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CHINA CLINICAL STUDIES III

ORIGINAL ARTICLE

The Treatment Efficiency Of a New Ear Molding Device In Infants With Congenital Ear Abnormalities

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Abstract

Objective: To observe the non-surgical treatment efficiency of a new ear molding device on congenital auricle deformities in order to promote clinical application. Method: Twenty-nine patients (38 ears) from Beijing Tongren Hospital Outpatient received ear molding treatment using the EarWell Infant Ear Correction System. We keep regular follow-up and close observation during the molding period. The treatment efficiency was judged by the Otologist, plastic surgeons and parents based on the pre-procedure and post-procedure photographs and divided into 3 grades: Excellent, good and poor. Result: Twenty-nine patients (38 ears) including prominent ear, 2 ears; cup ear, 7 ears; lidding/lop-ear deformities, 4 ears; Stahl's ear, 4 ears; helical rim abnormalities, 4 ears; conchal crus ear, 3 ears; mixed ear deformities, 4 ears; cryptotia, 5 ears; ear malformation, 5 ears; 2 patients (2 ears) stop molding after 3 days' treatment due to the low compliance of the infants. The remaining 36 ears received ear molding; all have improved. The success rate of the EarWell Infant Ear Correction System is more than 94% (good to excellent). Conclusion: EarWell Infant Ear Correction System have a significant molding effect and can achieve in early time. EarWell system has a high success rate in the treatment of neonatal auricle deformations and mild auricle malformations, depending on the severity of the deformations and the initiation of treatment time. The sooner the non-invasive molding begins (especially within one week after birth), the better effect and the shorter treatment time the patients will achieve.

Key words: Congenital Auricle Deformities; Non-Surgical Treatment; Ear Molding

INTRODUCTION

Congenital auricle malformation is mainly divided into structural malformations and morphological malformations. The former is the loss of the skin or the cartilage tissue caused by an atrophy or a dysplasia of the auricle, while the latter refers to the complete development of the auricle yet with abnormal morphology [1]. A variety of factors can lead to the occurrence of congenital auricular deformities. First, in the 5th to 9th week of pregnancy, if the embryo is poorly developed, a congenital loss of the important ear anatomy structures may occur. Secondly, the abnormal development of auricle cartilage in the late stage of embryogenesis can also lead to auricular morphological abnormalities, such as lop-ear, cup ear, protruding ear, etc., and its pathogenesis may be related to the deletion and division of single or multiple hillocks [2]. In addition, the prenatal intrauterine pressure and the birth canal resistance may also cause auricular deformities [3], and the type of deformity may relate to the direction of pressure, such as vertical pressure forming lop-ear, cup ear, and mild ring ears, and multi-directional pressure leading to irregular crimping of the flanges and etc. [4]. In addition, the auricle and the auricle inner muscle play an important role in the normal ear morphology [2]. It has been reported that abnormal insertion of the inner and outer muscles into the auricle cartilage produces an abnormal muscle motion vector and it is related to ear malformation [5].

It is well known that auricular malformation not only causes cosmetic defects in the aesthetic sense but also affects the physical (hearing) and psychological development of a child. The incidence of congenital auricular deformities is relatively high, especially in morphological abnormalities. The statistical results reveal that the incidence of the disease in newborns in Japan, China and the United States is 55.20%, 43.46% and 25.00% [6-8]. Affected by traditional treatment experience, most patients with congenital auricular deformity can only wait until 5 to 6 years old to undergo the surgery [9-10], and there are general anesthesia accidents, local scars, correction failure and other treatment risks. Before that, only observation and waiting can be done. In recent years, it has been found that the early neonatal auricle cartilage is highly plastic. In the golden shaping age, if shaping tools for early correction are applied, not only the psychological pressure of the parents will be released as early as possible, but the subsequent risk brought by invasiveness surgeries can be avoided as well. Therefore, non-invasive treatment of auricular deformity has gradually become a research hot spot in this field.

