

Caregiver's Guide

For the Treatment of
Deformational Plagiocephaly
& Other Head Shape
Deformities



My baby has been diagnosed with Deformational Plagiocephaly.



What is Deformational Plagiocephaly?

Deformational Plagiocephaly is an abnormal shape of a baby's head caused by external forces. The baby's head may appear to be misshapen or asymmetrical immediately after birth, or the abnormal shape may become noticeable in the first few months of life. Parents, grandparents, and caregivers are often the first ones to notice the unusual shape of the head and they usually bring it to the Pediatrician's attention during a regular visit.

What causes Deformational Plagiocephaly?

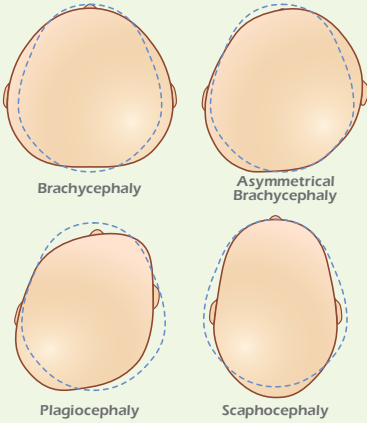
There are several causes of Deformational Plagiocephaly, and some of them occur before the baby is even born. Restricted space inside the mother's womb can create excessive contact in certain areas of the baby's head. This is often the cause of deformation in babies positioned in a breech position, cramped in utero due to multiple fetuses, or in babies who spend excessive time with the head confined in the birth canal. Suction or vacuum instruments can also create forces that can deform the newborn skull, which is soft and pliable. The skulls of premature

babies are particularly susceptible to deformation because the bone is thinner and more fragile than the skull of full term babies.

The skull is made up of several plates with fibrous sutures between them. This allows the skull plates to slide over each other to ease the passage of the baby's head through the birth canal. Usually, the baby's head becomes more symmetrical and better proportioned within about 6 weeks after birth if the deforming forces are no longer present. However, the flattened areas may not resolve if the baby's head continuously rests in the same position. This is particularly problematic if the baby has neck tightness at birth.

What other kinds of head shape deformities are seen?

Deformational Brachycephaly is present when the entire back of the baby's head is flat (central flattening) and the head is very wide. The forehead is often bossed or prominent on both sides and the height of the head is excessively high. In our experience, Deformational (symmetrical) Brachycephaly accounts for about 1 in 10 of the children referred for treatment.



Often babies with this problem have a history of excessive time in carriers, possibly due to gastric reflux or other medical conditions or circumstances that do not allow the baby to be placed on the tummy. Orthotic management attempts to correct the disproportion of the head shape and the associated deformities.

Asymmetrical Brachycephaly is a common type of Brachycephaly where the head is excessively wide and is also asymmetrical. Of the scans sent to Orthomerica for STARband fabrication, Asymmetrical Brachycephaly is second only to Deformational Plagiocephaly in incidence. Orthotic management focuses on improving both symmetry and the disproportion of the baby's head.

Deformational Scaphocephaly is characterized by a long and narrow head shape, sometimes caused by consistent positioning of the baby on his or her side. Like Symmetrical Brachycephaly, Scaphocephaly is mainly a deformity of proportion although the elongated shape can also produce abnormal frontal and posterior changes in the head.

Premature babies are particularly prone to Scaphocephaly because a side-lying position is often used in the Neonatal Intensive Care Unit (NICU) for easy access to monitors and other equipment. Orthotic management focuses on normalizing the proportion and overall shape of the head.

Are there other causes of head shape deformities?



Yes, another leading cause of abnormal head shapes in young babies is neck tightness caused by congenital muscular Torticollis or neck/trunk muscle

imbalance. Torticollis is usually caused by an imbalance in the sternocleidomastoid and other neck muscles, which prevents full range of motion in the neck. It is estimated that about 85% of the babies with Deformational Plagiocephaly also have some kind of neck involvement.⁷ Typically, the head of a baby with Torticollis is tipped to one side and rotated to the opposite shoulder, causing the head to consistently rest in the same position. The constant positioning of the head to the same side causes the head to become flat in the back. Torticollis can also pull abnormally on the base of the skull and cause the ear on the same side of the posterior flattening to be pushed forward. In severe cases, the forehead can also be pushed forward on the same side, and the facial features including the eyes, cheeks and jaw may not be symmetrical.



