SHINING 3D

Pediatric Cranial Remolding Orthosis: 3D Scan-Based Helmet Therapy

3D Digitizing Solution for Infant CRO

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This Article Provides Insights Into

1. The typical approach to CRO and its complications
2. Alternative 3D digital solutions
3. Advice to physicians on making CRO treatment more efficient and less troublesome

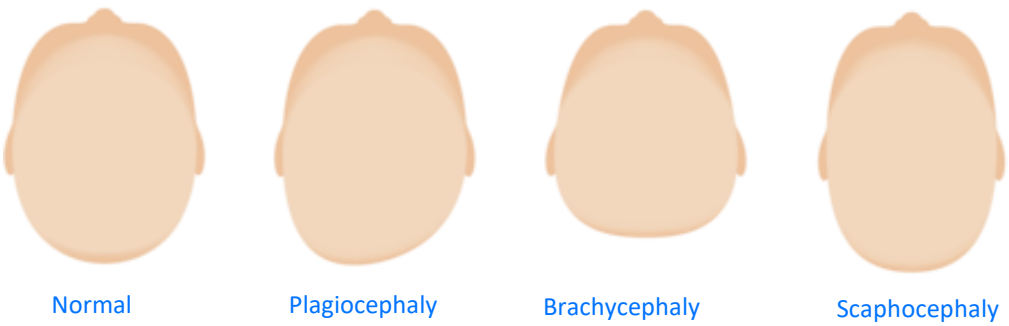
Understanding CRO

Pediatric Cranial Remolding Orthoses (CRO) are appliances used to correct head shape deformities like plagiocephaly, brachycephaly, and scaphocephaly. Helmet treatment works best for infants between 4-18 months. Starting the treatment early is ideal due to the slowing growth rate as the child ages.

The Pediatric Cranial Remolding Orthoses are tailored to the patient's head and serves two functions:

- It acts as a protective cushion to prevent high pressure on one side of the head, enabling better pressure distribution across the skull bones.
- The helmet is structured to allow skull bone expansion in flat areas, accommodating the brain's growth underneath.

TYPES OF HEAD SHAPE DEFORMATION



In 1998, the FDA ruled that cranial remolding orthoses fell into the category of Class II medical devices and required strict control standards.

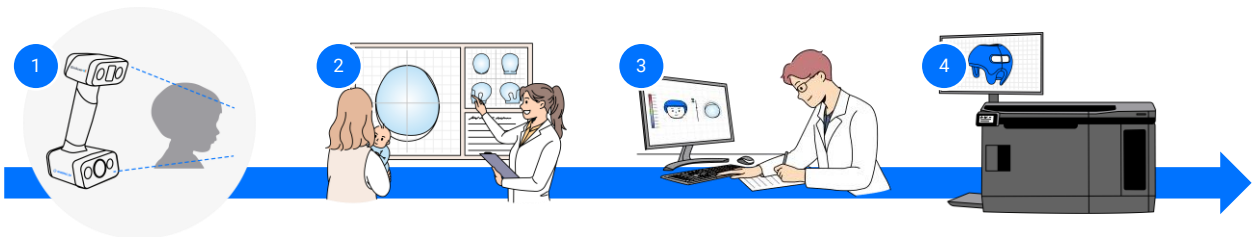
Orthoses center have to apply for and receive FDA 510(k) clearance, which is an expensive and labor intensive process.

Treatment Journey

The **cranial helmet treatment** involves a specially designed helmet tailored to fit the infant's head. This technique helps redistribute pressure and encourages skull growth in the targeted area.

Early intervention is key, with repositioning techniques suggested for mild deformities within the first few months. Yet, for moderate-to-severe cases showing no improvement by five months, orthotic therapy becomes a necessity, ideally between **4-14 months** of age.

The helmet must always be targeted at the specific conditions of the patients, as deformities are highly individualized.



