group's symmetry percentage starts and stays lower than the young group.

The trend line for the young group has a more positive slope in Figure 3 than that of the old group. This shows that the young group corrected more quickly than the old group. However, this graph does not take into account the severity of the plagiocephaly, so the correction percentage units are not uniform between patients as they are scaled to each patient's initial DD. There is one point in the old group and two in the young group where a patient's asymmetry worsened in comparison with their initial DD (the negative points on the y axis). Many points remain at 0% correction toward the beginning of treatment in each group, but all obtain some correction by the end of treatment.

Figure 4 takes into account the initial severity of each subject's plagiocephaly when comparing the amount of correction obtained at the end of treatment between the two groups. The trend lines show opposite tendencies for the amount of correction obtained between two groups. The slope of the young group's trend line is positive showing that the less severe the condition was initially, the greater the amount of correction obtained. The slope of the old group's trend line is negative showing that the more severe the condition was initially, the greater the amount of correction obtained.

DISCUSSION

The results in Figure 1 and Table 2 show that the treatment lengths for the young group are much shorter than the treatment lengths for the old group. All of the old group subjects had treatment lengths longer than the treatment lengths of 50% of the young patients. The long treatment outlier for the young group, which is exceptionally long for the young group, falls within the middle 50% of the old group subjects' treatment lengths, which would be considered average within the older population. The shortest treatment of an old group patient is 50 days longer, almost 2 months, than the shortest treatment of a young group patient, and the average treatment length for all the old group patients was almost double that of the young group patients. The treatment lengths for the old group were significantly longer than those of the young group when statistically analyzed, with a resulting p value of $p = 2.85 \times 10^{-5}$. These findings are

