CLINICAL REPORT

Acquiring Craniofacial Symmetry and Proportion Through Repositioning, Therapy, and Cranial Remolding Orthoses

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OVERVIEW

Symmetry is present in nature, art, mathematics, architecture, engineering, and the human body. It corresponds to an arrangement and balancing of the parts or elements of a whole in respect to size, shape, and position on opposite sides of an axis or center.[1] In the case of the human skeleton, many paired bones and extremities exist and those that are not paired, like the sternum, are positioned in the middle of the body. Symmetry is manifested in the face where there are two eyes and ears but only one nose and mouth that are precisely centered. This is also true for the skull, which has paired frontal, parietal, temporal, and sphenoid bones, with one occipital bone positioned in midline. This midline and paired orientation align the head in relation to the rest of the body, placing it in the optimal position to send and receive olfactory, visual, and auditory information. A disruption in this midline position through trauma or deformation can affect the processing of sensory stimulation and lead to visual disturbances. [2,3,4] It has also been shown that the mandibles are asymmetrical in infants with skull and facial asymmetry,[5] and this could result in temporal mandibular joint (TMJ) dysfunction over time.

For thousands of years, people around the world have used various means to change the shape of infants' heads. Whether the material used was string meticulously wrapped around the infant's skull, bark, a woven skull cap, or a backboard with wooden forehead restraint, all these cultures attempted to create a symmetrical shape and a specific proportion. In 1979, Sterling Clarren, M.D., published a paper in the Journal of Pediatrics entitled "Helmet Treatment for Plagiocephaly and Congenital Muscular Torticollis". [6] Cranial remolding orthoses were introduced as ways to achieve cranial symmetry (Figure 1) and correction of the congenital muscular torticollis was noted. A negative impression of the infant's head was obtained and the mold was modified to obtain a symmetrical shape and allow for growth. The custom-molded Clarren helmet was fabricated over a plaster model of the infant's head and the orthosis was worn 24 hours a day. Once these initial results were published, many medical centers across the United States began using cranial remolding orthoses to treat infants with skull and facial asymmetry rather than perform invasive and costly surgeries to correct these positional deformities.

CAUSES OF POSITIONAL PLAGIOCEPHALY

Cranial asymmetry is referred to as plagiocephaly (from the Greek word "twisted"), and the incidence has been increasing over the last ten years. This increase coincides with two factors that occurred in the early 1990's. The first contributing factor relates to infant sleep position. Babies have been put to sleep on their backs rather than their tummies since 1992 when the American Academy of Pediatricians and other physicians around the world initiated the "Back to Sleep" program. This recommendation was directly related to the fact that infants sleeping in a prone position had a higher incidence of Sudden Infant Death Syndrome (SIDS).[7] This very successful campaign has resulted in a 40% drop in the SIDS rate. In response to the increase in plagiocephaly associated with supine sleeping, the Academy now recommends that infants be placed in the prone position during the day when they are awake and supervised.[8] This information has been slow to be integrated into parenting practices, and positional plagiocephaly and other head shape deformations continue to be widespread.

The second factor relating to positional plagiocephaly is linked to the extensive use of infant seats and carriers. In the early 90's, these products were redesigned for convenient use in a variety of places with greater ergonomic efficiency for the parents. The multifunction seats that can be used in the car, stroller, high chair, etc. have become extremely popular in today's

mobile society. As a result, infants are often placed in them continuously throughout the day. This puts constant pressure on the back of the baby's head, in addition to the extended periods of time the infant is asleep. The soft bony plates of the infant's skull are easily shifted and misaligned with continuous pressure over time, and plagiocephaly can occur unless the infant's head position is varied. Some infants continue to resist repositioning and favor a "position of comfort". This position likely relates to the natural asymmetry of the neonatal head secondary to prenatal constraint and the birth process. Despite the best efforts of parents to provide contrasting positions while awake and supervised, many infants will develop craniofacial asymmetry.

