Application Of Non-Invasive Correction of Congenital Auricle Deformity

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Abstract

Objective: To investigate the application of noninvasive correction of congenital auricle deformity, and to analyze the cure rate and the causes of incidence of complications. Methods from January 2015 to December 2016, 33 patients with unilateral or bilateral congenital auricle deformities were treated with non-surgical correction technique in the Plastic Surgery Department of Guangzhou General Hospital. When the treatment was completed, the VAS score was used to assess the satisfaction of the patients' parents. Results from January 2015 to December 2016: 33 patients (53 ears) received non-invasive treatment of the ear deformity correction system. The average age of the patients was (63.5 ± 41.3) days, the average treatment time was (41.6 ± 15.4) days, and the average parental satisfaction was (3.76 ± 0.93; total score: 5 points). Significant difference was observed in auricle morphology data between pre- and post-treatment, except for cranioauricular angle ($P < 0.05$). Conclusions in this study: The cure rate for non-surgical correction was good; however, the satisfaction of treatment decreased with age. The most common complication of treatment was auricle skin damage. The reasons of causing complications may be the age, induced reduction of ear cartilage elasticity which brought great pressure on the ear, and the increase of the treatment time.

Key words: Ear, Auricular Deformity, Non-Invasive Correction

INTRODUCTION

Some foreign scholars have divided the neonatal auricular deformity into auricular dysplasia and auricular deformation [1]. Some scholars have found that the incidence of neonatal auricular deformities is still as high as 11.5/10 000 excluding patients with microtia [2]. In the preliminary survey of the Pearl River Delta region conducted by the Qi Xiangdong team [3], the incidence rate of auricular deformity is 43.46%. Foreign scholars use ear molds for non-surgical correction. This method is suitable for newborns with congenital external auricle morphological abnormalities in early birth. It can shape a satisfactory auricle shape for patients, and the incidence rate of complications is lower than surgical correction. [4]. A large number of maternal estrogens in the neonatal circulatory system increase the ductility and plasticity of the cartilage. This principle is used to mechanically correct the deformed auricle of the newborn, to avoid the risk and trauma of surgical correction at school age. The most commonly affected anatomical sites of patients with auricular deformity are the auricle and antihelix. This part of the auricle cartilage is relatively thin and soft, which also provides anatomical feasibility for the development of the ear molding technique. There is no report or research on systematic clinical application of non-surgical treatment for external auricular deformity in China. This study aims to provide demonstrations of treatment effects and relevant data analysis, to explore investigate the application of noninvasive correction of congenital auricle deformity, and to analyze the cure rate and incidence of complications, provide clinical data support for the development and promotion of this technology in China.

OBJECTS AND METHODS

Objects of Study

From January 2015 to December 2016, non-surgical correction techniques (EarWell Infant Ear Correction System) were used to treat 33 neonates with unilateral or bilateral congenital external auricular deformities (53 diseased ears) from the Guangzhou General Hospital of Guangzhou Military Region. The patients enrolled in the study were diagnosed with different types of congenital external auricular deformities via orthopedic surgeons. According to Byrd [1], the classification included: constricted ear, cryptotia, helix deformity, prominent ear, cup ear, laterally protruding ear, Stahl's ear, compound ear malformations, and degree I mictotia. Children with the following conditions were excluded from the study: Patients with degree II and III mictotia, age > 3 months, weight < 2.5 kg, gestational age < 34 weeks.

During the study, a total of 33 patients underwent noninvasive treatment with the EarWell ear deformity correction system, including 25 males (42 diseased ears) and 8 females (11 diseased ears). The mean age of patients was (63.5 ± 41.3) days (2-153 d). The external auricular deformities types of the children involved in the study included 4 (7.5%) cases with constricted ear, 10 cases (18.9%) with cryptotia, 4 cases (7.5%) with floppy ear, and 4 cases (7.5%) with helix deformity, 3 cases (5.7%) with prominent ear, 9 cases (17.0%) with cup ear, 7 cases (13.2%) with Stahl's ear, 5 cases (9.4%) with compound ear deformity and 7 cases (13.2%) with mild microtia. Only 3 patients had a family history of ear deformity, 2 patients complicated with craniosynostosis at birth, and 1 with neonatal pneumonia.

