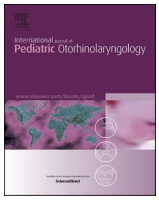
International Journal of Pediatric Otorhinolaryngology 178 (2024) 111876

Contents lists available at ScienceDirect

International Journal of Pediatric Otorhinolaryngology

journal homepage: www.elsevier.com/locate/ijporl



Analysis of the effect and influencing factors of EarWell auricle orthosis in the treatment of congenital auricle deformity in children

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ARTICLE INFO

Keywords:
Auricle deformity
Orthoses
Correction
Congenital
Complication

ABSTRACT

Objective: To observe the efficacy of EarWell ear orthosis in treating children with different types of ear deformities.

Methods: We selected 80 children aged <6 weeks with ear deformities (110 ears: 15, 30, 21, 25, and 19 ears with prominent ear, lop ear, cup ear, cryptotia, and helical rim deformity, respectively). Differences in effectiveness rate, treatment time, and incidence of complications among children with different types of auricular deformities were compared. Recurrence rates at 1 and 3 months after the treatment were compared.

Results: The overall success rate was 92.73 %, and the treatment effectiveness rate did not differ significantly among the children with different types of auricular malformations ($P > 0.05$). The correction time of the helical rim deformity was the shortest, and the correction times of the prominent and cup ears were significantly longer than those of the other groups ($P < 0.05$). The incidence of complications associated with helical rim deformity and lop ear was lower, and the incidence of prominent and cup ear complications was significantly higher than that in the other groups ($P < 0.05$). The recurrence rate in children with prominent and cup ears was higher at 1 and 3 months after correction, and children with a lop ear and cryptotia showed no recurrence at 1 and 3 months after treatment, which correlated with the correction time, incidence of complications, and recurrence rate ($P < 0.05$)

Conclusion: The EarWell auricle orthosis is an effective treatment in children with auricular morphological malformations. Correction time, complication rate, and recurrence rate were related to the malformation type.

1. Introduction

The incidence of congenital auricular malformation is relatively high; the incidence of neonatal auricular deformity in the Pearl River Delta area was 57.46 %, and the self-correction rate was 31.55 % at the 30-day follow-up [1]. Clinically, it is generally divided into seven categories based on its shape and location, including prominent ear, lop ear, Stahl's ear, cup ear, cryptotia, helical rim deformity, and compound ear malformation. Cryptotia is a common congenital ear deformity in Asian populations, where the upper third of the auricle is buried under the temporal skin. Stahl's ear is an anomaly of the external ear, characterized by a third crux in the antihelix. Auricular orthoses are mainly suitable for congenital malformations of the auricle and mild ear development abnormalities, including ringed ears and cryptotia [2]. The EarWell ear molding system was first introduced to China in 2015. The EarWell device costs approximately 10,000 RMB in China and cannot be covered by any medical insurance plan. This study used EarWell's auricle orthosis to correct congenital malformations of the auricle in children and analyze the corrective effect and related influencing factors to provide a certain reference value for clinical application.

2. Materials and methods

2.1. Research participants

We conducted an analysis of 80 children (110 ears) aged <6 weeks, including 43 males (59 ears) and 37 females (51 ears) with congenital auricular malformations who visited the hospital from June 2019 to June 2021. prominent ear, lop ear, cup ear, cryptotia, and helical rim deformity were observed in 15, 30, 21, 25, and 19 ears, respectively. This study was approved by the hospital ethics committee, and the parents of the patients signed an informed consent form.

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https://doi.org/10.1016/j.ijporl.2024.111876
Received 28 October 2023; Received in revised form 10 January 2024; Accepted 25 January 2024
Available online 8 February 2024

2.2. Inclusion and exclusion criteria

2.2.1. Inclusion criteria

①Aged <6 weeks; ② Abnormal shape or mild structural abnormalities of the auricle; ③ The skin of the auricle is intact, without eczema or skin lesions; ④ No external auditory canal or middle ear lesions.

2.2.2. Exclusion criteria

①Age >6 weeks; ② Small ear malformation grades II and III (Max classification) [3]; ③ Poor compliance and inability to follow up regularly.

