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Journal of Pediatrics & Neonatal Care

Review Article

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Reshaping the head: cranial remodeling orthoses (cranial helmet) in infants: a review

Abstract

Positional skull deformity (P.D.) is a frequent occurrence in neonates and infants, and most of them go unnoticed for lack of awareness. Severe deformity may lead to physical facial deformity and long-term neurological issues. Early detection and timely management are the keys to managing the condition. The evolution of newer digital technology like three-dimensional (3D) scanners improved the diagnosis accuracy and treatment process. Early initiation of physical therapy along with Cranial Remodeling Orthosis (Cranial Helmet) has shown to be effective in treating P.D. and preventing the development of complications.

Volume 13 Issue 3 - 2023

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Received: November 22, 2023 | **Published:** December 6, 2023

Introduction

Positional skull deformity is one of the most frequently encountered issues in infants and early childhood, mostly occurring in infants less than six months of age. They are characterized by flattening and asymmetry of the skull due to external force.[1] A multicenter study involving 530 premature infants showed that, when evaluated at six months of age, the incidence of positional skull deformity, plagiocephaly, brachycephaly, and dolichocephaly was 51.1, 85.1, and 3.0%, respectively, and those of right and left plagiocephaly were 69.4 and 30.6%, respectively. The incidence of skull deformity was higher in premature infants delivered at <32 weeks of gestation.[2]

Plagiocephaly, often referred to as "one side flat head syndrome," is characterized by anasymmetrical distortion (flattening of one side) of the skull in an infant. A central flattening at the occipital region characterizes Brachycephaly. Scaphocephaly or dolichocephaly are lesser presentations, mainly attributed to NICU stay.[3,4]

Positional skull deformity leads to facial asymmetry due to flattening one side of the head and forehead protrusions, which may lead to shifting of eyes and ears. Such facial deformity may persist, which leads to adverse psychosocial impact on the child and often leads to bullying. Severe skull deformity may lead to ear-nose and throat dysfunction.[5] Some evidence shows that the severity of positional skull deformity directly impacts abnormal childhood developmental scores (Bayley score of infant and toddler development).[6]

With an increase in an infant's age, the hardness of the skull and the range of head movement increases and is difficult to control. So, conservative management with shifting head position is ineffective. For moderate and severe P.D. after four months of age, the child may even need to wear a helmet or undergo corrective surgery.[7]

Cranial Remodeling Orthoses (C.R.O.), orthotic helmets, or head-shaping helmets treat deformed head shapes like brachycephaly and plagiocephaly in infants.[3,7] A study conducted in Japan showed a statistically significant improvement in skull deformity in those infants who completed helmet therapy (therapy started at an average of 4.7 months of age), evaluated by different scores like Argenta classification, cranial asymmetry (C.A.), and cranial vault asymmetry index (CVAI).[8]

Mechanism of cranial helmet therapy

Cranial helmets are designed to redirect the growth of an infant's skull gently. They are most effective when the skull is still malleable, typically used in infants aged 4 to 12 months. The helmet applies gentle, consistent pressure on the protruding parts of the skull, allowing room for growth in the flattened areas. The void space is created to steer the growth.[3,7]

The treatment program's effectiveness depends on the infant's age, the severity of asymmetry, and how quickly the skull responds to the treatment. Infants usually wear the helmet for 23 hours a day over several months.[9] Regular follow-ups are necessary to adjust the helmet and monitor progress. Each cranial helmet is custom-made for the infant's head, which involves taking precise measurements or digital scans of the infant's skull to ensure the helmet fits properly and applies pressure in appropriate areas.[3,7]

Myths and misconceptions

There are a few myths and misconceptions regarding using Cranial Orthosis, such as it stop brain growth and the head does not grow. These have been eradicated with proper justifications by many supporting scientific papers.[8,9] The growth is not affected at all. The growth is only steered in the required or desired areas, while the bony prominences are held with soft support. The therapy corrects the baby's head shape over time by redirecting natural head growth. Babies' skulls consist of bony plates joined by sutures, allowing brain growth and flexibility. The helmet uses these natural growth processes to reshape the skull effectively.