Methods of Study

At the initial visit, the patient underwent standard photo shooting and 3D laser scanning, and ear morphology data collection and epidemiological investigation. The measured auricle morphological data included: Morphological ear length, morphological ear breadth, physiognomic ear length, and physiognomic ear breadth, the vertical distance between the ears, and the cranioauricular angle. All patients wear ear molding correctors 24 hours per day, and the treatment shall continue until the anatomical structure of the auricle was normal for 2 weeks or until treatment for up to 2 months. If severe skin irritation or skin ulceration occurs, stop treatment immediately. Parents completed demographic and family history surveys at the initial visit, and received followed up after treatment to investigate auricle morphology data, satisfaction, ease of use, and complications. The Visual Assessment Scale (VAS) was used to evaluate the treatment satisfaction, with a score of 0-5. The higher the score, the higher the satisfaction.

Statistical Methods

The measured data of the simulated normal distribution were expressed as $x \pm s$, and the paired sample t test was used to determine the changes in auricular morphology pre- and post-treatment. The difference was statistically significant at $P < 0.05$. SPSS13 (IBM Inc, U.S.A.) is used for data processing and data analysis.

RESULTS

Clinical Effects

The mean duration of treatment for patients was 41.6 ± 15.4 days (14-60 days). The treatment effect was good, with obvious comparison pre- and post-treatment (Figure 1). The auricular data pre- and post-treatment were significantly different except for cranioauricular angle ($P < 0.05$) (Table 1). The mean parental satisfaction was 3.76 ± 0.93, and 84.8% of parents thought the treatment was effective (score ≥ 3). The best results were achieved when the corrector was applied to the newborns within 2 weeks of birth (mean satisfaction: 4). If the corrector was applied after 6 weeks of birth, the satisfaction of the orthopaedic condition is reduced (mean satisfaction: 3.5).

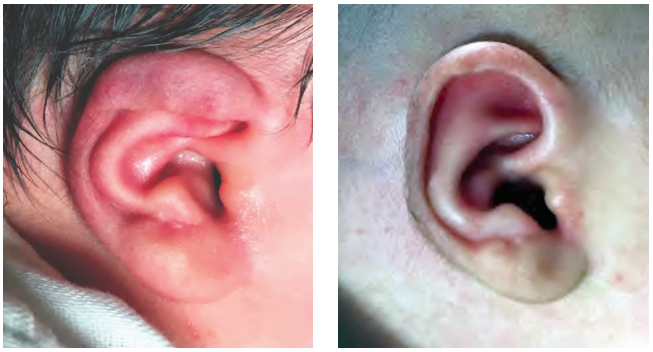
Table 1

The paired sample t test of auricle morphology data between pre- and post-treatment x ± s, mm

Measurement indicators of auricular morphology	*Pretreatment measurements*	*Post-treatment measurements*	*Standard Deviation*	*P value*
Morphological ear length	36.36 ± 5.98	40.21 ± 5.08	0.98	0.004
Physiognomic ear length	19.90 ± 4.23	22.08 ± 3.61	0.62	0.008
Morphological ear breadth	27.23 ± 3.43	30.07 ± 3.57	0.33	0.000
Physiognomic ear ear breadth	28.57 ± 3.12	31.88 ± 3.35	0.25	0.000
Vertical distance between skull and ears	11.50 ± 2.28	9.27 ± 1.98	0.32	0.000
Cranioauricular angle	43.94 ± 31.33	35.28 ± 21.02	3.92	0.058

Figure 1

Presented are examples of pre-treatment (a) and post-treatment (b) photographs of a child with a lop ear.



Complications

There were 8 patients (7/8 were over 6 weeks old) presented with auricular skin damage, among which 3 cases developed with mild pressure sores. All the patients with complications recovered completely without scars or other deformities.

DISCUSSION

There is no systematic clinical application reports on non-surgical correction of auricular deformity in China. This study takes the lead. In this study, the auricle morphology (including the morphological ear length, morphological ear breadth, physiognomic ear length, physiognomic ear breadth, and the vertical distance between the ear and the skull) changed significantly pre- and post-treatment. The length of the ear, the increase of auricle, and the narrowing of vertical distance between ear and skull means that the patient's auricle morphology is more consistent with anatomical standard. Parents' higher satisfaction to the treatment effect also confirmed that such non-surgical correction treatment has a good cure rate, which is worthy of further promotion and application. At the same time, the early non-surgical treatment saves costs compared with school-aged surgery, reduces the incidence of complications, and avoids the pain of invasive treatment [2].