RESOURCES AND METHODS

Clinical Resources

Screening for children with congenital auricular malformations was performed in the Otolaryngology-Head and Neck Surgery Clinic of Beijing Tongren Hospital from December 2016 to March 2017. A total of 29 children (38 ears) were enrolled in the study, including 13 males and 16 females, aged from 2 to 180 days, including 10 cases of left ear malformation, 10 cases of right ear malformation, and 9 cases of binaural malformation. Specific classifications are as following: 2 cases of protruding ears, 7 cases of cup ears, 4 cases of lop ears, 4 cases of Stahl's ears, 4 cas-

es of helix deformities, 3 cases of conchal crus malformations, 4 cases of compound malformations, 5 cases of cryptotia and 5 cases of structural malformations of which 2 cases (2 ears) gave up treatment halfway. A total of 27 cases (36 ears) were treated. According to the evaluation of auricle correction effect, there are three grades: Excellent (corrected to normal shape or improvement degree > 80%), good (improved 50% to 80%) and poor (improved mildness or improvement degree < 50%). Enrollment conditions: Neonates to 6 months of age, with auricular malformations or mild structural deformities, intact auricle skin and no eczema lesions. Exclusion conditions: Age > 6 months, small ear malformation grade II, grade III (Max Classification), poor compliance, poorly cooperating with regular follow-up.

METHOD

Orthodontic Material

EarWell Infant Ear Correction System (Figure 1) was used in this study to perform the treatment. It consists of one pedestal, one to two helix tractors, one concha cavity appliance, and one perforated front cover. There is an anti-allergy tape at the bottom of the base to adhere the device to the periphery of the ear, and a pair of helix pads are arranged on the base to guide the formation of the upper foot of the antihelix. The helix tractor is concave and has a certain radian. It can fasten the helix inside and fix it on the base to shape the fossae helices while pulling the helix. The concha auriculae appliance is made according to the shape of the concha auriculae cavity. It has a certain height, and there is an opening in the external auditory canal, which can not only ensure that the downward pressure is applied to form the normal concha auriculae cavity, but also avoid blocking the external auditory canal. If the height is not enough, it can be properly increased by adhering some sponge.

Orthodontic Method

1. Skin preparation: Use a special skin knife to shave hairs 3cm around the ear; 2. Disinfection: Use an ethanol cotton sheet to clean the skin, and remove the grease with the isopropyl alcohol cotton sheet, wipe the appliance assembly with an ethanol cotton sheet, and install the bracket after drying; 3. Installation: Choose the appliance model (medium, large) based on the size of the ear, and selectively adjust the appliance according to the deformity characteristics (Figures 2a-2d); 4. Care and follow-up: Educate the parents with observation and caring methods, give timely feedback, keep weekly regular follow-up and record the ear image data.

RESULTS

29 patients (38 ears) were treated with EarWell appliances, 2 cases (2 ears) with discontinuations of treatments. 33 ears (94%) achieved successful treatment (excellent or good) and obviously improved auricle details. No obvious complications occurred. 2 cases (6%) of pressure skin lesions and 2 cases (6%) of eczema occurred, all of which healed within 3 days after dismantling the appliance.

Protruding Ears

The protruding ears are more common bilaterally, mainly due to the oversized scapho-conchal angle (the angle > 90°, usually above 150°). The auricle is slightly larger, not completely symmetrical, and the antihelix is underdeveloped. The fossae helicis and the antihelix normal anatomy structure disappeared. A total of 2 cases were included in the study. The behind-the-ear support provides an upward force on the antihelix to deepen the fossae helicis, shaping the antihelix, and pull the auricle backward to correct the auricle forward tilt. The 2 cases treated in this study were satisfactory (Figure 3).

Cup Ear

The cup ear is similar to the protruding ear, but the ear canal and the triangular cavity are narrowed and do not disappear. When the patient is lying down, the auricle looks like an upward cup. The flange is tightened, and the auricle and the auricle cartilage are curled and adhered. The crura helicis moved forward and downward. The cup ear can be accompanied by smaller, shorter and/or lower auricle. A total of 7 cases of cup ear were treated in this study with satisfactory results (Figure 4). The average correction period was 18 days.