Another postnatal cause of abnormal head shapes occurs when the back of the baby's head rests for prolonged periods of time against a hard surface like an infant carrier, car seat, swing or stroller. Before 1992, babies were put to sleep on their tummies, which varied the amount of force on the back of the head. Since the American Academy of Pediatrics initiated the Back to Sleep Program in an effort to end Sudden Infant Death Syndrome (SIDS), babies now spend all night on their backs until they are able to roll and reposition themselves.² Unfortunately, the combination of the carriers we use to hold and position our babies during the day, and placing them to sleep on their backs all night has led to an increase in head shape deformities. It is very encouraging to note that the "Back to Sleep" Program has reduced the incidence of SIDS by 40%, so it is important to follow the regime of putting your baby to sleep on his or her back.² The best way to reduce the potential for head shape problems is to increase



the time your baby spends on his or her tummy during the day while the baby is awake and supervised.

What can I do if my baby has an unusual head shape?

The first thing you can do is talk to your Pediatrician about your baby's head. The American Academy of Pediatrics (AAP) suggests that Pediatricians evaluate the baby's head at each visit from the top, sides, front and back. The AAP also recommends that the physician talk to families about how to move the

baby into a lot of different positions

during the day, and stress the importance of "tummy"

time whenever the baby is awake and supervised.²

Tummy time is not only a good way to take pressure off the flattened areas, it also helps to build strong neck and trunk muscles and will help your baby learn to roll, sit, and crawl as they grow. If there

is neck muscle imbalance or a delay in development, your Pediatrician may refer your baby to a Therapist for physical or occupational therapy. The Pediatrician may also recommend that a Pediatric Craniofacial or Plastic Surgeon assess your baby's head shape to ensure that the sutures are all open and to check for any other skull shape disorders. The specialist will examine your baby and may order an X-ray, CT scan or MRI. These tests rule out the possibility of Craniosynostosis, which is a premature fusion of the sutures in the head and is much less common than Deformational Plagiocephaly.

Craniosynostosis can cause head shape deformities similar to the abnormal head shapes caused by deformation and may require surgery to remove the suture. After surgery, the physician may order a STAR Cranial Remolding Orthosis to provide additional correction of the head shape and protection of the incision site. When a STAR Cranial Remolding Orthosis is used after surgery, the same principles are used to correct the head shape as those used for babies with deformational head shape problems. Total contact is maintained over areas of bossing or prominence, and space is provided inside the orthosis in the areas where growth is desired to create a symmetrical and well proportioned head shape.

If your baby is diagnosed with Deformational Plagiocephaly, Brachycephaly or Scaphocephaly and is between the ages of 3 and 18 months, your pediatrician or specialist may refer you to a practitioner who specializes in providing STAR Cranial Remolding Orthoses. The STAR Orthosis is a plastic and foam or clear plastic, custom molded device designed to gently correct your baby's head shape.

How do STAR Cranial Remolding Orthoses work?

The STAR Cranial Remolding Orthoses redirect head growth to improve proportion and symmetry. They derive their name from their purpose — *Symmetry Through Active Remolding*. Cranial remolding orthoses are designed to provide total contact over the prominent or bossed areas of the baby's head to discourage additional

growth there. The orthosis is modified frequently to encourage growth in the areas of the head that are flat or depressed. The orthosis functions by creating a precise pathway to direct the baby's rapid head growth. The practitioner evaluates and adjusts the orthosis, precisely guiding growth, throughout the baby's entire orthotic treatment program.

What happens at the first STAR Cranial Remolding Orthosis visit?



The practitioner will review the physician's prescription or referral, conduct a thorough evaluation, talk to you about your baby's history and discuss the orthotic treatment program. In most cases, the practitioner will also take clinical photographs and a series of measurements with a caliper. Pictures will document your baby's head shape at the beginning of treatment and will serve as a reference throughout the entire treatment program. If you have an insurance plan that requires prior authorization, you may be asked to schedule a return appointment when the paperwork is complete. If you are ready to begin the process immediately, the practitioner will make a duplicate of your baby's head from a plaster impression or a

3D scan. Then an orthosis will be precisely fabricated to make your baby's head more symmetrical and well-proportioned.