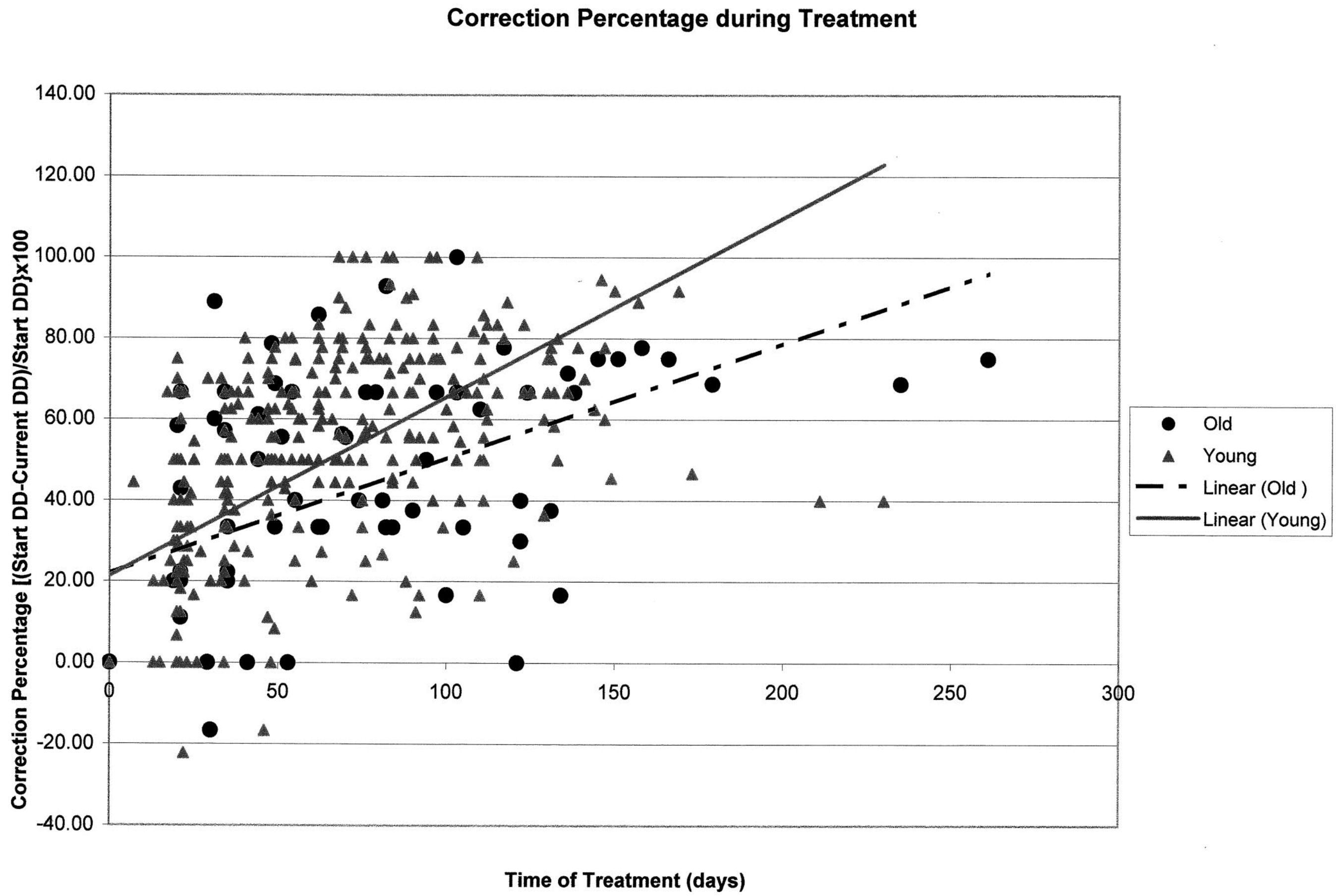

Figure 3. Each plotted point represents the correction percentage of a single subject's cranial measurements at one visit during the course of treatment. Each subject has multiple points plotted that follow the correction change throughout the cranial remolding therapy. The data show that both groups attained correction by orthotic treatment, with correction occurring in less time for the young group than the old group. The data also show that a few patients worsened near the beginning of treatment, but all improved by the end of treatment.

contrary to those of Graham et al.[11] who reported that treatment length was longer in younger patients. They did not give any possible explanations. Their protocol may have been to end treatment at the same age for every patient, thus their older patients would have shorter treatment lengths as they would begin closer to the end of treatment age. If that was the case, their finding does not contradict the data from this study as different protocols were used. The data from this study supports the well-known idea that younger is better for treatment as the therapy length is dramatically shorter for the younger aged children.

Results in Table 2 and Figures 2–4 show a tendency for young group patients to have better results than old group patients; however, old group patients still benefit from treatment. When compared through statistical analysis, the asymmetry correction attained through orthotic treatment of the young versus old group patients was not significantly different ($p = 0.95$), but was almost equal. In Figure 2, the trend lines for both groups are similar, showing that old group patients in this study benefited nearly as much from treatment as younger patients. Therefore, parents of older infants (inquiring about treatment around 10 months of age which was the average start age for the old group) should not be discouraged from pursuing treatment purely because of the child's age. The young trend line is noticeably steeper than the old group's in Figure 3, unlike those shown in Figure 2. This again shows that younger patients will see correction faster; however, this difference may be deceiving as the larger difference in trendline slope in Figure 3 versus Figure 2 is due to the different ways of calculating the symmetry and correction percentages. The symmetry percentages in Figure 2 are calculated taking into account the current size of the child's head at each visit, whereas the correction percentages are calculated using only the starting size. The inclusion of the child's overall growth in Figure 2 decreases the impact of the growth in the flat areas. The younger children's craniums grow faster than the older children's, which causes the flat areas to fill in faster than the older children's. This shows up in Figure 3 in that the younger children correct faster as the growth is compared only with the starting asymmetry. When the new growth is considered along with the overall head growth as in Figure 2, the results are less dramatic, but still show improvement in both groups.