Diagnosis

Diagnosis of craniofacial disorders typically requires clinical examination by trained craniofacial physicians. However, the detection and classification of exact craniofacial type and quantification of the condition rely on more clinical methods like Computed Tomography (C.T.), plain radiography, and morphometric evaluation. These

processes are subjective and vulnerable to bias.[4,10] Earlier, the measurement process was cumbersome, with Plaster of Paris cast over the baby's head, which was too scary for the whole team and, hence, had fewer people opting for it. With the recent advancements in computer technology and artificial intelligence, new, less subjective methods are used, such as in Smart SOC and STAR scanner devices. These are infant- friendly, non-invasive, and faster methods. It takes only a few minutes to complete the scanning process which acquires all the required data, besides providing a 3-dimensional (3D) pictographic model.[10] This also helps parents understand the deformation's severity, treatment process, and duration. The literature review proves that compliance with the wearing schedule and intervention at an early age lead to 95-99% achievement in symmetry.[7,9,11] CROs are generally safe when used under professional guidance. Potential side effects can include skin irritation and discomfort. Maintaining good hygiene and regularly cleaning the helmet is essential to prevent skin issues, like itchiness due to sweating.[9,12]

Management and follow-ups

A healthcare professional, usually a pediatrician or a specialist in pediatric neurosurgery, assesses the head shape of the infant. A Cranial orthoptist should be consulted to rule out cranial deformation, which follows a scan and provides a detailed report with indices. The treatment protocol follows repositioning along with physiotherapy sessions. Before considering a helmet, alternatives like supervised "tummy time" when the infant is awake and repositioning the baby's head during sleep are recommended to prevent plagiocephaly. These methods are often effective in mild cases. They are best started when the baby is very young.[3,6,7] For moderate to severe cases, Cranial remolding orthosis is prescribed at the earliest.[11] The decision to use a helmet is typically based on the severity of skull asymmetry and the lack of improvement with other non-invasive methods like repositioning the baby's head during sleep.[8,9,12,13]

Parents and caregivers need to follow healthcare professionals' guidance in diagnosing and treating plagiocephaly. The decision to use a cranial helmet should be based on the severity of the condition and the child's specific needs, as determined by a medical professional. Regular follow-up and proper helmet maintenance are crucial for the effectiveness of this treatment.

Effectiveness of cranial helmet

The effectiveness of cranial helmet therapy in infants with plagiocephaly (flat head syndrome) has been the subject of various studies and medical analyses. Here are some key findings from different sources:

1) **Effectiveness in moderate to severe cases**:[14] Hyehoon Choi et al. study suggests helmet therapy might be effective for infants with moderate to severe brachycephaly, provided there is good protocol compliance. It also notes that younger treatment initiation age and less severe and less asymmetric brachycephaly can significantly shorten the treatment duration.

2) **Comparison with physiotherapy**:[15] Josefa González et al. aimed to compare cranial helmet therapy (C.H.T.) with physiotherapy (P.T.) for the effective treatment of positional plagiocephaly in infants in terms of improving functional recovery. This study involved a prospective cohort of 48 infants aged 5–10 months with cranial deformities. They found no statistically significant differences between C.H.T. and P.T. However, after treatment, improvements from baseline measurements were observed in each cranial deformity reading. This study is limited by being a single-center study and using only one anthropometric measure, which could raise questions about the generalization of the results.