Compared with conventional non-surgical correction methods, the silicone ear molding method is simpler, more convenient and safer. The conventional method uses a metal wire that is cut and pre-bent to match the length and curvature of the normal flange, and cotton, fabric or plastic hose is wrapped around the wire to form a metal splint fit for the shape of the auricle, and is applied with plastic tape to adhere to the skin behind auricle so that the preformed metal splint is fixed along the base of the auricle, reshaping the auricle and antihelix [6]. [1-3, 5-7]. However, the sharp end of the metal wire may cause damage to the auricle skin of the newborn. Numerous reports have shown that the use of non-surgical corrections in the neonatal period to treat external auricle deformation is clinically significant [1-3, 5-7]. In 2010 and 2015, American scholars reported 488 cases (831 diseased ears) and 96 cases (158 diseased ears) of non-invasive neonatal auricle correction using the ear orthoses reported in this study. The response rates are 90% and 96%, respectively [1, 5].

Compared with foreign treatment data, the response rate of this clinical treatment is low. This may be due to the fact that the age of the child's visit is elder than that of the foreign country. The mean age of the patients in this visit was far elder than 6 weeks. The best treatment time has been missed, the auricle cartilage was harder than the newborn, and the molding ability was worse. The author took a prolonged treatment time to achieve better results, but the treatment effect was still affected. At the same time, the increased resistance between the hardening ear cartilage and the ear molds might be the reason why the patients in this study were more prone to have complications of skin damage and pressure sore than the literature reported [5]. The auricle cartilage has very good plasticity in the newborn period. This is due to the presence of maternal estrogen in the neonatal systemic circulation, which peaked on d3 after birth and returned to baseline at week 6. The plasticity of neonatal auricular cartilage is closely related to the content of hyaluronic acid, which is the main component in auricular cartilage, increases with the elevation of circulating estrogen. Therefore, the newborn ears are soft and moldable during this period, which provides a short time window for non-surgical correction. After 6 weeks old, as the estrogen returned to normal limits, the newborn's auricle became more elastic and rigid, and lost good plasticity. The increasing wear time with age grow can also lead to more complications. In this study, the duration of wearing the ear mold was determined according to the age, the hardness of the ear cartilage, the type of ear deformities and the treatment process. The treatment duration for children aged < 1 week was no more than 2 weeks, for 1-6 weeks old Children was within one month, and for children aged > 6 weeks can be treated for up to 2 months. Patients with cryptotia and some patients with cup ears need to be corrected in 2-3 stages, and the duration of treatment can be extended. During the treatment, the treatment duration can be shortened or extended according to the treatment effect. For example, if complications such as skin damage and pressure sore occur, the treatment can be suspended and continued after the tissue is healed. Data have shown that if the ear can be corrected within 6 months old, it can lead to a life-changing auricular anatomy [8]. Non-invasive correction of ear mold for congenital auricular deformity is an effective treatment, which has the advantages of non-invasive, simple, definitive curative effect and less complications. It is worthy of promotion and application. This technology advocates early treatment to avoid prolonged treatment and increased incidence of complications.

In this study, given the facts that the sample scale is small and the age of the visited patients is too old, the measurement error of the auricle morphological data is high, and the evaluation of the efficiency may have errors. Based on humanistic care, this study didn't set up the blank control group that contains patients with ear deformities who give up treatment. Therefore, the self-healing rate of ear deformities was not evaluated, and the judgment of treatment effect was also biased. The further phase of clinical trials for observation based on larger scale of sample and supplement of blank control was pending to be done.

In addition, for patients with over-aged ear deformities, there is still hope for non-invasive correction to avoid the pain of long-term surgery. Some scholars have reported the applications of laser-assisted ear mold in the treatment of adult prominent ears [9], the principle is to reshape the auricle cartilage by laser-assisted cartilage reshaping (LACR) technique [10]. It is necessary to uniformly heat the whole layers of cartilage to achieve stress relaxation without damaging the chondrocytes and matrix.

LeClere, et al, [10-11] used 1 054 and 1 064 nm Nd:YAG lasers to irradiate the of adult patients with prominent auricles respectively, and then used silicone ear mold to reshape the auricle shape and achieved good results. This technology provides a novel treatment notion and is instructive for the future treatment of non-invasive ear malformation in children over the age of treatment and even adults. At the same time, the development of new technologies such as 3D printing and its increasingly widespread application in medicine have made personalized treatment possible [12].

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