

## CHINA CLINICAL STUDIES I

ORIGINAL ARTICLE

# Deformational Auricular Anomalies in Newborn Infants: Early Recognition and Non-surgical Correction

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# **Abstract**

Congenital ear anomalies are defined as either malformations (microtia) or deformations. About one-third of these could self-correct, leaving a large need for acceptable corrective methods. Some reports have shown that molding the deformed ear, especially if started within the first 7 days of birth, can lead to satisfactory results and obviate the need for surgical repair and the complications of surgical intervention. Combined the newborn hearing screening and these deformities picking up can be effective in finding out the newborn infants who need the molding therapy within the first 3 days of birth. In brief, early recognition and non-surgical correction are a cost-effective, minimalist and safety method to manage newborn infants with deformational auricular anomalies and worth of spreading.

#### Kev words

Congenital Auricular Deformity; Newborn Infants; Splinting; Molding; Nonsurgical Correction

#### INTRODUCTION

Congenital ear anomalies are common newborn malformation, and are related to abnormal development of the auricle cartilage. Based on the different stage of auricle cartilage malformation, congenital ear anomalies can have diverse clinical manifestation, and can be classified into different categories based on embryo development, lesion range and treatment regime, including Max (1926), Rogers (1977), Tanzer (1978), Weerda (1988), Zhuang (1999), Hunter (2009), Luquetti (2013). Clinically it is classified as malformation or deformation based on whether there is the absence of skin or cartilage. Ear malformation refers to microtia deformity/microtia, and is usually combined with external canal or middle ear malformation, or is part of the clinical manifestation of a certain syndrome. It is related to infection, genetic variation, abnormal migration of neural crest cells, etc. Deformation is characterized by auricular abnormalities without skin or cartilage defect, and is considered as type 1 according to Weerda's category definition. It is described as ear deformation to distinguish with ear malformation like microtia. It includes prominent/cup ear, lidding/lop ear, cryptotia, Stahl's ear, etc. and is associated with the internal or external pressure on the auricle during pregnancy, resistance of birth canal during delivery or the abnormal development of extrinsic muscles [1].

Sequential treatment intervention procedure for microtia has reached consensus in China <sup>[2]</sup>. However, there has not been a guideline for treating auricular deformation. The incidence rate of infant ear deformation was reported as 43.36%, less than 55.2% reported in other countries. Currently the surgery for correcting auricular deformity is mature, and around 200 types of surgical operations could be performed. Nonetheless, these surgeries usually have to wait until the children aged six, the development of their auricle reached 85% of adult level, and these surgeries are invasive, with a risk of general anesthesia and further complication. Among children with deformation, around 30% of them could recover on their own, and the rest usually remain the same or even become more severe. It is important to note that we cannot predict or judge what are the deformities that could self-recover. Auricular

deformation has adverse effect on children's psychological and social development, and should be intervened early to relieve their psychological pressure as much as possible [3].

In the 1980s, Japanese plastic surgeons first proposed and conducted non-surgical treatment for infant auricular deformation cases without skin and cartilage defects <sup>[4]</sup>. Afterwards, treatment has been implemented in European and American countries. Clinical and experimental studies on non-surgical treatment for infant congenital ear deformation has been very successful and such treatment has been widely used. Recently, orthopedic treatment of auricular deformities has been conducted in China, especially when EarWell, the non-invasive orthopedic system of infant auricular deformation system was introduced in 2015. The concept and effect of orthopedic treatment of auricular deformities has been recognized by experts and parents of the patients. In 2016 and 2017, such treatment has reached 406 cases, with a success rate over 99% (3 cases withdrew).