There are many causes of positional plagiocephaly including: intra-uterine positioning, prematurity, trauma during the birth process, breech presentation, early descent into the maternal pelvis, congenital disc problems, and congenital muscular torticollis. Before 1990, head shape deformities often resolved after birth, most likely because the infant was in many different positions throughout the course of the day and night. With the Back to Sleep program and the popularity of infant carriers, however, head deformities are less apt to correct without specific intervention(s) because the deforming forces are continuous. In addition, babies that sleep supine do not acquire motor milestones as quickly as prone sleeping babies, and therefore it takes infants longer to learn to roll, sit, creep, crawl, and pull to stand.[9,10] (Refer to Figure 2.) In the first six months of life, the infant skull is very moldable and even a few weeks delay in rolling can have a significant effect on skull shape. In no way should the "Back to Sleep" program be compromised; rather, it is daytime prone positioning that needs to be incorporated into every infant's daily routine.

THERAPEUTIC INTERVENTION

Positional plagiocephaly is associated with congenital muscular torticollis (CMT) and is estimated to occur in about 1 of every 300 live births.[6] CMT is identified by a constriction of one side of the sternocleidomastoid muscle that flexes the head, turns it and laterally rotates the head to one side. When the two conditions occur together, the deformational forces can be quite severe and result in rotational changes in skull and facial bones. When recognized in the first few months of life, parents are taught massage and repositioning techniques that include both passive alignments and active exercises. The infant is monitored closely for symmetry, neck strength, trunk control and range of motion in all directions. Therapy is indicated for moderate to severe torticollis that does not resolve with repositioning and stretching. The physical or occupational therapist teaches the parents how to stretch the sternocleidomastoid, upper trapezius, and the ipsilateral trunk muscles. Developmental exercises, midline weight bearing, and bilateral midline activities are included if the infants display high tone and/or developmental asymmetry.[11] Therapy is often prescribed before, during, and after orthotic management for positional plagiocephaly, and may also include a cervical collar to block lateral flexion to the involved side. If the torticollis is severe and does not resolve with physical therapy, surgery may be considered to lengthen the contracted muscle.

Figure 2. Prone positioning facilitates neck and trunk extension.

ORTHOTIC MANAGEMENT OF POSITIONAL PLAGIOCEPHALY

Repositioning and stretching programs are most effective during the first three to four months of age. If the infant's head has not become more symmetrical during this time, diagnostic tests are undertaken to determine if the deformity is due to craniosynostosis or some other anomaly such as a hemivertebrae. Tests may include an x-ray, magnetic resonance imaging (MRI), or three-dimensional computed tomography (CT scan). If there is no evidence of craniosynostosis, the infant is referred to an orthotist for further evaluation and a cranial remolding orthosis. The cranial remolding orthosis provides total contact over the bossed or prominent areas of the infant's head, and allows space in the flattened areas to provide a pathway for growth to occur. The rapid growth of the infant's brain in the first twelve months of life, and to a lesser extent in the second year, expands and pushes against the plates of the skull in the areas of least resistance (the areas

of space).[6] Consequently, the synergy between the inherent symmetrical brain growth and the skull's natural flexibility and plasticity in these early months creates dynamic correction and improves cranial shape (Figure 3). In some cases, improvement in the alignment of facial structures is also noted.

CONTRAINDICATIONS

Contraindications to cranial remolding orthoses include young infants (under three months of age) who can benefit from intensive repositioning and stretching. Infants with unmanaged hydrocephalus should be stabilized prior to beginning treatment with a cranial orthosis, and infants with craniosynostosis are not candidates for orthotic intervention until the fused suture has been surgically addressed. Young children, older than 18 months, do not benefit as much from cranial remolding orthoses because peak growth periods have already transpired. However, if the deformity is moderate to severe, and there is remolding potential remaining, young children into their second year may still experience some correction.[14]

Photographs courtesy of Lisa Schoenmaker, CPO.

Figure 3. Top row: Before orthotic treatment for positional plagiocephaly. Bottom row: After treatment with a STARband™ cranial remolding orthosis.