3D Scan | Measurement | 3D Design | 3D Printing

Fabrication | Shipping | Fitting | Treatment and Result

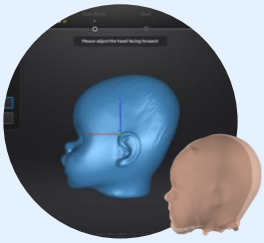
Full 3D Digital CRO Process

Traditional Method VS 3D Digitization

Check the 3D digitizing workflow

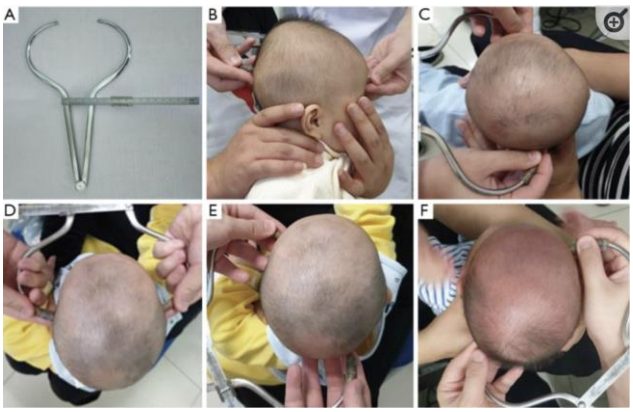
Generally speaking, the production of helmets usually includes three important stages, namely **measurement, customization, and manufacturing**.

The traditional way is usually contact-based, using calipers and plaster molding, which may cause discomfort to children during the process, and parents may also worry about the trauma caused by chemical substances.

STEP 1: Measuring	 Traditional spread caliper	 3D data acquisition
STEP 2: Customized Design	 Plaster casting	 3D modeling
STEP 3: Manufacturing	 CNC form helmet	 3D printed helmet

Caliper VS 3D Scanner

3D scanners, like the EinScan H2, offer up to 0.05mm accuracy, surpassing calipers. They're safer, avoiding potential pain or injury from caliper usage on children. The scanned 3D data files can be preserved and visualized interactively, for doctors and parents to view, track long-term and analyze; 3D data also facilitates doctors to communicate with the factory remotely and timely.



	Traditional Spread Caliper	3D Scanning Measurement
Accuracy	Manually depend on proficiency	Depend on the scanner accuracy EinScan H2: Up to 0.05mm
Speed	Measured **3 times** to take the average value	Scan in **a few minutes**
Data Archiving	Not good to track	**3D data saved which can be archived** and compare in follow-up assessment
Comfort	Contact to skin, **may cause pain**	**Non-contact**
Modeling	A **plaster casting** process will be followed	3D head data can be directly **3D modeled in computer**

Plaster Casting VS 3D Modeling

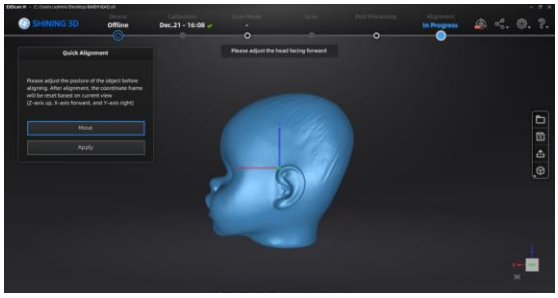
The casting process involves laying a series of plaster splints over the infant's head and molding them as they dry. Then the cast is removed to produce a negative impression of the infant's head. The entire process takes between 15 and 30 minutes.

Traditional Plaster Casting

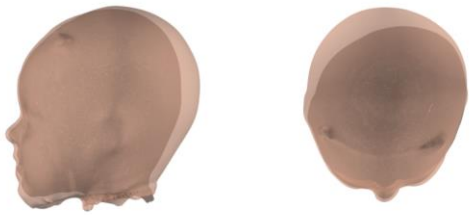
- Messy and hard time for little infant
- Time-consuming
- We must also consider the space needed in the clinic to make and store plasters.