2.3. Method

The EarWell ear orthosis (USA) was used for shaping, and at least one follow-up visit was performed per week; the position of the orthosis was adjusted according to the improvement in the auricle shape. The orthosis was worn for 1 week after the shape was satisfactory; in cases of no improvement in the shape of the auricle after continuous wearing for 3 weeks, the treatment was discontinued [4]. A schematic diagram of the appliance accessories and the orthodontic process is shown in Figs. 1 and 2.

2.4. Complication management

During the follow-up, we carefully observed the skin for eczema, pressure ulcers, etc. When complications such as skin ulcers or eczema occurred, we temporarily removed the orthosis and reinstalled it after returning to normal.

2.5. Efficacy evaluation criteria

① Healing involves correcting the shape of the auricle to its standard shape; ② Effectively improving the appearance of the auricle compared to before correction, but not reaching normal appearance; ③ Ineffectiveness means no significant improvement compared to before correction. Effectiveness rate = (cured + effectiveness) number of cases/total cases × 100 %.

2.6. Statistical analysis

Statistical analysis was performed using SPSS 22.0. Quantitative data ($x \pm s$) that conformed to normal distribution were compared between groups using F-test; Qualitative data (%) was used for inter-group comparison χ^2 inspection. Statistical significance was set at $P < 0.05$. Pearson correlation analysis was used for correlation analysis, with $P < 0.05$ indicating a significant correlation.

Fig. 1. Ear molding systems.

3. Results

3.1. Correction effect

The overall success rate was 92.73 %, and the success rate of helical rim deformation was 100 %. The treatment effectiveness rate of children with prominent ears, lop ear, cup ear, cryptotia, and helical rim deformity did not differ significantly ($P > 0.05$). Eczema was the only complication encountered in this study; when it occurred, the orthosis was removed for 1–3 days. No severe complications, such as skin ulcers, necrosis, or exfoliative dermatitis, occurred (Table 1). The typical cases are shown in Figs. 3–7.

3.2. Comparison of correction time, incidence of complications, and recurrence rate among children with different types of deformities

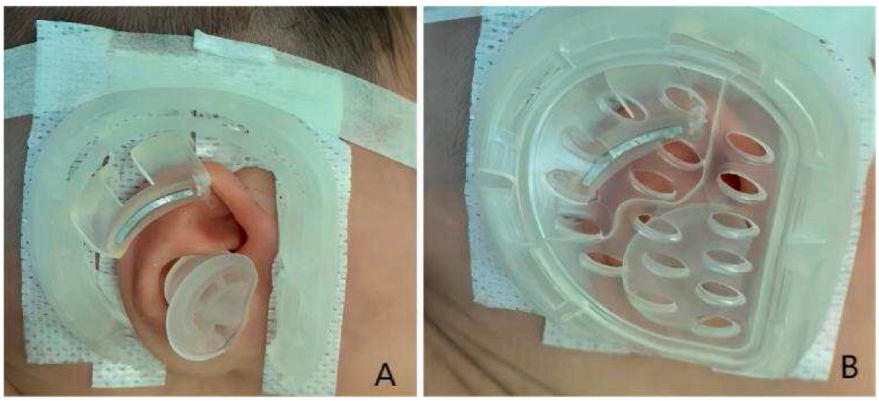
The correction times for different types of malformations in children were compared, and the correction time for helical rim deformities was found to be the shortest. The correction time for the prominent and cup ears was significantly longer than that of the other groups, with a statistically significant difference ($P < 0.05$). The incidence of complications in children with different types of deformities was compared. The incidence of complications in the prominent and cup ears was significantly higher than that in other groups, with a statistically significant difference ($P < 0.05$). Regarding the recurrence rates of children with different malformations, there was no recurrence after 1 and 3 months of observation for children with lop ear and helical rim deformity. The recurrence rate was higher in cup ears (Table 2).

3.3. Correlation analysis between types of auricular malformations and treatment time, incidence of complications, and recurrence rate

There was a correlation between the type of auricular malformation and the treatment time ($r = 0.381$, $P = 0.015$), the incidence of complications ($r = -0.132$, $P = 0.004$), and the recurrence rate ($r = 0.651$, $P = 0.001$) (Table 3).