What is the casting process like?

The casting process takes about 15 – 30 minutes and you can stay with your baby the entire time. This procedure is not harmful or painful, although your baby may get fussy during the process. A cotton



stockinet is placed over the baby's head with an opening for the face. A series of plaster strips are applied from the eyebrows to the base of the neck, along the sides of the head covering the ears and along the sides of the face. It is helpful to bring a bottle, music, favorite toy, or even another person to help distract your baby during the casting process. It may also be comforting for the baby to use a towel and soap that you can bring from home to wash up after the procedure. When an accurate cast has been obtained, the plaster cast is removed, packed carefully, and sent to Orthomerica for fabrication.

What is the STARscanner™ Laser Data Acquisition System?

The STARscanner is an eye-safe, Class 1 laser scanning system that allows the practitioner to scan the baby's head in 1.5 seconds, instead of casting the head. The STARscanner captures detailed head



shape information in a three-dimensional scan that is emailed immediately to Orthomerica for fabrication of a STAR Cranial Remolding Orthosis. The STARscanner Laser Data Acquisition System is one of the safest kinds of Class 1 laser systems available to acquire the scan of your baby's head. It is also the most comprehensive data acquisition system with software specifically designed to capture 3-D data that can be viewed in multiple planes.

What happens next if my baby gets a STAR Cranial Remolding Orthosis?

Your baby will be fit with the orthosis within two weeks of the casting or scanning date. You will be taught to monitor your baby's skin closely as he or she adjusts to wearing the orthosis. Within about five days of the fitting, your baby will progress to wearing the orthosis 23 hours with one hour off for bathing, skin checks, and cleaning each day. About a week later, you will see your practitioner to evaluate the fit and to address any questions you may have. The frequency of follow up visits is dependent on your baby's age, unique head shape and response to the STAR Cranial Remolding

Orthosis. At each appointment, the practitioner will check the baby's skin, fit, and function of the orthosis.

At follow-up visits, the practitioner will make any modifications necessary to gently reshape your baby's head into a more symmetrical and well proportioned shape. You are encouraged to contact your practitioner immediately if you have concerns or feel that your baby needs an adjustment before the next scheduled appointment.

How long will my baby wear a STAR Cranial Remolding Orthosis?

Most babies wear a STAR Cranial Remolding Orthosis less than 4½ months if they begin treatment prior to 8 months of age. Research indicates that babies treated with cranial remolding orthoses who are older than 8 months tend to have less correction in the shape; however there is still significant improvement compared to the original head shape.³ Although early intervention is optimal, orthotic treatment can still be successful up to about 18 months of age, at which time the slowing of head growth and thickening of the skull make the head more resistant to change.

How will I know when my baby is done with treatment?

The practitioner will document your baby's head shape throughout the treatment program with measurements, or clinical pictures. Periodically, the documentation will be compared to the original measurements and pictures



Before STARband Treatment



After STARband Treatment

to see what progress has been made. Typically, the decision to discontinue treatment is made at the time the baby starts to outgrow the band. At that time, the caregivers, physician, and other professionals will check the progress and decide if the band has corrected the head shape to a point where continued treatment is no longer necessary.

How can I get a STAR Cranial Remolding Orthosis for my baby?

Your Pediatrician or specialist can write a prescription for a STAR Cranial Remolding Orthosis. You can take this prescription to a practitioner who provides STAR Cranial Remolding Orthoses in your community. Visit the web site www.starbandkids.com to find a STARscanner location near you.



Will my insurance pay for the orthosis?

In most insurance policies, cranial remolding orthoses fall under the category of orthotics and prosthetics. This category is typically listed under “Durable Medical Equipment” (DME) in most insurance plans. Check with your insurance company to determine whether your policy includes this coverage. Some carriers will pay for the orthosis if measurements show that the baby's head has a moderate-to-severe deformity and if your physician writes a letter stating that a custom cranial remolding orthosis is medically necessary. This letter may also specify whether the deformity was present at birth and/or highlight potential problems that might occur if the problem is not treated during the first 18 months, while the skull is rapidly growing. Present or potential issues documented in the research of babies with head shape deformities include visual tracking



problems,⁴ mandibular asymmetry,⁵ auditory threshold insufficiency,⁶ and developmental delays.^{7,8,9} If your insurance policy covers cranial remolding orthoses, you may be required to use a preferred provider. Many orthotic and prosthetic facilities have contracts with managed care companies and provide services for orthotics, prosthetics, and DME. If your policy does not cover these orthoses, you may want to discuss a payment plan with the orthotic facility you choose for your baby's treatment program.

