

Comparison of the treatment duration and nursing requirements of the EarWell infant ear correction system for different types of auricle deformities



Original Article

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Abstract: **Objective:** To observe whether the EarWell infant ear correction system makes any difference in terms of the treatment effect, duration, complication rate, and nursing care requirements in different types of infant auricle deformities.

Methods: A total of 93 infant patients with auricular deformity (age: <3 months of age) who were diagnosed and treated in Guangzhou Children and Women's Medical Center from April 2018 to September 2020 were selected and treated with the EarWell infant ear correction system. We observed and recorded the effects of the EarWell infant ear correction system, the treatment duration, the number of rebound cases, and complications that are likely to occur during treatment, and noted the related factors causing complications and the relative requirements for nursing care.

Results: The Earwell infant ear correction system could effectively correct infant auricle deformities. Among the 93 cases, 90 cases had positive therapeutical outcome and the effective rate was 96.77%. The treatment duration for lop ear and protruding ear was longer than for other auricle deformities; the deformity recoil and the treatment compilation rates were much higher for these 2 deformity types, and the difference was statistically significant ($P < 0.05$).

Conclusions: The treatment suggestion for the wearing duration of the EarWell infant ear correction system for lop ear and protruding ear is a prolonged duration compared with that for other infant auricle deformities. Further, the requirements for nursing care intensity and infant patient's guardian's nursing knowledge and skill are obviously increased for these 2 types of auricle deformities.

Keywords: complication rate • correction effect • EarWell infant ear correction system • infant auricle deformities • nursing care and patient guardian education • treatment duration

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1. Introduction

Infant auricle deformities with a relative high prevalence rate are divided into 2 major types: morphological and structural abnormalities. Surgical correction is advocated for structural abnormalities. The focus of this research is on morphological abnormalities treated with the noninvasive EarWell infant ear correction system.

Morphological deformities refer to the distortion of the auricle caused by ear attachment to the muscle, dysplasia, or abnormal force without obvious sufficient cartilage.^{1,2} Some of the morphological deformities are temporary lasting about a month; however, majority of them need medical intervention in a timely manner.

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Common morphological deformities include protruding ear, Stahl's ear, lop ear, cup ear, cryptotia ear, conchal crus ear, mixed ear deformities that combine more than 2 deformities, and other kinds of auricular deformities.²⁻⁶ During the correction therapeutic process, we found that the treatment course and recoil rates for the different deformities are significantly different. These differences can guide clinical practice related to the EarWell infant ear correction system, such as to indicate the treatment end point and provide different guardian home-nursing-care education programs for individual auricle deformities. With the well-implemented guardian home-nursing-care education program, the guardian can identify the recoil case and inform the physician for prompt care plan with an adjusted nursing care plan.

2. Materials and methods

2.1. Subjects

A total of 93 auricle deformities treated with the EarWell infant ear correction system in Guangzhou Children and Women's Medical Centre were included in our observation study. The mean age at the initiation of the correction system treatment was 32.87 ± 19.44 d. The types of auricle deformities included lop ear (19 cases), protruding ear (14 cases), cup ear (10 cases), constricted ear (17 cases), cryptotia ear (8 cases), helical rim ear (15 cases), and Stahl's ear (10 cases). The inclusion criteria were as follows: (1) infants with clinical diagnosis of auricle deformities; (2) the observation period was from 1 week to 1 month after birth (individual deformity types required different observation courses); and (3) the babies were all <3 months old. The exclusion criteria were as follows: (1) babies older than 3 months of age at the time of initiation of therapy; (2) skin problems around the ear that need to be treated; (3) ear malformations characterized by a partial absence of the skin or cartilage, requiring surgical correction; and (4) a history of allergic reaction to adhesive tape.

All patients' guardians were informed regarding the study protocol, and they signed the consent form. In addition, the patients' guardians received a modularized nursing care education program, which included how to maintain the tape, as well as daily care to prevent inflammation symptoms and other complications; the critical parts detail how to identify the relative auricle deformity recoil.

2.2. Methods

2.2.1. Correction materials

The EarWell correction system is mainly composed of a base, an outer cover, a retractor, and an ear concha

cavity orthosis. The material is made of medical polyurethane thermoplastic elastomer material, which is nonirritating, nonsensitizing, and nontoxic to baby skin. The material is soft and has a certain degree of toughness to maintain a certain shape, and its clinical complications are minor and few. Skin ulcers, necrosis, or exfoliative dermatitis caused by stress reactions rarely occur, as recognized by auricular orthopedic therapists.