3) **Comparison between traditional head measurements and Three-dimensional (3D) scanning techniques**: A study by Zhi-Feng Wu et al.,[16] evaluated the correlation and consistency between traditional head measurement and structured light three-dimensional (3D) scanning parameters when measuring infant skull shape. They observed that the 95% confidence interval of traditional head measurement and structured light 3D scanning was between 0.633 and 0.988. Pearson's correlation coefficient indicated a high correlation between the two methods (r=0.793-0.980). The P values of the above measurement data were all <0.001, indicating they were closely related. They concluded that, while both methods are well suited for infant head shape measurements, structured light 3D scanning can deliver additional parameters. It is helpful for infants with an abnormal head shape and is also convenient for designing a customized helmet for skull correction.

In a study, Felix Nieberle et al.,[17] showed that direct anthropometry overestimates cranial asymmetry, and 3D digital photography proves to be a reliable alternative. In this study, a total of 111 infants (103 with plagiocephaly and 8 with brachycephaly) were included. Direct anthropometric measurements and 3D photographs were obtained in each infant, and then the cranial index (CI) and cranial vault asymmetry index (CVAI) were calculated. Measured cranial parameters and CVAI were significantly more precise using 3D digital photography. They observed that manually acquired cranial vault symmetry parameters were at least 5 mm lower than digital measurements. Differences in CI between the two measuring methods did not reach statistical significance, whereas the calculated CVAI showed a 0.74-fold decrease using 3D digital photography and was highly significant ($p < 0.001$). The authors concluded that using the manual method, CVAI calculations overestimated asymmetry, and cranial vault symmetry parameters were measured too low, contributing to misrepresenting the actual anatomical situation and leading to errors in therapy choices. So, they suggested implementing 3D photography as the primary tool for diagnosing deformational plagiocephaly and positional head deformations.

4) **Conservative therapy and helmet therapy**: In a study by Steinberg, J. P et al.,[18] A total of 4378 infants were evaluated for deformational plagiocephaly and brachycephaly. Of these, 3,383 infants were assigned to conservative, and 997 were subjected to helmet therapy (n = 997). Patients were followed until complete correction (diagonal difference <5 mm and/or cranial ratio <0.85) or 18 months. They observed that complete correlation was achieved in 77.1% of the conservative treatment group compared to 94.4% of the helmet therapy group. They also observed that 15.8% of the conservative therapy group required helmet therapy. There was a complete correlation in 96.1 percent of infants who received helmets after failed conservative therapy ($p = 0.375$). The risk factors for helmet failure included poor compliance (relative risk, 2.42; $p = 0.025$) and advanced age (relative risk, 1.13 to 3.08; $p = 0.011$). The authors concluded that conservative and helmet therapy is effective for positional cranial deformation. The study also suggests that delaying helmet therapy for a trial of conservative treatment does not preclude complete correction, indicating the possibility of using conservative methods before opting for helmet therapy.

Citation: Mishra S, Dash SK. Reshaping the head: cranial remodeling orthoses (cranial helmet) in infants: a review. *J Pediatr Neonatal Care*. 2023;13(3):246–248. DOI: 10.15406/jpnc.2023.13.00527

Conclusion

Positional skull deformities are a significant problem in early infancy, particularly in premature babies who are delivered before 32 completed weeks of gestation. If not diagnosed or treated early, this may lead to irreversible facial and skull deformity. The deformity increases the chance of long-term developmental delay and neurological sequels. Early diagnosis and management can prevent and treat deformity and associated complications. With the development of computer technology, artificial intelligence, and digital technologies, new, rapid, baby-friendly, and more accurate 3D scanning techniques are used to diagnose skull deformity. The 3D digital method is safe and more accurate than the traditional methods. Cranial helmet (Cranial remolding orthosis) is effective as a primary modality in managing positional skull deformity or in cases where traditional physiotherapy failed. If used in conjunction with 3D scanning technology and physiotherapy, the cranial helmet can revolutionize the therapy of positional skull deformity.

Acknowledgments

None

Funding

Internal or external sources do not fund this article.

Conflicts of interest

The authors declare that there are no conflicts of interest.

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