INDICATIONS AND TYPES OF HEAD DEFORMATION

Cranial remolding orthoses are now used as the primary treatment method for infants older than 3 months of age with moderate to severe positional plagiocephaly and other skull deformities that have not benefited from repositioning and stretching.[15,16,17,18] Head shapes are classified according to a specific pattern of deformity. The term positional plagiocephaly usually refers to a head shape that has unilateral occipital flattening, anterior progression of the ear, and varying degrees of forehead or frontal bossing—all on the ipsilateral side as the flattening (Figure 4). In effect, the continuous pressure on one side of the cranium causes all the bones on the same side to progress forward—creating asymmetry and sometimes malalignment of the facial structures.

The term (positional) brachycephaly refers to a head shape that is short and wide. The occiput is flattened to a similar degree on both sides, and the dimensions of the width and length are disproportional (Figure 5). Infants with this head shape often have a prominent or bossed forehead and increased cranial vault.[19] Normal anthropometric data for 6-month old infants indicates that the cephalic index (ratio of the cranial width to the cranial length) is about 78%. Infants with brachycephaly often exhibit ratios greater than 85% for girls and 90% for boys (approximately 2 standard deviations above the norms).

Another head shape seen in children with cranial deformities is called scaphocephaly (Figure 6). These infants have a long and narrow head that often develops as a

Figure 4. Child with positional plagiocephaly before and after STARband treatment.

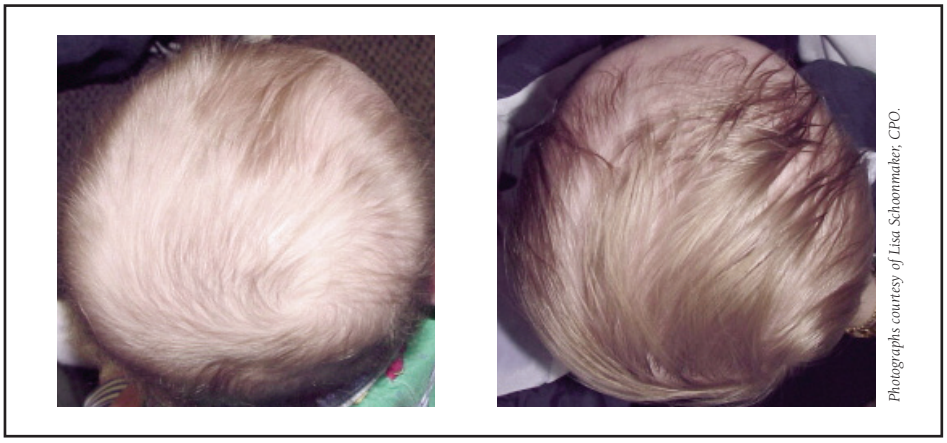

Figure 5. Child with brachycephaly before and after STARband treatment.

result of extended time spent in a side-lying position. Side-lying is the position of choice in neonatal intensive care units due to the need to monitor the infants. The cephalic index in scaphocephalic infants is very low, and the ratio of the cranial width-to-length measurement considered to be normal is significantly less than 78%.[19] Premature infants are particularly vulnerable to the development of this deformity because the cranial structures are even softer than the flexible heads of full term infants. These infants tend to have delayed head control related to their prematurity, and the long narrow head shape places the neck muscles at an additional mechanical disadvantage. Breech positioning will also produce this head shape even with cesarean delivery.

PATIENT EVALUATION PROCEDURE

It is difficult to assess and relate the complexity of cranial deformations simply by viewing x-rays or photographs. A thorough patient history and "hands on" clinical examination of the infant's head, neck, and trunk are required. Relevant history is obtained from the parent, and the infant's head is examined from all angles. Manual examination of the cranial sutures is performed, noting any areas of ridging and/or prominence of the cranial bones. Abnormal soft spots, ear orientation and alignment, facial alignment and symmetry, and head control and positioning should be recorded. Neck tightness or preferential posturing

Figure 6. Infants with a scaphocephalic head shape have difficulty lifting their heads against gravity.

should be referred to therapy for further evaluation and treatment. A minimum of five measurements are obtained which include: (1) head circumference at the equator; (2) right oblique transcranial distance; (3) left oblique transcranial distance; (4) cranial width (Figure 7) and (5) cranial length to calculate the cephalic index. These measurements are repeated at each visit to quantify the structural alignment secondary to the directed translational movements of the cranial bones. Five photographs are also taken that record the frontal view, side views, superior view, and posterior view.

