NOBBE ORTHOPEDICS, INC.

Rebuilding Bodies, Restoring Lives...

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CRANIAL REMOLDING ORTHOSIS

Cranial remolding may be prescribed by a child's pediatrician as one of the interventions for treatment of Deformational Plagiocephaly.

WHAT IS PLAGIOCEPHALY?

Deformational Plagiocephaly is the abnormal shape of a baby's head caused by external forces. The baby's head may appear 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 bring it to the attention of the pediatrician.

There are several causes of deformational Plagiocephaly, and some of them occur before the baby is 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 intrauterine space due to multiple births, or 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 full term babies. The skull is made up of several plates with fibrous sutures in between. These plates slide over each other to ease the passage of the baby's head through the birth canal. Usually, the baby's head becomes symmetrical and better proportioned within about 6 weeks after birth when the deforming forces are no longer present.

Another leading cause of deformational plagiocephaly 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. Typically, the head of the baby 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 it 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 as the posterior flattening to be pushed forward more than the opposite ear. 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.

Deformational plagiocephaly may occur postnataly when the back of a baby's head rests for prolonged periods of time against a hard surface such as an infant carrier, car seat, swing, bed or infant stroller. Before 1992, babies were placed on their tummies for sleep which varied the amount of force on the back of the head. But for the past decade, since the "Back to Sleep" program was initiated in an effort to end Sudden Infant Death Syndrome (SIDS), babies spend all night on their backs until they are able to roll and reposition themselves. It is estimated that the Back to Sleep program has reduced the incidence of SIDS by 40%, and it is very important to follow the regime of placing your baby on his/her back for sleep. 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 lead to the increased potential for the development of head shape deformities.

WHAT CAN I DO IF MY BABY HAS AN UNUSUAL HEAD SHAPE?

The first thing to do is to see your pediatrician. The American Academy of Pediatrics suggest that a pediatrician evaluate the baby's head at each well baby visit from the top, both sides, and the back. The AAP also recommends that the physician talk to families about how to move the baby into different positions during the day, and stress the importance of "tummy time" whenever the baby is awake and supervised. "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 neurosurgeon 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 Xray, 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 deformational plagiocephaly and may require surgery to remove the suture. After surgery, the physician may order a cranial remolding orthosis to acquire additional correction of the head shape or for protection of the incision site.

If your baby is diagnosed with deformational plagiocephaly and is between the ages of 3 and 18 months old, your pediatrician or specialist will refer you to a practitioner, such as Nobbe Orthopedics, Inc., that specializes in providing cranial remolding orthoses.

WHAT HAPPENS AT YOUR BABY'S FIRST APPOINTMENT AT NOBBE ORTHOPEDICS?

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. Clinical photographs, a series of measurements with a caliper, and a STARscan will be completed. Any questions you have about your baby's orthotic care will be answered at this time.

WHAT IS THE STARSCANNER?

Nobbe Orthopedics' skilled technicians utilize the STARscanner System instead of the traditional plaster casting method. The STARscanner is an eye-safe laser system that allows the practitioner to scan the baby's head in less than 2 seconds. The scan provides detailed head shape measurements and symmetry analysis. The 3-D scan is e-mailed to Orthomerica for fabrication of the STARband cranial orthosis. The STARscanner is the only data acquisition system with software specifically designed to track head shape changes in babies. Nobbe Orthopedics, Inc is the 7th location in California to obtain the STARscanner system. Nobbe Orthopedics, Inc. is the only location in the Tri-Counties area to utilize this safe, accurate, and fast data acquisition technology!

WHAT IS THE STARBAND?

The STARband cranial remolding orthosis manufactured by Orthomerica derives its name from its purpose – Symmetry Through Active Remolding. The custom orthosis is fabricated from a model of the infant's head to obtain optimum fit and function. The rigid outer shell maintains the structural design integrity and is lined with closed cell foam to allow progressive adjustments and promote hygienic conditions. The side opening makes it easy to put on and take off and accommodates circumferential growth of your baby's head.

The STARband received FDA clearance in July of 2000 and is classified as a Class II medical device.

HOW DOES CRANIAL REMOLDING WORK?

The STARband is a plastic and foam device designed to gently correct your baby's head shape. The orthosis, or "helmet," redirects head growth to improve proportion and symmetry. They are designed to provide total contact over prominent or bossed areas of the baby's head to discourage addition growth in this area. The inside of the band is modified every one to two weeks to provide space for the areas of the head that are flat or depressed. The baby's rapid head growth and the shape of the band direct growth into the areas of least resistance and create a precise pathway for growth to occur. The orthotist progressively removes the foam liner or modifies the clear plastic over the course of the treatment program.

Your baby will be fitted with the orthosis within two weeks of the scanning date. During the first week you will monitor your baby's skin as he/she adjusts to wearing the orthosis. Within about 5 days your baby will progress to wearing the orthosis 23 hours a day with one hour off for bathing and cleaning each day. About a week later, you will see your practitioner for a check of the fit and to address any questions you may have. After that, visits are usually every 2-3 weeks depending on how fast your baby grows. At each appointment the orthotist will check the fit and function of the orthosis, document changes in head shape, and make adjustments necessary to direct growth into the flattened areas. You are encouraged to contact us immediately if you have concerns about the fit, skin problems, have any questions, or feel that your baby needs an adjustment before the next scheduled appointment.

