Orthotic Management with Helmet therapy for Infants with Positional Plagiocephaly and Other Head Shape Deformities

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Cranial Anatomy

• Unossified membranous connections accommodate the brain’s growth and expansion during the first years of life.

Cranial Anatomy (Dobson, 1994)

• Fontanels (soft spots) are present at every junction of the two parietal bones and the other skull bones
• Largest anterior fontanel closes at 24 months
• Other fontanels close by 1 year
• The fontanels and the un-fused sutures allow the brain to grow and the skull to expand.
COMMON HEAD SHAPE DEFORMITIES

Plagiocephaly
(Plagiocephaly (mild))
Plagiocephaly
(mod to severe)
Brachycephaly
Scaphocephaly

Positional Plagiocephaly

<table>
<thead>
<tr>
<th>Positional Plagiocephaly</th>
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</thead>
<tbody>
<tr>
<td>Ear on affected side is pushed forward toward the face.</td>
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<tr>
<td>Compensatory bossing or bulging of the forehead on the side of the posterior flattening.</td>
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<tr>
<td>Head is shaped like a parallelogram (i.e. a crooked rectangle).</td>
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Causes of Positional Plagiocephaly

• More common in multiple births.
• Less intrauterine space.
• Soft, malleable skulls.

Causes of Positional Plagiocephaly

Positional Molding

- Right occipital flattening
- Right forehead bossing
- Right ear moves forward
- Left occipital bossing
- Left forehead flattening
- Facial asymmetry

Causes of Positional Plagiocephaly

• Congenital disk malformation
Causes of Positional Plagiocephaly

- Birth trauma
- Skull is moldable due to open sutures
- Shape should improve within six weeks

Causes of Positional Plagiocephaly

- Congenital muscular torticollis

Brachycephaly

- Bilateral occipital flattening
- Frontal bossing
- High cranial vault
- Width of head is greater than 85% of the length and may exceed 100%
Scaphocephaly
- Long, narrow head shape
- Prevalent in infants with sagittal synostosis and NICU babies due to side-lying position
- Width of head is less than 75% of the length
- Infant's neck muscles have difficult time extending the head due to head shape

“Back to Sleep” Program
- About 1 in 100* babies develop positional plagiocephaly
- Positional plagiocephaly has increased since the “Back to Sleep” program began in 1992
- Increase also corresponds to introduction of convertible infant carriers

(*Estimates of actual incidence vary greatly.)

40% Drop In SIDS

SIDS Rate and Sleep Position, 1985-97 (deaths per 1,000 live births)
Diagnosis of Positional Plagiocephaly

These heads used to “shape up” on their own. Why don’t they do that anymore?

- Infants in the first 6 months in the United States spend very little time in prone so they have little opportunity to stretch neck extensors.
- Infants sleep all night in supine
- Infants spend excessive time in infant carriers during the day
- Supine sleeping infants roll later than prone sleeping infants so they are unable to reposition themselves in the early months of life.

Sustained Supine Positioning
Sustained positioning

• ...a necessity for any parent on the go, this stroller allows you to transport baby without the hassle of removing child from infant carrier...
• The infant not only has constant force on the posterior aspect of the head-- it is exactly the same posterior force and angle all day.

Who thought about reshaping a head?

Intentional Cranial Deformation

Definition:
- The product of the dynamic distortion of the normal vectors of infantile neurocranial growth through the agency of externally applied forces.
Intentional Cranial Deformation

- Zaire. Mother and child whose skulls have been shaped with twisted liana.

In the Beginning ...

- From Dr. Clarren's original paper in 1979:
  - Four-month old infant:
    - Torticollis.
    - Positional plagiocephaly.
  - Origin of the development of the cranial remolding orthosis.

Infant Head Molding

- Original helmet made with fiberglass and plastazote lining.
- Rubber straps maintained head position.
  - Torticollis resolved in seven to ten days.
- Orthotic treatment program persisted, but torticollis treatment was dropped due to non-compliance
Cranial Remolding Orthosis

• Application of an external remolding orthosis does not alter the magnitude of the intrinsic growth but only its direction.

Pollack et al., 1997

• Infants with a molding helmet had a significantly greater decrease \((p < 0.001)\) in posterior cranial asymmetry than did infants treated by positioning alone.

Mulliken et al., 1999

Principals of Orthotic Intervention for Positional Plagiocephaly

• Provide total contact in the areas where growth is to be curbed.
• Allow space in the areas where growth is desired, (redirectional growth)
• There is a critical window of opportunity, specifically between 4-12 months of age, when the head is actively growing.
• The symmetrical helmet creates a pathway for growth to occur.
• Infants between 4 and 7 months generally complete treatment in 4 months or less. Older infants take longer to acquire improved symmetry.
Helmet Redirectional Forces

- To provide total contact in the areas where growth is to be curbed and to redirect growth to open areas in the helmet where growth is desired.
- Daily follow up by parents on skin condition and weekly by practitioners for growth, allow the helmet to be modified for proper fit and head correction.