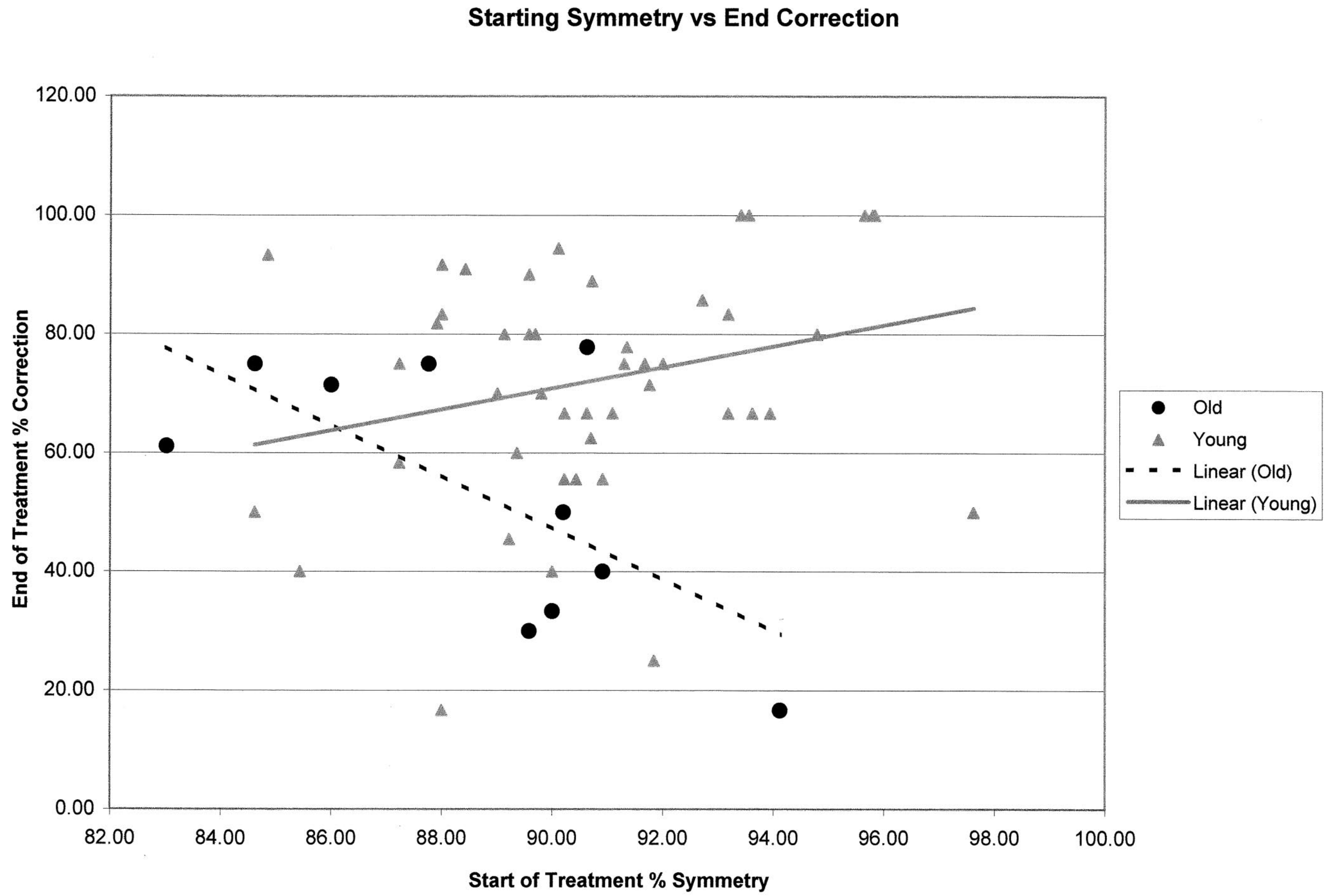

Figure 4. Each subject has only one data point in this graph, which compares the initial severity of plagiocephaly with the amount of correction obtained at the end of treatment. The data demonstrate that the more severe the patients in the young group were at the beginning of treatment, the lower the correction percentage attained by the end of treatment. Conversely, the more severe the patients in the old group were at the start of treatment, the greater the correction percentage attained by the end of treatment.

Figure 3 has a few points where subjects' asymmetry increased during the course of treatment, although they all improved by the end of treatment. Most of these instances occurred toward the beginning of treatment. One theory that can explain this occurrence is lack of wear time compliance early on. Many parents express doubt about effectiveness of treatment or concern about the effects treatment may have on their child's sleep or comfort. These same parents often times admit to taking longer than the standard 5 day break-in to full time 23 hrs per day wear, but generally work up to full time wear. The patients may continue to worsen while not yet wearing helmets full-time, but then begin to correct once full-time wear is achieved. As we did not use any means to obtain factual compliance data, we cannot know if this theory is correct.

Figure 4 takes into account the initial severity of the plagiocephaly along with the results of the treatment. This graph is interesting in that the trend lines are opposite each other; one is positive and one is negative, showing that there is indeed a difference in treating younger patients compared with older patients. The young group acts as expected in that the closer the subject was to beginning perfectly symmetrical, the closer the subject will be to perfectly symmetrical in the end. If the child starts out more severe, but is about the same age and undergoes the same length of treatment as a child who is less severe, we can expect similar amounts of growth to occur. This means the child who started more severe will most likely remain more severe as that child needed more growth to reach perfect symmetry. The data for the older group did not follow this pattern. In the older group, the more severe the subjects were initially, the more correction the subject obtained through treatment. Further investigation is needed to explain this data.

The findings from this study show that treatment is beneficial to both younger and older patients and that similar correction can be obtained in older children as younger children, although treatment times are almost double for the older children in comparison with the younger children for this to occur.