Figure 7. Measuring the cranial width.

Figure 8. Traditional casting procedure to obtain impression of infant's head.

OBTAINING A PLASTER MOLD OF THE INFANT'S HEAD

Traditionally, a plaster impression is taken of the infant that encompasses the entire cranium, forehead, and the sides of the face. Although parents are often concerned about the casting process, it is a safe and simple method of obtaining a custom mold of the infant's head (Figure 8.) The process takes about 20 to 30 minutes, and parents are included in the casting process as much as possible. The mold is then shipped to Orthomerica for modification and fabrication.

STARSCANNER™ NON-CONTACT LASER DATA ACQUISITION SYSTEM

The STARscanner™ is a non-invasive, eye safe, laser data acquisition system that acquires head shape data in 1.5 seconds. The STARscanner™ system was awarded 510(k) clearance from the FDA to be used for the fabrication of Orthomerica's cranial remolding orthoses. This rapid and accurate scanning system eliminates the need for the casting process (Figure 9). Two lasers are mounted into each side of a flatbed scanner and shine a beam of light on the infant's head. Four cameras on each side of the scanner record the laser data, where it is interpreted by the scanner's software. The scans are then e-mailed to Orthomerica where they are carved into a three-dimensional model of the infant's head. A variety of different cranial remolding orthoses can then be fabricated according to the physician and orthotist's specifications.

Figure 9. Scanning an infant's head with the STARscanner™.

MOLD MODIFICATION

A positive model is either made from the plaster impression or carved on the 5-axis carver so that it can be modified depending upon the severity of the condition, design of the orthosis, and protocols of the treating orthotist. A custom thermoplastic cranial orthosis is then fabricated according to the design and manufacturing specifications determined by the 510(k) application and FDA clearance. FDA clearance is mandatory for all cranial remolding orthoses, and helps to ensure that the infant is receiving an orthosis that has passed strict design, labeling, and manufacturing specifications.

CLINICAL DOCUMENTATION

There are several ways to document head shape changes over time. Traditionally, measurements are taken by hand and recorded at each visit. Clinical photographs are taken before and after treatment, and the pre-treatment mold of the infant's head can be compared to the infant's head at the end of treatment. It can be challenging to acquire consistent measurements taken in the same location each time on an active, awake infant.

The STARscanner™ can be used more reliably to acquire head shape data and document change over time. The infant is scanned with a stockinette over the hair and ears to eliminate extraneous data. Markers are placed on anatomical landmarks to create an anthropometric reference for future comparisons. From these landmarks, a plane is defined based on an anatomical coordinate reference. Twelve cross sections with scaled spacing are constructed. Any cross section can be displayed on the screen in full or partial scale and can be printed out with measurements of the area and arc angles for each quadrant of the cross section. Quadrant volumes are also calculated between two cross-sectional slices. The orthotist can also cursor-pick any two points on the drawing and the software will measure the line that is formed. Another screen provides a circumference, cranial width, and cranial length measurement for each cross section.

In addition, the STARscanner™ has software that allows two scans to be overlaid and compared by matching the anatomical landmark-based reference frame (Figure 10). This utility program allows the practitioner to compare the measurements of

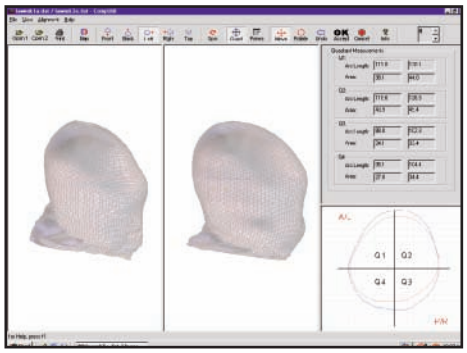

Figure 10. Evaluation of before and after scans with the comparison utility program.