Orthotic Treatment Components

- Non-synostotic positional plagiocephaly
  - Diagnosed with x-ray, CT, and/or MRI to rule out craniosynostosis
- Uniform growth
  - Brain determines size and shape of cranium.
- Maximum growth
  - Treatment is most effective when the head is actively growing
  - 4-7 months is ideal timing
  - Children can be treated up to 18 months
- Compliance
  - 23 hours per day.

Contraindications

- Craniosynostosis
  - STARband can be used post-operatively as an adjunct to surgery.
- Hydrocephalus
  - STARband can be used post-operatively with special care taken to prevent occlusion of the shunt.
- Children younger than three months
  - Aggressive repositioning efforts are recommended.
- Children older than eighteen months
  - Case by case assessment, minimal change expected.
Craniosynostosis

- A premature fusion of the cranial suture(s) resulting in disproportionate growth of the cranial bones and as a sequence the growth of the facial bones are also involved
- Cranial orthoses are contraindicated until the fusion is released. Post-operatively, the orthosis can be used as either a remolding or protective orthosis.

Ruling out Craniosynostosis

- Visual and hands-on screening
- X-ray is a good initial screening tool
- 3-D CT scan is most definitive but even this can be difficult to interpret
- If head shape does not improve with a cranial remolding orthosis, child should be referred to the physician
- If head growth is limited or head shape gets worse with orthotic treatment, refer to a physician

EVALUATION

AND EDUCATION !!
Visual and Hands-On Assessment by referring physician

- Infant should be viewed from the top, front, both sides, and back
- Neck range of motion should be evaluated if plagiocephaly is present
- Stretching, massage, repositioning, and developmental therapy program should be considered

Refer for physical therapy

- Therapist can measure and assess neck tightness
- Developmental evaluation and treatment
- Therapist can work toward improving upper extremity, trunk, and lower extremity symmetry
- Develop and teach home repositioning and stretching program to caretakers

Alternate positioning when awake and supervised
Stretching Exercises for the Sternocleidomastoid Muscle

• POSITIONING – Right side tightness.

Stretching Exercises for the Sternocleidomastoid Muscle

• CARRYING – Right side tightness.

“Tummy Time”
Growth

- Head circumference-for-age
  - Boys
  - Girls
- Normal infants do not acquire significant head control until about 12 weeks of age.
- Infants benefit most when they have orthotic treatment during a period of active growth.
- Ideally treatment is complete by 12 months but some correction is possible up to 18 months (corrected age).

Who should get referred for a Cranial Remolding Orthosis

- **Plagiocephaly**
  - Mild: Posterior quadrant involvement. Minimal ear shift (Refer for baseline)
  - Moderate: Posterior quadrant involvement and ear shift (REFERRAL)
  - Severe: Posterior quadrant involvement, ear shift, and forehead involvement (REFERRAL)

- **Brachycephaly**
  - Moderate: Max 95% M-L to A-P
  - Severe: 96% or more M-L to A-P ratio

Refer moderate and severe infants

Scaphocephaly and Brachycephaly

- These cranial deformities are related to disproportion rather than to asymmetry.
- Cephalic ratio is most significant measure.
- Scans can be augmented by clinical photographs.
### Means for Cephalic Index

<table>
<thead>
<tr>
<th></th>
<th>Age</th>
<th>-2SD</th>
<th>-1SD</th>
<th>Mean</th>
<th>+1SD</th>
<th>+2SD</th>
</tr>
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<tbody>
<tr>
<td><strong>Male</strong></td>
<td>16 days to 6 months</td>
<td>63.7</td>
<td>68.7</td>
<td>73.7</td>
<td>78.7</td>
<td>83.7</td>
</tr>
<tr>
<td></td>
<td>6-12 months</td>
<td>64.8</td>
<td>71.4</td>
<td>78.0</td>
<td>84.6</td>
<td>91.2</td>
</tr>
<tr>
<td><strong>Female</strong></td>
<td>16 days to 6 months</td>
<td>63.9</td>
<td>68.6</td>
<td>73.3</td>
<td>78.0</td>
<td>82.7</td>
</tr>
<tr>
<td></td>
<td>6-12 months</td>
<td>68.5</td>
<td>74.0</td>
<td>78.5</td>
<td>83.0</td>
<td>87.5</td>
</tr>
</tbody>
</table>

Check the baby’s head shape from all sides! Deformity may not be obvious in the frontal view!