HOW LONG WILL MY BABY WEAR AN ORTHOSIS?

Most babies wear a cranial remolding orthosis for 4-6 months if they are between the ages of 4 and 7 months at the beginning of treatment. Older infants may require a longer treatment program because head growth slows after 12 months. Research indicates that the greatest symmetry can be attained before the baby is 12 months old, although correction is possible in babies up to 18 months.

WILL MY BABY HAVE DISCOMFORT?

In most cases children adapt quite easily to the orthosis. As your infant begins to wear the orthosis, any concerns you may have can be addressed by your orthotist.

HOW SOON WILL WE SEE IMPROVEMENT?

This varies, but some parents have seen improvement after only 2 weeks of treatment. Correction continues over time and requires complete compliance to achieve the greatest degree of symmetry.

HOW DO WE KEEP THE CRANIAL REMOLDING ORTHOSIS CLEAN?

In some cases a mild unpleasant scalp odor may develop. It is easily controlled with daily washing of the head and the orthosis. You may also remove the orhtosis for a few minutes during the day to towel or blow-dry your baby's head and orthosis. The orthosis may also have a mild chemical smell that dissipates within a day or two.

DO WE NEED FOLLOW UP?

YES! Your child will be seen at a minimun of every 2 weeks to evaluate treatment progress and fit of the orthosis. Contact the orthotist sooner if the orthsis seems tight or you notice any problems.

WILL MY BABY NEED MORE THAN ONE ORTHOSIS?

Most babies require only one orthosis. In case of moderate to severe deformational plagiocephalyc, it is possible to outgrow the orthosis befor all possible correction may be achieved. If this happens, the physician, orthotist and parents play an active role in determining if another orthosis is appropriate. An additional orthosis will require a new insurance billing and prior approval is recommended before proceeding.

HOW WILL I KNOW WHEN MY BABY IS DONE WITH TREATMENT?

The decision to end the orthotic treatment program is made by the entire team, which includes the caregivers, referring physician, therapist, and orthotic practitioner. The practitioner will continue to document the head shape throughout the treatment program with measurements, scans, or clinical pictures. Periodically the documentation will be compared to the original measurements, scans, and pictures to see what progress has been made. Typically, the decision to discontinue treatment is made at the time the baby starts to outgrow the helmet. At that time, the orthotist will check progress and decide together with the team if the helmet has corrected the head to a point where continued treatment is no longer necessary. Treatment may be

discontinued even if the head shape is not fully corrected since some mild asymmetry or disproportion is normal in all individuals.

WILL THE HEAD REVERT BACK TO THE FLAT SHAPE AFTER TREATMENT?

It is not common for the head shape to revert back to it's original shape. As children get older, they spend more time sitting, crawling, and walking which minimizes the amount of time they spend on their backs. In fact, further skull shape improvement may occur over time. If your child was diagnosed with torticollis, it may be necessary to continue the stretching program to maintain correction achieved by the orthosis.

WILL MY INSURANCE COVER A CRANIAL REMOLDNG ORTHOSIS?

These orthoses fall under orthotics and prosthetics, which typically is a subsection under "Durable Medical Equipment" (DME) in most insurance plans. Some carriers will pay for the orthosis only if measurements show that the baby's head has a moderate to severe deformity. Nobbe Orthopedics staff will assist you in contacting your insurance carrier regarding coverage.

CASTING VS SCANNING

CASTING

This process takes about **30-45 minutes**. The procedure is not painful, but may cause a child to be fussy or frightened. A cotton stockinet is placed over the baby's head with an opening for the face and ears. 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. Distraction with a toy, bottle, or music is beneficial. Once the plaster has cured, the negative mold is removed. The child is then cleansed to remove plaster residue. The cast is shipped to Orthomerica for fabrication.

While casting has been in use for many years, it has the potential to distort during removal from the child or during shipping to the lab. With the casting technique, approximately 10-12 working days are required for fabrication, further increasing the potential for fitting and tolerance problems, due to infants' rapid growth.

NON CONTACT LASER DIGITAL SCANNING

Obtaining data with the use of the STARscanner takes about **1.5 seconds**! A cotton stockinet is placed over the baby's head with an opening for the face and ears. A reflective sticker is placed near the tragion bilaterally for 3-D landmarking and comparison. The child is placed supine in the scanner with parental assistance. The scan is acquired, data is compiled for the child specific needs (including colors, patterns, etc.) and the information is electronically transferred to Orthomerica for manufacturing. Fabrication time is reduced to five working days resulting in markedly improved fitting and comfort. The scan is safe, fast, and is a useful tool for evaluation of progress throughout treatment. All scans are retained and can be superimposed for comparison

purposes and mapping of future orthosis modifications to channel growth. It provides reproducible documentation of deformation prior to prescription and for insurance coverage purposes. (Some carriers only reimburse when a symmetry assessment is provided via the Starscanner). Our service includes the initial scan, a follow-up scan at eight weeks post delivery and at discharge. Other scans are used during periods of rapid growth to monitor changes and plan adjustment strategy.

Nobbe Orthopedics is the 7th practice in California to obtain a STARscanner and is the only location in the Tri-Counties area! Nobbe Orthopedics utilizes only Orthomerica, the world's largest manufacturer of FDA approved cranial remodeling orthoses.