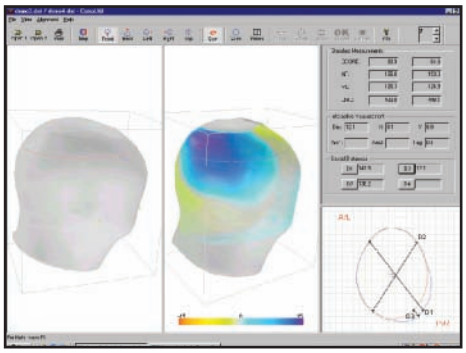

Figure 11. STARscanner™ color map provides a visual representation of change.

the first and successive scans side by side, in addition to providing views of both 3-D images on the screen from every angle. Another component of the comparison utility produces a color representation of changes that have occurred in the head shape throughout the treatment program (Figure 11). The STARscanner provides printed documentation to parents, physicians, and third party payers regarding the need or the efficacy of treatment. It is a valuable research tool and is used to study and document untreated positional plagiocephaly, and many other topics pertinent to infants with cranial and facial deformities.

CRANIAL REMOLDING DESIGNS

The design and application of a cranial remolding orthosis does not alter the magnitude of intrinsic brain growth but merely its direction.[16,20] Symmetrical growth is directed by consistent evaluation and adjustment of the orthosis based upon the infant's head shape and growth pattern. Many different orthotic designs have been developed over the last twenty years to effectively address this patient population. Whether the design is active or passive in nature, rigid or flexible, hinged or circumferential, the basic principle of all cranial remolding orthoses is to create a pathway for symmetrical growth to occur.

STARBAND™ CRANIAL REMOLDING ORTHOSIS

The STARband™ uses a 3/16" copolymer plastic to provide a rigid framework with 1/2" foam interface. This design allows the orthotist to provide ongoing modifications to the band as the infant's head begins to fill into the previously flattened areas. Data presented by Children's Healthcare of Atlanta in April, 2002 at the Association of Children's Prosthetic and Orthotic Clinics and at the American Cleft Palate and Cranial Association meeting in May, 2002 illustrates the effectiveness of the STARband™ design for promoting symmetry (Table 1).

The cranial vault asymmetry index (CVAI) [22] is determined by comparing the right and left oblique transcranial measurements relative to a 30 degree deviation from midline. Perfect symmetry would be calculated as zero. Table 1 reports the initial and end CVAI for a group of infants diagnosed with positional plagiocephaly and treated with the STARband cranial remolding orthosis. Ten subjects completed this study. Mild, moderate and severe classifications were awarded based upon 0–4%, 4–7%, and greater than 7% asymmetry, respectively. Results of treatment are shown in the table and record significant improvements in overall symmetry with use of the STARband cranial remolding orthosis.