What role does the orthotist play on the craniofacial team?

Credentialed orthotists and prosthetic practitioners have provided cranial remolding orthoses since 1979. These health care professionals maintain high standards of continuing education through national certifying bodies and many have specialized pediatric orthotic

practices. These practitioners bring value to the orthotic treatment program with a strong background in anatomy, biomechanics, material science and patient care. They work closely with other craniofacial team members to help your baby achieve optimal correction and results.

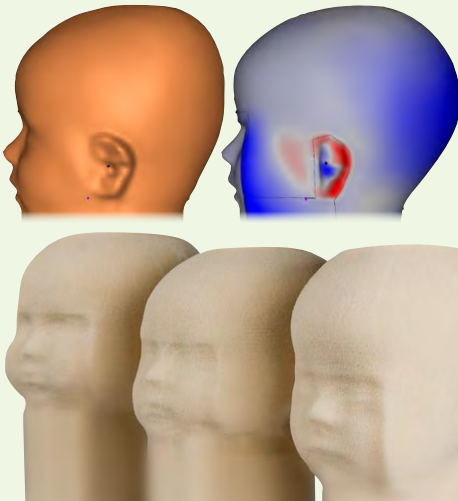
Who manufactures STAR Cranial Remolding Orthoses?

Orthomerica Products, Inc. manufactures several unique FDA cleared remolding designs, including STARband & STARlight Cranial Remolding Orthoses. Our goal is to provide quality educational and support services to the practitioners, therapists, physicians and caregivers who treat babies with cranial abnormalities. Orthomerica provides ongoing consultation and a cranial online course through its team of Certified Orthotists and trains orthotic residents in university orthotic programs across the country. Orthomerica's staff of Certified Orthotists has trained thousands of practitioners

and established treatment programs across the world making STAR Cranial Remolding Orthosis treatment universally available to children everywhere. We are dedicated to creating the finest cranial remolding orthoses and providing clinical education throughout the world.

Whom do I contact if I have questions about my baby's STAR Cranial Remolding Orthosis?

Notify your practitioner if you have any questions or concerns about your baby's care. This health care professional is in the best position to give you specific information about your baby's treatment program and progress. Orthomerica wishes you and your baby a very successful STAR experience. For additional support information, visit our web site at www.starbandkids.com.



One Family's Experience

Around five months of age, we started to notice our son's head becoming flat in the back on the left side. Lucas continually favored his left side while lying down and also while in his swing, car seat and bouncy seat. When we voiced our concerns to our pediatrician, she referred us to a neurologist specializing in pediatrics.

After the initial exam, the Neurologist prescribed a STARband Cranial Remolding Orthosis. We were concerned that Lucas would not tolerate wearing an orthosis for 23 hours a day for 3 months. We were also concerned as his parents, how the stigma of Lucas wearing an orthosis would affect us. We recognized the need for him to wear the orthosis and knew it was the right thing to do in order for his head to form properly.

Our concerns quickly subsided when we met an orthotist who worked directly with Orthomerica, the manufacturer of the STARband. Everyone involved made us feel comfortable and answered any questions we had. They were especially nice and gentle to Lucas during the fitting process. After just

a few outings with Lucas wearing his new "jungle print STARband," we were no longer concerned with how people would react.

A major factor that made us feel even more comfortable was that the STARband did not bother Lucas. From the first time he put it on, he never tried to take it off and he was quickly wearing it 23 hours a day with no problems. Right away, we decided as a family that we would be dedicated to following the program. After three months of wearing the STARband, we were so very pleased when the Neurologist told us that Lucas' head was corrected, and he no longer needed to wear it. Now at almost eight months old, no one would know that he had a problem with his head.

As a Pediatric Nurse, I am well aware of the benefits of early intervention. As a mother, I understand the concerns parents face in caring for a child with this condition. Thanks to our Orthotist and Orthomerica for making our experience a pleasurable one.

— Elyse and Paul Davis



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