There are many limitations and confounding factors involved in this study. The older children tended to present more severe than the younger children, which makes the results from each group much more difficult to compare because they did not start from the same baseline. There were almost five times as many subjects in the young group as in the old group, which makes the data from the old group much less reliable than that from the young group because of smaller sample size. Actual age, not corrected age was used in this study, so prematurity was not taken into account. Premature children tend to present similar to patients younger than they are. The effect of the premature patients' presentations can also skew results, again making the data difficult to truly compare.

Practitioner protocol can create limitations in the reliability of the results. At the facility, protocol is to have the same practitioner measure the patient all the way through treatment. However, this is not always possible depending on practitioners' availability at the parents' desired appointment times. Grouping the different patients seen by the different practitioners also limits reliability as no interrater testing has been conducted. Many of the older patients come in for a consult for the practitioner's opinion on the possible effectiveness of helmet therapy. The protocol at this facility is to feel for the size or existence of the anterior fontanel ("soft spot"). This skews the results by not including those children who present with a closed anterior fontanel in the study even if they are still within the same age range of some patients included in the study. The decision whether or not to begin cranial remolding therapy is also influenced by the patient's corrected age and degree of severity. The closer the child's age to 12 months and the less severe the case, the less likely the practitioner is to recommend treatment. The combination of the three factors is also a reason why there are fewer subjects in the old group versus the young group. Another way in which protocol can affect the results is that the treatment tends to be dragged out past the point of reaching acceptable stopping symmetry in the really young patients. The young patients correct quickly, but their anterior fontanels are still open, so the practitioners recommend the patients stay in the helmet until the child ages further to prevent the possibility of the flat spots reoccurring as there is still a lot of growth remaining.

The documentation methods also pose limitations to study reliability. Although photographs are taken along with measurements at each visit, photographs were not used for comparison because there is no standard photographic evaluation technique available. Each photograph between patients and between the same patient's many pictures is different as the pictures are taken at different distances and at slightly different angles. The inability to stop a child's movement completely increases the difficulty of getting pictures from the exact same angles. Despite the difficulty in taking pictures, the measurements taken do not fully describe the asymmetries, so the photographs are used as a visual qualitative record in conjunction with the measurement to more fully tracks the child's progress.

Concurrent diagnoses can also create limitations as they affect the treatment length recommended by the practitioners. Patients who have torticollis or neck hypotonicity (one or both sided neck weakness) are at risk for flat spot reoccurrence if helmet treatment is concluded while the anterior fontanel remains open and these other conditions have not been resolved. In these situations, the treatment may be extended to decrease the risk of flat spot reoccurrence.

Parents also play a large role in the results, creating further uncontrolled variables and thus study limitations. The parents are responsible for bringing the child in for follow ups, wear time compliance, and are ultimately the deciding factor in when the child stops using the helmet. Many parents report that they are tired of "dealing with the helmet" and choose to stop treatment once some correction, although not all that is possible, is attained. Many parents have researched helmets and have read that at 12 months of age treatment is no longer effective, or correction is very slow in coming after that point, so they may choose to stop treatment at that time. As seen in Table 1 almost half of the patients excluded from the study were due to lack of therapy completion, which ranged from only getting casted and never returning to have the device fit, to stopping shortly before the practitioners and physicians would have recommended. Further study should be done to determine what deters parents from continuing with helmet treatment.

CONCLUSION

It is a well-known fact that 85% of cranial growth occurs in the first 12 months of life, making it optimal for cranial reshaping treatments to occur during the first year of life. Current literature on cranial remolding orthoses follows this idea, stating that treatment is best before 12 months, but can be effective up to 18 months of age. This standard is stated in almost every piece of literature, yet there is little evidence that tests whether or not treatment is effective after the first year of life, and how the effectiveness compares with children treated at a younger age. The purpose of this study was to determine whether there was a difference in results and treatment length between children who are less than 12 months of age for at least half their treatment time and those who are 12 months or older for at least half their treatment time in cranial remolding orthoses.

The results of this study showed that cranial remolding treatment is effective for patients in the old group, and that there is not a significant difference in the amount of asymmetry correction that can be attained by patients in the old group in comparison with patients in the young group. However, a significant difference in treatment length exists, with treatment length almost doubling for similar amounts of correction to occur in the old group as in the young group. Educating physicians on the importance of encouraging parents to start treatment as early as possible may help to increase effectiveness by increasing parental compliance as treatment length is almost halved by starting a few months earlier.

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