High cranial vault and poor neck extensor muscles.
Broad face, asymmetry through the eyes and ears, and high cranial vault.

Left posterior flattening

Referral for a STARband or STARlight Cranial Remolding Orthosis

- Orthotic Consultation
  - The child is referred to the orthotist through a pediatrician, pediatric orthopedist, cranial-facial neurosurgeon, plastic surgeon, physiatrist or other physician
  - The orthotist takes pictures/scan during this initial physical/visual evaluation.
  - Orthotist records progress and shares the information with caregivers and the medical team
Parameters for helmet therapy

- Children's hospital of Atlanta

Parents commitment

- It is a commitment by the parents to participate in helmet therapy
- Easiest part of helmet therapy is that the child will not remember ever wearing the helmet
- The hardest part of helmet therapy is the social stigma attached to a parent of a child wearing a helmet

Orthotic Evaluation

- Measurements
- Pictures
- Scanning
- Peer development milestones
- Neuromuscular milestones
Head Measurements

- Measurements part of the indicators of helmet therapy
- Note eye asymmetry
- Circumference measurement taken just above the eyebrows at the equator.

Head Measurements

- Cranial Index is the relationship between the width and length of the skull
- Find the widest width of the skull (eurion to eurion)
- Find the longest length of the skull (glabella to opisthocranium)
- Divide the width by the length to get the cranial index or ratio.

Head Measurements

- Cranial vault measurements are difficult to reproduce at the same point each time.
- From lateral edge of each eyebrow, measure on a diagonal to the longest and shortest point.
- Subtract the difference to get the cranial vault asymmetry.
- This measurement will not be significant for infants who are disproportional rather than asymmetrical.
Head Measurements

- Width
- Circumference
- Cranial vault

Cephalic or cranial index is the maximum width of the head divided by the maximum length.

STARscanner

- Non contact laser scanner
- Scan takes 1.5 seconds
- Complete documentation
- Comparison Utility Program shows head shape changes over time
- FDA 510K Clearance
THE STARscanner DATA ACQUISITION SYSTEM

- Completely replaces the casting process
- Eliminates hand measurements
- Scan is completed in 1.5 seconds
- Provides a three dimensional image of the child's head

STARscanner

- Eye safe laser requires no eye protection
- It is a Class 1 Laser - similar to the lasers used to read grocery store barcodes
- Two lasers on each side shine a flat beam to make a line of light around the surface of the head shape
- Four cameras on each side of the scanner record the surface data

Ease of Documentation

- Documents measurements in 1.5 seconds.
- Calculates cephalic ratio from skull width and length measurements at every scan.
- Overlay demonstrates area of growth visually.
Reporting

- Provides clear reports for inclusion into chart notes
- Can be included with letter to referring physician, healthcare team members, and insurance companies.

Comparison Utility Program

- Allows two scans to be overlaid and compared
- Provides potential for comparison at 12 different cross sections
- Allows self-selected measurements at two different locations

3-Dimensional Visual Comparisons

- Compares two scans and calculates differences
- Vertex, right and left sagittal views, posterior and frontal views available
FDA 510(k) Clearance Requires

- Specific controls documenting skin biocompatibility testing requirements.
- Labeling stipulations.
- Clinician/parent instructions.
- Bench study or clinical study
- Storage of molds or electronic scan for 2 years or longer.

Acquiring head shape data with the STARscanner

- Data acquisition for acquiring head shape depends on areas of mass data like differences between color (ex. Hair, ear holes etc)
- The use of a white stocking to cover the head distinguishes the differences between areas of high data.

Acquiring head shape data with the STARscanner

- The use of the stocking on the child's head illustrates the true shape of the head without hair interference
Acquiring head shape data with the STARscanner

- The use of a Tragion stickers sets the parameters of the head measurement for a baseline shape and for comparison shapes in the future.

Acquiring head shape data with the STARscanner

- The STARscanner is an open air stand alone device which allow the child to just lay on his back in the sight of the parents without any external restraining forces.

Acquiring head shape data with the STARscanner

- The scan takes less than 2 seconds with no other information needed.
- Scan can be taken with the child on a pacifier or taking a bottle.
- It is just like taking a picture.
Acquiring head shape data with the STARscanner

- If the first scan does not capture the data the scanner can be reset without the child be moved or bothered in any way.

Scanner Video

Helmet Therapy

- There are many factors in prescribing a cranial remolding orthosis for helmet therapy
  - Age
  - Visual asymmetry of the head shape and face
  - Cephalic ratio/index deviations
  - Radial symmetry index
  - Cranial vault asymmetry
  - Anterior and posterior symmetry ratio deviations
  - Orbitotrigial depth
Acquiring the head shape model

Traditional Casting Process
- To obtain a model of the child's head traditional casting of the child's head is done.
- Casting maybe messy and can be upsetting for the infant and parent but it is safe and time-limited.
- Documentation of treatment is achieved by visually comparing the mold to the head at each appointment and by taking measurements by hand.