Lop Ear

The helix folds itself, and the upper part of the auricle hangs down in a curtain-like shape, covering the upper leg of the helix, and the height of the auricle is lowered. In this study, 3 cases (4 ears) of lop ear were corrected, and the effect evaluations were excellent. All 3 cases were plasticized within 1 week after birth, and the shaping time was < 3 weeks, of which 2 cases were shaped for 2 weeks. The normal auricle morphology has been restored (Figure 5).

Stahl's Ear

Stahl's ear can be described as following: There is an abnormal protrusion between the upper leg of the antihelix of the antihelix, forming an abnormal third leg of the antihelix; the fossae helicis disappears; the upper 1/3 of the helix is flat, losing the normal aesthetic curvature, and the protruding antihelix does not curl. Normally, the upper foot of the antihelix is missing or deformed. In this study, 4 cases of Stahl's ear were treated successfully, but 1 case was accompanied by eczema, and 1 case had pressure ulcer. The treatment continued after partial treatment and suspending correction for 1 week (Figure 6).

Helix Malformation

The deformity of the helix can be described as following: The flange is not curled, and the helix is flat and even disappears. The missing of the helix does not form a normal helix curvature, and because the helix adheres to the antihelix, the ear canal may disappear due to the pressure. In this study, a total of 4 cases of helix deformities were treated, and the results were excellent after a 2-week-shaping by the helix tractor (Figure 7).

Conchal Crus Malformation

Conchal crus malformation is mainly characterized by abnormal protrusion of the middle ear and concha auriculae of the ear cavity. Some protrusions can be extended to the pair of antihelix, which is the extension of the helix leg in the concha auriculae cavity, which is known as the elongated helix leg. In this study, 3 cases of Conchal crus malformations were treated (Figure 8). The correction of the ear cavity angle was improved to different degrees. 1 case of pressure ulcers occurred, which may be related to the excessive compression of the concha auriculas by the ear cavity appliance.

Compound Malformation

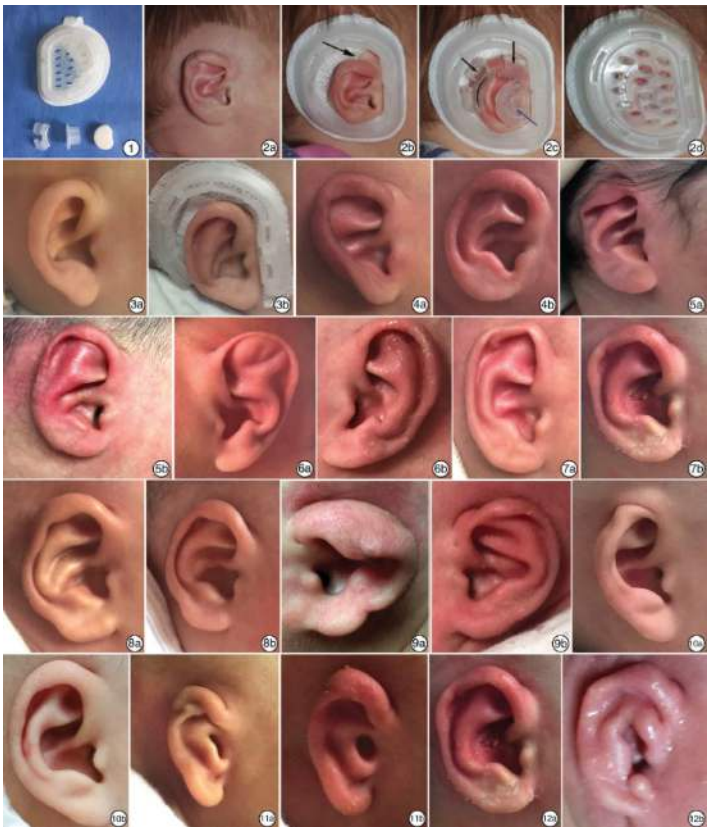
The compound malformation is characterized as a combination of two or more malformations. A total of 4 cases were included in the study, and the results were satisfactory (Figure 9).