4. Discussion

Although not causing hearing impairment, congenital auricular malformation is a common congenital malformation that can affect facial aesthetics and even lead to abnormal psychological development in children [5]. Traditionally, treatment is delayed until the child turns 6 years old before undergoing auricular plastic surgery. This treatment method carries risks and may also result in late complications, such as postoperative pain, hematoma, infection, scars, and recurrence of deformities [6]. EarWell ear orthosis corrects newborn ear deformities non-invasively, avoiding surgical trauma and opening up a new path for treating ear deformities. A study from China suggests that the EarWell system has a high success rate in treating neonatal auricle deformations, and the sooner non-invasive molding begins (especially within 1 week after birth), the better the effect and the shorter the treatment time [7]. Our study reported similar results to theirs. In a retrospective study, Charipova et al. [8] developed a tailored approach for each specific type of ear deformity. The use of modifications to adapt standard ear molding techniques for each unique ear malformation has been described; however, for children with different types of deformities, EarWell ear orthosis can use its components (screw tractors, shaping sponge, conchal former, and different anterior shells) to achieve good corrective effects. The success rate of this study supports the above viewpoint. Xiong et al.



A. Place ear supports, traction devices, and accessories; B. Fixed ear cover

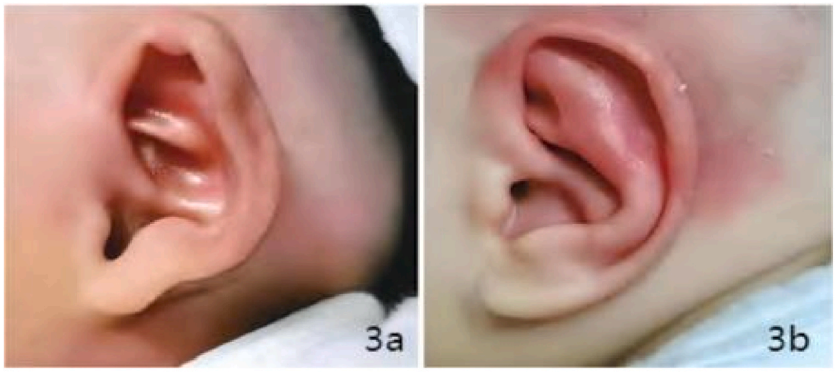
Fig. 2. Orthopedic placement process.

Table 1
Treatment effects of different types of malformations in children.

type of malformation	ear count	effective/[Ears (%)]
prominent ear	15	13(86.67)
lop ear	30	28(93.33)
cup ear	21	18(85.71)
cryptotia	19	18(94.74)
helical rim deformity	25	25(100.00)

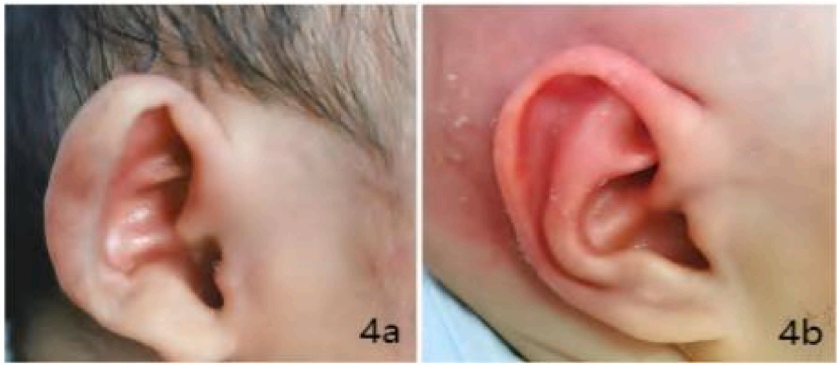
[9] analyzed the differences in effectiveness between the two ear molding systems. The effectiveness rate was comparable between the EarWell and LiangEar systems for the four types of auricular deformities; however, the costs for the LiangEar systems were half as much as those for the EarWell systems. This is good news for children from rural families as they have the option of cheaper LiangEar systems. However, further research is required to determine the differences in the incidence of complications between the two ear molding systems during the treatment process.