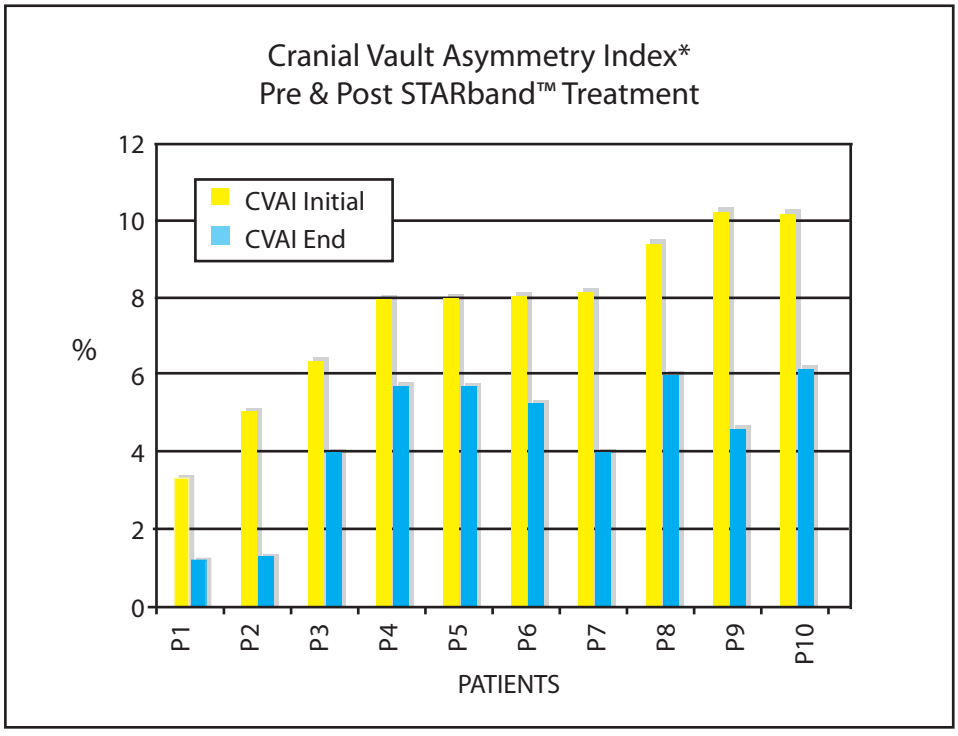

Table 1. Quantification of the efficacy of the STARband treatment program.
**Cranial Vault Asymmetry Index (CVAI) based on Loveday and de Chalain, 2001[22].*

Currently, there are 75 patients enrolled in this initial study and further data collection and analysis are being continued. The average length of treatment for this group was two months, and most of the infants receiving treatment fall in the moderate to severe CVAI classification. Ninety percent (90%) of parents involved in the study reported that they preferred the scanning process over the casting process as a way to minimize stress to their infant and to document quantitative changes and progress. The STARband and the STARscanner were found to be extremely efficient and cost-effective clinical tools in the treatment of positional plagiocephaly.

These preliminary results are part of a long-term study on the use of the STARscanner laser data acquisition system to document head shape changes in infants with positional plagiocephaly. Data relating to head shape change in infants with brachycephaly and scaphocephaly is also being collected, as well as the natural progression of untreated plagiocephaly. Previous studies have compared orthotic management to infants treated by repositioning alone, but no study has compared these two treatment modalities with infants that have the same degree of asymmetry and severity.[15,21,22,23,24,25]

STARLIGHT™ CRANIAL REMOLDING ORTHOSIS

The STARlight™ cranial remolding orthosis (Figure 12) is made of clear plastic and has been successfully used for the treatment of positional plagiocephaly. The clarity of the plastic allows visual inspection, and assures that the areas of void and contact are strategically placed

Figure 12. The STARlight™ cranial remolding orthosis is made of clear plastic.

for optimal results. The bi-valve design is especially indicated for scaphocephalic head shapes that benefit from anterior and posterior directed forces. Infants experiencing skin reactions to the foam liners of other designs seem to acclimate to the clear band styles well. Orthomerica received FDA clearance for the STARlight™ cranial remolding orthosis in July 2002.

THE CLARREN HELMET

The Clarren Helmet has been continuously used in practice since it was first developed by Dr. Clarren over 23 years ago. This design includes a chin-strap, is easy to apply, and is modified to accommodate projected head growth. This growth allowance provides a clinical "end point" to treatment that is finalized when the infant grows into the symmetrical helmet shape.[6]

CONCLUSION

The outcomes of orthotic treatment are dependent upon a definitive diagnosis, available brain/cranial growth, the age of the infant at the beginning of treatment, and compliance with the treatment protocols. (Figure 13) Cranial remolding orthoses for infants with positional plagiocephaly and other head shape deformation patterns use the rapid period of infant brain growth, particularly in the first year, to create greater facial, cranial, and core symmetry. Therapy and orthotic treatment can improve the infant's cranial alignment and shape, visual tracking, overall postural alignment, and provide a more symmetrical head position for acquiring developmental skills. Early intervention, team networking, and consistent care are the key components of an effective treatment program with measurable outcomes. ■

Figure 13. Cranial remolding orthoses are worn 23 hours per day to obtain optimal results.

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