Preparation for casting:
- “Poncho” made of stockinette.
- Helps to keep the baby warm and clean.
- Caregiver also needs cover as they will be “helping”.

Traditional method of taking an impression of the infant's head
Mark eyebrows, midline, ears
Stacks 1, 2, and 3 in place

Stack 4—lay across the top of the head. Add parting agent around the entire posterior opening as a separator.
The sub-occipital area is well molded into the impression.
Crosshatch and Remove

Finished cast!
Scanning for helmet

- If the child has already been scanned for the evaluation and parents want to participate in helmet therapy then the evaluation scan can be used for helmet fabrication.

Scanning for helmet

- If insurance authorization is needed after the evaluation scan then a follow up scan is needed for helmet fabrication, scans are only used for fabrication if they are less than 48 hours old.

Scanning for helmet

- For the model the stocking is placed on the head.
- The Tragion stickers are applied to the head.
- The child is placed in the STARscanner.
Scanning for helmet

- Less than 2 seconds the image is acquired without any hassles
- Everything is done!

Cast modification/ fabrication

- Once the scan is done a model is fabricated to the original shape of the child's head by a Computer Aided Machine (CAM)

Cast modification/ fabrication

- The cast is modified for symmetry and growth
- 2 cm of circumferential growth is added to the model
- Unilateral or multiple areas symmetry modification are done to the mold
Mold is modified to greater symmetry

- Areas of bossing and flattening are noted.
- Head is divided into quadrants.
- Plaster is added to fill in the areas of flattening.
- No material is removed from areas of bossing.

STARFamily of Cranial Remolding Orthoses

- STARlight Bi-Valve
- STARlight Side-Opening
- STARlight Cap

- STARband
- Clarren Helmet

STARband™

- Cleared by the FDA in July of 2000
- Available to certified orthotists
- Patients can be fit in their own community
- Treatment usually lasts 12-16 weeks with follow up
STARband

• Single side opening cranial remolding orthosis
• It is hard on the outside and soft on the inside
• It uses a closed cell hypoallergic foam on the inside that does not absorb water

STARband

• You cannot make the orthosis too tight, it has a foam spacer to limit over tightening
• Lateral “side burns” help control rotation of the orthosis

Bivalve STARband

• Same materials as the STARband
• For anterior/posterior control and reshaping of the head
• Single posterior strap
Bivalve STARband

- Able to separate the two parts for easier helmet modification
- For anterior and posterior control to redirect growth medially and laterally

STARlite

- Clear single side opening cranial remolding orthosis
- Lighter in weight than the STARband
- Easier to clean
- Can visually see any skin irritation

Fitting Procedures

- The STARband is designed to be a dynamic and progressive orthotic system.
- Requires specific adjustments over critical time periods to achieve desired results.
- Initial fit encourages symmetrical molding
- Follow-up adjustments involve the removal of liner material or recontouring the plastic to promote growth in desired areas and accommodate circumferential increases and head shape changes
Success depends on 23 hour per day compliance and excellent patient management.

Wear and care of the orthosis

- Check the skin throughout the day
- Redness that disappears in 15 minutes is to be expected
- Redness longer than that time, the orthotist should be contacted

Wear and care of the orthosis

- Wash the child’s hair daily
- Use the same soap that you wash the child’s hair to wash the helmet
- Rinse well; it is usually the soap residue that irritates the skin or a change of the soap
Wear and care of the orthosis

- Helmet can smell so keep it clean!
- Use alcohol if additional cleaning is needed
- With skin irritations ointment can be use like diaper rash ointments (examples A&D, balmex, aquaphor, destin clear, Healthy babies, etc.)
- Do not use gasoline, acetone, toothpaste, baking soda to clean the helmet…No Powders!

Appointment protocol

- Initial evaluation which includes pictures, measurements and scan
- Fitting of the helmet
- One week follow up
- Two week follow up
- Rescanning for comparisons 6-8 weeks

Length of treatment

- Minimum of 3-4 months depending on growth, age and skull maturity
- Reaching bilateral peer development with motor skills
- Statistical correction stated from the scan reports
- Parents approval of child’s head shape
Visual Comparisons

- With the aide of the scanner comparison reports are generated for outcome studies
- Here is a sequence from start to finish of the actual head shape

Follow Up Is Essential for Great Outcomes

Thank You For Your Attention!

For more information contact:
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