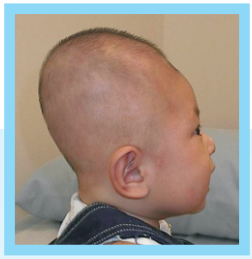
History of Cranial Molding

Cranial deformation has been practiced for centuries. Hypocrites described procedures used on females to alter head shape. Ancient Egyptian royalty had elongated, towering heads (similar to the Marge Simpson character on The Simpson's) as early as 2000BC. Early North Western Indian tribes flattened and elongated infants heads by binding strips of cedar bark to the skull.

Fast forwarding to 1992, the American Academy of Pediatrics, after some research, dictated a policy to have all infants placed on their back to sleep. No longer would stomach sleeping be recommended. This new policy resulted in a 40% drop in SIDS related deaths. What the AAP failed to promote was Tummy Time while the child was awake. Many parents would **only** place their infants on their back, causing prolonged, and deforming pressures to act on the soft skull. Devices such as infant swings, car seats, infant carriers, reclining bouncy seats and the like, also contribute to deformation of the infant skull.

Cranial synostosis (a fused skull suture) is a rare condition comprising less that 1% of all live births. The standard form of treatment for cranial synostosis is surgery, to release the suture and allow the skull to expand with the growing brain. Believing it to be cranial synostosis, surgeons would operate on children with Deformational Plagiocephaly. After seeing there was no fusion of the skull suture it was discovered that the soft bones of the infant skull were being deformed by their hard crib mattress.



Out of this new mandate by the AAP grew a new industry, that of cranial remolding. Cranial remolding helmets/bands (the difference between a helmet and band is the size, or lack there of, of the opening at the top) were first considered to be a class III neurologic device by the FDA. Class III devices include internal implants, artificial hearts, pace makers, devices which were surgically implanted into the body. Papers were filed with the FDA around 1998, to demonstrate this device was more appropriately classified as a class II neurologic device. This level of classification required much less oversight by the FDA and data reporting by manufactures. The FDA subsequently created a strict set of guidelines and manufacturing standards for the production of cranial remolding devices. In the field of Prosthetics and Orthotics, only the cranial remolding band carries a class II neurological device designation.

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The basic theories of cranial remolding are:

Constrain the growth of the abnormal shape of the cranium by only allowing growth in a symmetrical and /or proportional environment.

Control the growth during the final stages of rapid growth, from 4-16months of age.

Complete treatment before the sutures close.

The principals of cranial remolding are:

Provide total contact in the areas of the skull where growth is to be curbed.

Allow space in the areas of the skull where growth is to be allowed.

Provide treatment during the critical growth period between 3-8 months of age, when the skull is most actively growing.

Create an orthosis, which sets up the environment for the skull to symmetrically reshape.

There are three ways in which the cranial band effects a change in the shape of the skull. The human body reacts to pressures as a defense mechanism. In cranial remolding, the gentile constraint of the cranial band will cause the bones of the skull to shift, thus reducing the pressure the band exerts on the skull. The second way the cranial band helps correct the deformity is to allow growth on the flattened side of the skull. Within the cranial band, the flattened portion of the skull lies opposite a void built into the band. When your infant has a cranial growth spurt the brain pushes on the flat plate of the skull, thus causing it to round. The third way the cranial band works is when your infant tries to lie on the flattened side of the skull, the cranial band suspends their head and prevents the deforming forces of the mattress from acting on the soft skull.

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