The theoretical basis for the treatment of congenital auricular



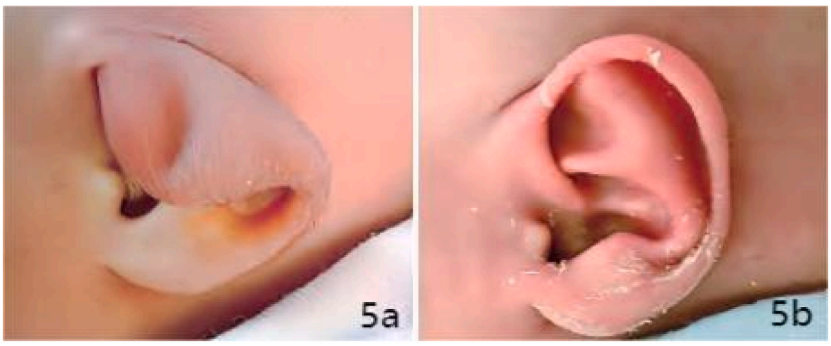
7-day-old child. 3a. Before correction; 3b. Eleven days after correction.

Fig. 3. A child with helical rim deformity before and after correction.



5-day-old child. 4a. Before correction; 4b. Three weeks after correction.

Fig. 4. A child with a cup ear before and after correction.

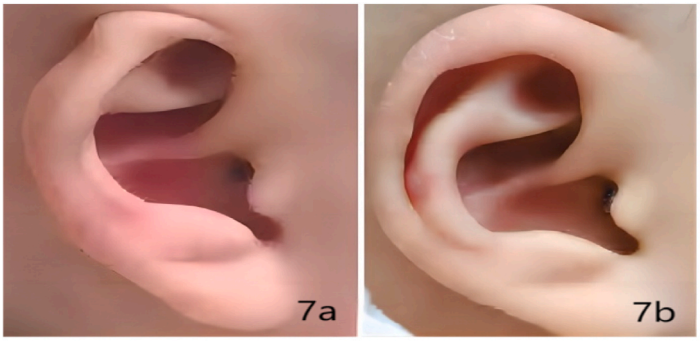


3-day-old child. 5a. Before correction; 5b. Nineteen days after correction.

Fig. 5. A child with lop ear before and after correction.

20-day-old child. 6a. Before correction; 6b. One month after correction.

Fig. 6. A child with prominent ear before and after correction.



35-day-old child. 7a. Before the correction, 7b. Twenty-four days after the correction

Fig. 7. A child with cryptotia before and after correction.

Table 2
Comparison of correction time, incidence of complications, and recurrence rate among children with different types of deformities ([¯x ± s, ear (%)]).

type of malformation	ear count	correction time/day	Complication	1-month recurrence rate	3-month recurrence rate
prominent ear①	15	38.13 ± 9.28*	5(33.33)	1(6.67)	2(13.33)
lop ear②	30	21.07 ± 4.23*#△	4(13.33)#△	0(0.00)△	0(0.00)△
cup ear③	21	42.18 ± 8.08*	8(38.10)	1(4.76)	3(14.29)
cryptotia④	19	20.51 ± 4.65*#△	4(21.05)#△	1(5.26)△	2(10.53)△
helical rim deformity⑤	25	15.16 ± 4.35	3(12.00)#△	0(0.00)△	0(0.00)△

Note: * represents a comparison with ⑤, $P < 0.05$; # Compared with ①, $P < 0.05$; △ represents a comparison with ③, $P < 0.05$.

Table 3
Correlation analysis of deformity types with correction time, incidence of complications, and recurrence rate.

	type of malformation	
	correlation coefficient	*P-value*
correction time	0.381	0.015
incidence of complications	−0.132	0.004
recurrence rate	0.651	0.001