Cryptotia

The cryptotia is also called the bag-shaped ear, which is characterized by the upper end of the auricle cartilage hidden under the skin of the scalp. The upper cranial groove becomes shallow or disappears, and there is no obvious posterior sulcus. Pulling the upper part of the auricle with the fingers can reveal the entire auricle, but when released, it is restored to its original state due to the tension of the skin and the elasticity of the cartilage. Mild patients are only short of the upper auricle; in severe cases, in addition to severe skin shortage, the cartilage in the upper auricle is also obviously poorly developed, which is character-

ized by the forward curling helix, the deformation of the fossae helicis socket, and the buckling deformation of the antihelix (Figure 10). In this study, a total of 5 patients with cryptotia were treated, and the results were excellent. The average correction time was 24 days, and 2 cases (3 ears) > 3 months, indicating that the appliance was applicable to older patients.

Figure 1



1: EarWell ear appliance assembly.

Figure 2a-2d

EarWell ear appliance installation; 2a: Before treatment; 2b: Antihelix pads on the base (black arrow); 2c: Helix tractor (black arrow), concha auriculae appliance (blue arrow); 2d: After the installation of the appliance.

Figure 3a-3b

Comparison between before and after the treatment for 4 months old children 3a: Before treatment; 3b: After 4 weeks of treatment.

Figure 4a-4b

Comparison between before and after the treatment for 8d cup ear infants, 4a: Before treatment; 4b: After 3 weeks of treatment.

Figure 5a-5b

Comparison between before and after the treatment for 7d lop ear infants 5a: Before treatment; 5b: After 2 weeks of treatment.

Figure 6a-6b

Comparison between before and after the treatment for 3d Stahl's ear infants 6a: Before treatment; 6b: After 4 weeks of treatment.

Figure 7a-7b

Comparison between before and after the treatment for 15d helix malformation infants 7a: Before treatment; 7b: After 2 weeks of treatment.

Figure 8a-8b

Comparison between before and after the treatment for 39d conchal crus malformation infants 8a: Before treatment 8b: After 2 weeks of treatment.

Figure 9a-9b

Comparison between before and after the treatment for 14d compound malformation infants 9a: Before treatment; 9b: After 4 weeks of treatment.

Figure 10a-10b

Comparison between before and after the treatment for 5m cryptotia infants 10a: Before treatment; 10b: After 4 weeks of treatment.

Figure 11a-11b

Comparison between before and after the treatment for 15d structural malformation infants 11a: Before treatment; 11b: After 2 weeks treatment.

Figure 12a-12b

EarWell complications 12a: Pressure ulcers in patients with ear canal; 12b: Eczema of auricular skin.

Structural Malformation

The structural malformation is characterized by a deformity with a partial loss of skin and cartilage. Relatively speaking, non-invasive treatment is most suitable for auricular morphological malformations, but it also has some improvement effects on some less serious structural abnormalities. This study included 5 cases of structural malformations, 2 of which were poorly shaped, with an improvement of < 50%, but a partial improvement has been achieved in auricle morphology (Figure 11).

Complications

EarWell has fewer and minor complications, mainly eczema and local skin pressure sores. A total of 2 patients (6%) had localized skin lesions in this study: 1 in the ear canal and 1 in the helix leg. Neither cases have cartilage exposure (Figure 12). The cause of the lesion is mainly excessive pressure or loose chassis, which causes the internal components to deviate from the original position. Stop wearing EarWell immediately after the appearance of the skin lesions, and keep the area clean and apply erythromycin ointment. The cases healed themselves in 2-3 days. Another 2 cases showed obvious eczema in the ear, and EarWell was temporarily removed, the Revnol was applied and both eczema cases disappeared within 2 days.

DISCUSSION

Shaping Time

Congenital auricular malformation has a high incidence in neonates, especially in auricle deformities. The cartilage is mainly composed of chondrocytes, extracellular matrix, and fibrous tissue. The ductility of cartilage mainly depends on the amount of extracellular matrix, especially hyaluronic acid, and the content of the latter is regulated by estrogen. Hung, et al (1978) reported that the level of free maternal estrogen in the body was higher within 72 hours after birth, and reached the same level as that of the older child until 6 weeks after birth. It can be seen that making full use of the plasticity of the cartilage in this golden period as early as possible for non-invasive treatment can achieve satisfactory results in detail and avoid the risk of late surgical treatment as well.