In fact, parents in China usually have extremely poor understanding, knowledge and level of emphasis towards auricular deformation, usually choose to wait and see, hope it will recover on its own, or even turn a blind eye on it. Rarely any parent respond actively. Surprisingly, many pediatric, otolaryngology and plastic surgeons also do not have enough knowledge and emphasis to the occurrence and treatment of this disease, which leads to untimely treatment and poor clinical outcome. Therefore, the promotion of non-surgical correction of auricular deformation is urgently needed. Through the diagnosis of deformation subtype, diagnose and treat non-invasively at the early stage is important. Due to the limit of best treatment window, the Mayo Clinic trained

newborn hearing screening staff, and combine auricular morphological screening with hearing screening  $^{[5]}$ . Our department also adopted this screening approach, that move forward the screening time-frame, standardize screening staff, ensure early diagnosis and treatment, and have achieved great outcome.

#### **PRINCIPLE**

The core of auricular deformation orthopedic is fix and reshape ectopic auricular composite tissue using instruments. The principle is that the auricle cartilage has small elasticity and strong plasticity at the early stage. Cartilage is composed of chondrocytes, extracellular matrix and fibrous tissue, and its extensibility is decided by extracellular matrix especially the amount of hyaluronic acid. Since estrogen can increase the level of hyaluronic acid, the level of estrogen in the body is higher during the first three days after birth, and drops rapidly in the circulatory system after a few days, and stays the small level with older children at the sixth week, during this period the elasticity gradually increases. Therefore, it is feasible to use non-surgical method to adjust auricular deformities at the early stage and the timing is extremely important.

## INDICATION OF CORRECTION

**Indication:** Auricular deformities without skin or cartilage defect, or providing foundation for future orthopedic surgeries (Table 1).

Table 1

Non-surgical correction indication of deformational auricular anomalies in newborn infants

1. Lop ear	6. Prominent ear
2. Stahl's ear	7. Cryptotia
3. Helical rim abnormality	8. Conchal crus
4. Constricted ear	9. Mixed ear deformity
5. Cup ear	10. Preoperation unfolding; Post-operation fixed

## **TIMING**

There has been different initiating time for auricular deformation in the domestic and foreign literature. Domestic molds are recommended to be worn starting 5-7 days after birth and within one month. The length of molding time depends on the treatment initiation time, types and complexity of deformation. Treatment after one month will lead to difficulty in achieving normal morphology and long duration of treatment. For patients aged over three months or correction treatment failed, or symptoms recurred, current treatment regime is surgery at school age. Age preference for cryptic patients could be within one-year-old.

#### **INSTRUMENT**

The development of non-surgical correctional treatment is closely related to the continuous improvement of treatment concepts and techniques by health workers, and the significant advance in the development of orthopedic materials. A variety of corrective materials have been applied to clinical care.

Currently, the orthopedic materials could be classified into four categories [6,7]: Class 1, using only surgical tape or bandages, which has achieved good clinical outcome; Class 2, plastic composition + tape or bandage. The plasticity compound combined with tape and bandage could ensure more durable plasticity; Class 3, wire splint + tape or bandage, or commonly referred to as splint therapy. It is the upgrade of many other orthopedic materials, and researchers has been using linear brackets that are bendable and flexible, with a silicone rubber tube or suction tube positioned out at the scaphoid fossa. This could position the helix and antihelix respectively, and also be used as an upward support force to correct the lidding/lop ear deformity; Class 4, EarWell infant ear correction system, developed by Byrd et al. The system consists

primarily of a rear base, 2 traction hook, 1 ear cavity former and 1 anterior shell. The EarWell system combines the advantages of a previously shaped material to restore the upper one-third of the important anatomical structure of the ear, and also can be used to form the normal conchal cavity-mastoid angle structure, and reduce the recurrence rate. This is an effective and comprehensive orthopedic system. The author believes that another contribution of EarWell is the material—it uses polyurethane thermoplastic elastomer (TPE), which is non-irritating, non-sensitizing, non-toxic, soft and has certain tenacity to maintain the morphology. The clinical complication is rare, skin ulcers, necrosis or exfoliating dermatitis caused by stress reaction is rare, thus well-recognized by the industry.

