

Restoring Form, Transforming Lives

The Easy To Use, Non-Surgical Ear Molding Solution For Infants With Ear Deformities





MISSION

"To provide an innovative, nonsurgical solution to correct ear deformities in infancy, thus improving a patient's appearance for a lifetime..."

Congenital Ear Deformities

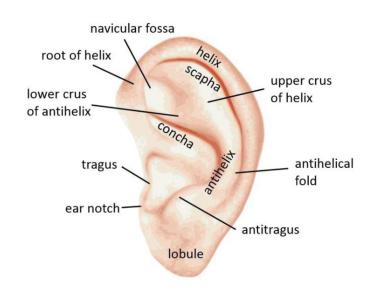
Congenital anomalies are of two major categories, malformations and deformations. Strictly speaking, malformations are anomalies in which parts of the ear are missing or malformed. Deformations are conditions in which all or most of the ear is present, it is just folded over, has additional pleats and creases, or is prominent.

It has long been taught that many ear deformities resolve and no treatment is necessary. Recent evidence concludes that this is not the case. **Up to 70% of all ear deformities do not correct on their own.** In a study from China involving over 1500 patients, the incidence of ear deformities was 58% and only one-third of these resolved at 30 days. [1]

Another study from Japan noted that, although some of these deformities resolve, many do not, and it is recommended that all deformities be treated. [2]

Almost 1 of 3 newborn infants will have an ear deformity at birth

Normal Ear Anatomy



- 1. A Morphometric Study of the Newborn Ear and an Analysis of Factors Related to Congenital Auricular Deformities, Zhao H, Ma Limin, Et Al . Plastic and Reconstructive Surgery, (In Press). China
- 2. Nonsurgical Correction of Congenital Auricular Deformities, Matsuo K, Hayashi R, Kiyono M, Hirose YT, Netsu Y Clinics in Plastic Surgery Volume 17, No 2, April 1990, p 383-395 (Japan)

COMMON EAR DEFORMITIES



PROMINENT EAR



LOP EAR



STAHL'S DEFORMTY



MIXED DEFORMITY

Psychological Impact of Ear Anomalies

In the last 10 years, there has been a 30% increase in surgical procedures to correct ear deformities attributed to a significant increase in bullying. Corrective surgical procedures are often performed between the ages of 5 to 10 years. However, these procedures are costly, painful, and avoidable.

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INCREASE IN SURGICAL EAR PROCEDURES IN THE LAST 10 YEARS DUE TO BULLYING

Now, ear deformities can be corrected within days after birth with the InfantEar, Non-surgical Ear Molding System that can be performed in your office. These ear molding procedures are effective and helps children avoid surgery later in life, particularly if performed within the first two weeks of age.

THE PSYCHOLOGICAL EFFECT

The psychological distress caused by ear deformities, such as prominent ears and others, can be significant. This can lead to negative self-esteem, social avoidance behavior, poor performance in school, and a general reduced quality of life.

Teasing at school causes both short-term unhappiness and a potential long-term impact on perception of self-image and self-worth. Children and adults alike with an ear deformity may experience a damaged psyche secondary to outside ridicule and self-criticism.[3]







^{3.} Handler EB, Song T, Shih C; Complications of otoplasty. Facial Plast Surg Clin North Am. 2013 Nov21(4):653-62. doe: 10.1016/j.fsc.2013.08.001.

Ear Molding During Early Infancy

Newborns have high levels of maternal estrogen (which crossed from mother to baby while in the womb). Because of the increased estrogen levels, infant ears are very moldable, soft and responsive to external molding during the first few weeks and months after birth. By six weeks of age, the levels of maternal estrogen fall to normal, and the ears become more rigid and less pliable. This is why early intervention is so important.

Ear deformities can be corrected by initiating appropriate corrective molding in the first week of life. Neonatal molding reduces the need for painful and costly surgical correction with results that often exceed what can be achieved with the surgical alternative.[4]

Examples of InfantEar Molding Outcomes





Before After

Mixed deformity

Stahl's deformity



Helical rim deformity



After

Before After

The InfantEar Molding System

After decades of clinical experience and research on infant ear anomalies, Dr Scott Bartlett, the former Chief of Plastic and Reconstructive Surgery at The Children's Hospital of Philadelphia (CHOP), formed TalexMedical, LLC to develop and bring to market, InfantEar Non-surgical Ear Molding System — an innovative, simple and effective solution for the early treatment of newborn ear deformities.



Scott Bartlett, MD FACS



InfantEar Kit Includes:

- 1 Base Plate
- 1 Rim Piece
- 2 Caps, Pink and Blue
- 2 Standard Conformer
- 2 Edematous Conformer
- 1 Silicone Matrix
- 1 Plunger for Silicone
- 2 Mixing Tip
- 1 Mini Hair Trimmer
- 1 Ventilated Beanie

- 3 Adhesive Remover
- 1 Adhesive
- 1 Marking Pen
- 1 Instructions For Use (IFU)
- 1 Parent Guide

6-Step Application Process

The Easy To Use, Non-Surgical Ear Molding System

The application of the InfantEar™ System is simple and easily performed in any office setting. In most cases, the duration of ear molding treatment is for 2 to 3 weeks. After this time, the device is removed by gently lifting it off the skin and ear. An adhesive remover (included in the kit) may aid in this process.

1 - REMOVE HAIR / CLEANSE SKIN. A small amount of hair will be shaved from the scalp around the ear and the skin will be cleaned of any oils and patted dry.

2 - POSITION BASE PLATE

The 2-sided Base Plate, made of Velcro and an adhesive (approved for use in children), will be applied. The tab will be removed and Base Plate adhered to the skin.

3 - SELECT A CONFORMER

Standard or edematous Conformers, covered with Velcro, are placed along the rim of the ear to normalize the shape and set the ear in the desired position.







4 - SECURE THE RIM PIECE

The flexible Rim Piece, affixed with Velcro, attaches to both the Conformers and the Base Plate and allows for additional customization of the correction to precisely fit your child's ear.

5 - APPLY MATRIX MATERIAL Clear matrix material (silicon

Clear matrix material (silicone) is then injected between the conformers, rim piece, and into the newly created ear folds.

6 SECURE CAP AND FIT BEANIE

A pink or blue InfantEar™ Cap is applied, then an infant Beanie, will be fitted over the infant's head, which will help protect the device from dislodgment.