The core of non-invasive treatment of congenital auricular deformity is the process of cartilage remodeling, so timing is the most important. Early neonatal auricles have good ductility and cartilage shape, but

their hardness increases with time and plasticity are poor. Therefore, it is emphasized that non-invasive treatment should be early. The average correction time of children under 7 days of age included in this study was less than 3 weeks, and the shaping effect was more satisfactory. Despite the survey data, about 30% of patients with mild auricular morphological abnormalities can improve by themselves, and most of them occur in early period [7, 9]. The current waiting period for observation is not uniform. Byrd, et al, suggested that the auricle malformation of newborns should be re-examined 5 to 7 days after birth. If there is no self-improvement, the correction needs to be taken in time; if partial improvement, continue to observe for 1 week until no further improvement after 1 week, then perform correction in time [7]. The study found that parents are often inclined to choose timely correction because they are worried that observation waiting may delay the optimal treatment timing. For infants with compound ear malformation or delayed correction, they will experience longer the treatment time and the lower the success rate of the recovery [10].

Plastic Mechanics

The complex three-dimensional structure of the auricle makes the clinical manifestations of the ear deformity various. EarWell can personalize the ear canal, the helix, the antihelix and the ear cavity according to the fine structure of the auricle. The two helix tractor in front of the ear can compress the shape of the helix while pressing to shape the ear canal, which has an advantage in treating the patient with the helix deformity, the lop-ear, and cryptotia; the antihelix support on the base is behind the ear, and its installation should ensure consistency with the direction of the upper antihelix leg, so as to guide the formation of the upper helix leg. Meanwhile, the helix support pad can be trimmed as needed to lower the height of the support pad; the ear cavity appliance shapes of the ear cavity. At the same time, it can also be pressurized by adhering the sponge on the pad. In this study, the convex ear horn of conchal crus is used, and the ear-arm cavity appliance is used to pressurize. The results are beneficial.

Correction Cycle

The treatment cycle of EarWell non-invasive treatment is mainly affected by the initial treatment time and the degree of auricular deformity. In this study, the correction period was 2 to 6 weeks. The children who started treatment within 7 days after birth, has an average correction time less than 3 weeks, and the shaping effect was more satisfactory. Meanwhile, the treatment of simple lop-ear and cup ear deformities is often effective within 2 weeks. Similar results were found in Doft, et als, research. They treated 96 patients (158 ears) using EarWell neonatal ear deformity appliance and found that if the treatment was performed within 7 days of birth, the treatment cycle could be reduced from 6 to 8 weeks to 2 weeks. The success rate is also higher [11]. VanWijk, et al. [12] found that the initial correction time was negatively correlated with the success rate, and the duration of treatment was positively correlated with age.

Caring and Complications

The installation of the EarWell appliance is as important as later care, and improper care can lead to complications. Therefore, before the correction, the degree of deformity should be evaluated and analyzed, and the parents' expectations should be scientifically guided. Parents should carefully educate the nursing points. For example, the front cover with holes should be opened regularly to observe the skin color, wipe the skin, keep it dry to avoid rashes. During the sleeping and breastfeeding period, avoid the long-term pressure of the ear with correcting. Avoid spilling milk during feeding, and contact the follow-up visit if abnormalities are found.

The incidence of complications in EarWell appliance was relatively low. In this study, only 2 cases showed pressure lesions, but no cartilage was exposed. The erythromycin ointment was applied during the follow-up. After 3 days of treatment, the patients returned to normal and continued to be treated. During the operation, we found that improving the installation skills can effectively avoid the occurrence of pressure skin lesions, such as proper decompression of the front cover, avoiding the crossovers of the retractor and the helix support pad. Two patients developed eczema, but the degree was mild. It is considered to be related to the fact that the parents may not open the cover lid for nursing regularly, or spill the milk.

It is effective to use the EarWell ear appliance for the treatment of auricular morphological abnormalities, and the results were satisfactory in the early stage. The effect of EarWell correction depends on the severity of the auricular deformity and the time at which the correction begins. The earlier the non-invasive treatment begins (within 1 week after birth), the better the effect, and the shorter the wearer's wearing time.

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