Currently, the patent infant orthopedic system "Yi Er" developed by Jiang Haiyue and team has been put into clinical use and received good results. Besides, for patients without opportunity for clinical care, home-made linear splint and tape bandage could be applied under doctor's guidance.

#### **APPLICATION**

Taking EarWell, the non-invasive orthopedic system of infant auricular deformation system, as an example (Figure 1):

- 1. Admission of newborns and patients aged below 6 weeks, with ear anomalies and suitable for orthopedic treatment.
- Patient evaluation: Exclude patients with auricular skin lesions, rashes, severe auricular deformities, complication of other severe organ disorders, and cannot ensure follow-up visits.
- 3. Record personal information, auricle pictures and sign application consent.
- 4. The parents should assist in keeping the ear upwards. Prepare the skin (3-5cm around the ear), use alcohol cotton ball to disinfect the auricle and preparation area, choose the suitable orthopedic system based on the size of auricle. After placing the base, place 1-2 traction hook based on actual condition, and then place the ear cavity appliance, attach the anterior shell, and finish the application.
- 5. Details for application:
  - a. When installing the base, observe whether there is any neo plasm or fistulas around the ear, and try to avoid them.
  - b. The position of the antihelix former should be right at the position of the antihelix. Do not stick to the root of the ear.
  - c. Pay attention to the antihelix while applying the traction hook, the hook should be in the position side above.
- d. The base can be trimmed as needed.
- e. Details can be adjusted using laps. After installation, observe for a minute or two and then apply the shell to observe for blood supply after skin compression.
- f. Pay particular attention to whether there is a narrowing of the external auditory canal. If there is, it is necessary to perform an orthodontic treatment.
- The treatment cycle is 2-6 weeks, and weekly follow-up is needed post-application. Treatment cycle will be decided during follow-ups.
- 7. Open the shell during every follow-up, to observe the color of the skin, look for complications, take a picture. While detaching the system please take a picture, evaluate, document the complication and summarize.
- 8. Train the parents on the family care of the orthopedic system, and ensure their assistance.

#### Figure 1 EarWell System application process.



A. Shave the scalp hair B. Place the posterior cradle C. Place the retractor system and compressible conchal former D. Attach the anterior shell to the posterior cradle

## **OUTCOME**

In 2010 and 2015, researchers in the United States reported 488 cases (831 ears) and 96 cases (158 ears) using EarWell non-invasively treating auricular deformation, and the success rate was 90% and 96% respectively [8-9]. In 2017 several research teams in China conducted retrospective analysis of non-invasive treatment for infant auricular deformation, including Zhao [10], Qi [11,12], Fu [13], and the success rate are all above 90%, with significant clinical outcome. Major complication includes mild skin lesion, the incidence of which is between 6 and 15%. Using antibiotic ointment and recuperating, all patients with complications recovered without scars or other deformities. The occurrence of complication is associated with patients' time of diagnosis, complexity of deformities, and also associated with doctors' experience. The incidence of complication will decrease with the promotion of orthopedic technology, increased understanding of such procedure and also accumulation of experience.

Figure 2 Typical results of auricular splinting before (left) and after therapy (right).



A. Stahl's ear B. Constricted ear C. Lop ear

China is a populous country with around 16 million newborns each year. According to the incidence survey of congenital ear deformation in selected areas of China, the rate was 50% and only 30% could recover on its own. Based on the calculation, nearly 5.6 million newborns need orthopedic treatment, which is astonishing. Fortunately, with the promotion and education, more health workers and patients' family now know more of deformation treatment, which is a significant result.

Therefore, non-surgical treatment of auricular deformation in early neonatal stage is a safe and effective approach. Doctors and patients' parents should work together and adjust at treatment window, and promote the healthy development of children with auricular deformities. This has long term and positive significance in terms of social and economic benefits.

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