Advanced 3D Digital Method

- **Improved patient experience:** Non-contact measurements allow for a precise fit and increased comfort.
- **Reduced Costs:** The cost of scanning with a 3D scanner is far less than the cost of materials and labor to make a mold.
- **Time Saving:** 3D scanning takes only minutes.



Head shape



CNC Milling VS 3D Printing

CNC Milling

Use CAD/CAM software to program and use CNC machine to carve a foam replica of the patient's head. The foam head mold is then corrected using plaster. The helmet is fabricated on top of the modified foam mold.

3D Printing

Use CAD software to design the helmet model based on the baby's cranial scan data, and print it directly. The helmet can then be tried on and fitted immediately. Printing takes just a few hours, and the helmet can be shipped to the clinic and received by the customer within a few days.

	Traditional Foam Helmet	3D Printed Helmet
		
Fabricate time	**In weeks**	**Several days** Faster fabrication to start treatment earlier
Comfort	Customized with fun styles But **hotter, bulkier and heavier** Uncomfortable	Able to design ventilation Much **thinner and lighter** More comfortable

3D Digitizing Solution and Key Features

Combining 3D high accuracy and easy-to-use handheld scanners with traditional CRO production processes is a solution to improve the productivity of head correction physicians. Adding 3D scanners to common workflows can increase more possibilities, including less painful data collection, using this data for long-term tracking, etc.

In addition, because handheld scanners are very flexible, they can be placed in examination rooms for centralized examinations, or moved to the patient's home for home treatment and examination.

Finally, this solution is integrated into SHINING 3D's software with a one-click, intuitive software is easier to use and set up, with a short learning curve, and can be operated by staff with lower technical qualifications.

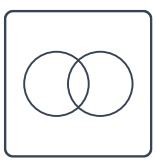
Benefits

Easy-to-use and simple operation

Plug and play, the handheld 3D scanner is very simple to use and operate; ergonomic design for a comfortable grip; and the short learning curve of the 3D scanner makes it easy to get started.

Efficient data acquisition

The 3D scanner (for example, EinScan H/H2)'s smooth scanning performance quickly captures 3D data of an infant's head, eliminating the need for caliper and other expensive solutions.



Portability

The weight of the EinScan H2 is only 731g, and it can be operated with one hand. At the same time, the device is equipped with a cloth box that is convenient for travel and storage. Users can take the box anywhere, such as the patient's home.

SHINING 3D's EinScan H2 3D scanner, with enhanced tracking capabilities, have rapidly elevated our cranial orthotics capabilities. Paired with the Cranial software, this advanced solution streamlines our workflow, saving time and setting a new industry standard for accuracy. SHINING 3D has quickly transformed and elevated our capabilities in the cranial orthotics field.

Matej Dily

Clinical Specialist, Invent Medical

Benefits

Reliable accuracy

With the help of advanced 3D scanning technology and software, clinicians can achieve unprecedented levels of precision in diagnosing and treating cranial deformities. In white light scanning mode, the scanning accuracy is up to 0.05mm, providing clinicians with precise 3D data.

Intuitive software process

User-friendly data presentation allows cranial specialists to prepare the scan in just a few clicks in under 3 minutes. The Quick Alignment feature saves time for subsequent data processing.

Seamlessly dock to professional software

It provides users with a fast and simple way to export scanned data to various third-party developed professional order software. The software helps accurately assess and visualize cranial deformities, and part of the software can even intelligently generate reports, offering unparalleled efficiency and a handy tool to communicate with caregivers and keep them motivated. The order software also enables customizing the cranial helmet color, text, and symbol to make the experience more personal.

In conclusion, the integration of 3D scan-based helmet therapy represents a significant advancement in pediatric cranial remolding orthosis. As healthcare continues to evolve, embracing technologies like 3D scanning will be key to optimizing pediatric cranial care and ensuring better long-term outcomes for patients.

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