malformations with auricle orthosis is the changes in estrogen levels in newborns, which reach a significant peak within 72 h after birth, then gradually decrease, returning to normal levels at 6 weeks after birth; the plasticity and ductility of cartilage also decrease accordingly [10–12]. Byrd et al. [2] found an excellent correction in 488 children (831 ears) treated within 7 days after birth; however, the effectiveness was only 50 % when treated after 3 weeks of birth. Yotsuyanagi [13] found that the treatment success rate for children with auricular deformities aged 0–1 months reached 91.3 %, decreasing to 80.7 % at 1–3 months. The efficacy rate was only 33.3 % by the age of 9 years. Zhou et al. [14] compared the corrective effects in children grouped according to their age and found that the effect of wearing appliances in newborns can reach 100.00 %; however, the effectiveness decreases to 72.73 % at 2–3 months of age. Chen et al. [15] observed 91 ears and found that 85.8 % of patients were successfully corrected. Early molding (<14 days) resulted in a significantly higher success rate. In this study, 80 children (110 ears) received EarWell ear orthosis treatment within 6 weeks of birth, with a total effectiveness rate of 92.73 %. The treatment effectiveness rate for children with ear malformations was 100 %. Therefore, early detection and treatment are recommended in children with congenital auricular malformations.

Zhao et al. [1] observed that the self-correction rate of auricular malformations at 30 days of birth was 31.55 %, with the helical rim deformity having the highest self-correction rate (42.78 %), followed by the loop ear (42.55 %). This study found that the correction rate for lop ear and helical rim deformity were good (93.33 % and 100 %, respectively), and the wearing time of the appliance was shorter [(21.07 ± 4.23) and (15.16 ± 4.35) days, respectively]. No recurrence was observed 1 or 3 months after the completion of correction. Byrd et al. [2] recommended that children with congenital auricular malformations undergo follow-up examination 5–7 days after birth, and if there is no improvement, they should wear orthotics promptly. Tian et al. [16] believed that children with mild auricular malformations should have a window period of 14 days, and those who cannot self-heal should receive further correction; some scholars believe that the self-correcting rate of auricular malformations is relatively low, while the success rate of orthodontic treatment is over 90 %. Authors advocated that children with auricular malformations should be treated directly after birth without observation [17,18]. Clinically, it has been found that the earlier the correction, the better the effect. However, considering a self-correcting rate of approximately 30 % for auricular and milder deformities, especially in children with a loped ear and helical rim deformity, observation can be carried out for 7 days after birth. The observation can continue for 2 weeks if there is improvement. Early correction is recommended for children with severe deformities or a family history.

Zhao et al. [1] believe that there is generally no self-correcting tendency in the development of prominent ear, and the incidence rate has increased from 3.1 % at 7 days of birth to 4.6 % at 30 days. This may be one of the reasons affecting the effectiveness of correcting prominent ear. This study found that the effective rates of corrective treatment for prominent and cup ears were relatively low (86.67 % and 85.71 %, respectively), and the recurrence rate was relatively high at 1 month and 3 months after the completion of corrective treatment. In addition, the correction time for prominent and cup ears was longer than for other types of deformities, and the incidence of complications was higher. Therefore, we recommend early correction for children with prominent and cup ears to avoid prolonged observation waiting that may affect the effectiveness of the treatment. The incidence of complications during the wearing process of EarWell orthosis is relatively low, mainly including pressure ulcers, eczema, etc. We observed that the occurrence of these complications is mainly related to environmental temperature and longer treatment time. We did not observe any other complications such as necrosis or severe infection.The orthosis is removed during orthodontic treatment, and the skin is cleaned and disinfected. When necessary, an antibiotic ointment was applied externally. After the skin returns to normal, the orthosis is continued. To reduce the occurrence of complications, it is required that the child be followed up at least once a week to observe the condition of the auricle skin. The incidence of complications during treatment was related to the type of auricular malformation, with the incidence of complications in prominent and cup ears being significantly higher than in other groups. It may be related to the longer treatment time for children with the above two types of deformities and the prolonged contact between the orthosis and the skin. Therefore, parents should be fully informed of the treatment time and complications before correction for children with prominent and cup-shaped ears, and the frequency of follow-up should be increased.

Early detection and correction are still the treatment principles for children with congenital auricular malformations. In the future, it will be necessary to strengthen the promotion of non-invasive correction techniques for newborns with ear deformities, thoroughly observe the factors that affect the correction of auricular deformities, and further improve the treatment success rate.

CRediT authorship contribution statement

Jie OuYang: Formal analysis, Methodology, Data curation, Writing – original draft. **Xiaoqin Wang:** Writing – review & editing, Modify, Data curation.

Declaration of competing interest

The author(s) declared no potential conflicts of interest with respect to the research, author-ship, and/or publication of this article.

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