2.2.2. Steps in the correction method

- (1) Assess the size of the auricle of the infant to select an appropriate orthosis.
- (2) Skin preparation: remove 3 cm of hair around the ears of the infant.
- (3) Degreasing: apply alcohol cotton pads to degrease the skin for the mounting base and tape.
- (4) Position during EarWell system installation: The infant is carried in the arms by the parents, lying on his or her side, with the treatment ear facing up. The breastfeeding or sleeping condition will facilitate the installation process.
- (5) Put the base, traction hook, and ear concha cavity into proper position. Regular weekly return visits to the outpatient clinic are advised, and the position of the corrector is adjusted according to the specific improvement in the shape of the auricle. After obtaining satisfactory auricle correction effect, the EarWell system is kept in place for another 7 d. Fix with tape for another week when further correction treatment is necessary and then end the treatment and continue to observe.
- (6) Nursing and follow-up: Educate the parents about nursing methods, such as not allowing the eardrums to retain water; the method to strengthen the tape after relaxation (nursing package with a roll of tape); to observe the position of the treatment module; and contact the health-care provider when the skin color changes any time. The image of the affected ear is retained at each visit.

2.3. Analysis of the effectiveness and treatment duration for the EarWell System

2.3.1. Evaluation of correction effect

The effect rating was divided into 3 grades⁷: excellent (normal), good (basically normal with slight deformity), and poor (slight or no improvement in morphology).

2.3.2. Determination of time of correction effect

After removing the EarWell system, the health-care provider will evaluate the final treatment effect 6 months later. If symptoms of rebound are found during the period, parents should inform the health-care provider, re-wear the EarWell system to continue intervention, and extend the treatment duration accordingly.

2.4. Statistical analysis

The statistical software SPSS 21.0 (IBM Corporation, Armonk, New York, United States) was applied for data analysis. The enumeration data were expressed as percentage and number of cases, and χ^2 test was used for comparison between groups. The measurement data are represented by ' $\pm s$ ', which is in line with the data of the positive distribution. The t -test was used for comparison between groups, and the nonparametric test was used for data that do not conform to the positive distribution. A value of $P < 0.05$ was regarded as statistically significant.

3. Results

3.1. Comparison of different types of correction effects

The overall correction effect of the EarWell System was significant: the total rates of excellent and good effects were 96.77%, and the rate of poor correction effect was 33.33%. Among the 7 types of deformities, cup ears, constricted ears, cryptotia ears, helix deformities, and Stahl's ear showed no significant difference in the correction effect in terms of excellent, good, and poor outcomes ($P = 0.13$). There was a statistically significant difference in the ratio of excellent, good, and poor correction effects for other types of auricle deformities. There was a statistically significant difference in the ratio of excellent, good, and poor correction effects for lop ears, protruding ear ears, and other types of auricle deformities.

3.2. Comparison of rebound rates, EarWell wearing times for different types of ear deformities, correction effects, and complication rates

There was no significant difference in the correction days for cup ear, constricted ears, cryptotia ear, helix deformities, and Stahl's ear, and there was no rebound during the correction process. The rebound rates of protruding and lop ears were, respectively, 28.6% and

31.6% higher than those for other auricle deformities and the difference was statistically significant. The statistical data showed that the EarWell correction system treatment duration for protruding and lop ear is longer than for other auricle deformities (Figure 1 and Table 1).

When the treatment duration was prolonged, the incidence of skin eczema increased. There was no statistically significant correlation between the incidence of skin lesion and the treatment duration (Table 2).

4. Discussion

The incidence of auricle deformity at birth is as high as 43.46%–55.2%,^{5,8} which affects the future appearance, in addition to affecting their mental health. When children are aware of their auricle deformities, they will be prone to suffering from inferiority complex, unsocial behavior, cowardice, depression, and other related psychological disorders. Therefore, early effective intervention ought to be administered to children with auricular deformities to prevent psychological disorders.⁹

In recent years, with the development and improvement of clinical medical technology, ear auricle correction has been proposed. Ear auricle correction is a nonsurgical treatment method that is suitable for correcting the deformity of the auricle in newborns, and it can achieve better clinical results. Due to residual maternal estrogen in the blood circulation of neonates, the maternal estrogen peaks within 3 d after birth, which can increase the expression of hyaluronic acid in the cartilage. The younger the infant, the higher is the hyaluronic acid content in the cartilage, the stronger is its plasticity, the better is the correction effect, and the shorter is the wearing time.¹⁰ As the age increases, the hyaluronic acid in the cartilage decreases, and the plasticity decreases dramatically. On the basis of theoretical analysis, the EarWell infant ear correction system can restore the deformed shape of the auricle to the normal shape through the ear molding process of the corrector, taking advantage of the infants' strong plasticity of the auricle during the neonatal period.¹¹

In this study, the EarWell infant ear correction system demonstrated a significant effect in terms of the treatment of congenital auricle deformities, but the rebound rates of protruding ears and severe lop ears were relatively high; moreover, there was a difference between groups in terms of the cure rate of other types of auricle deformities. It is recommended to extend the wearing duration. In order to avoid rebound, it is recommended that patients with severe lop ears wear it for 2–3 weeks after the ear appearance is normal. After the correction treatment is completed, tapes can be used to

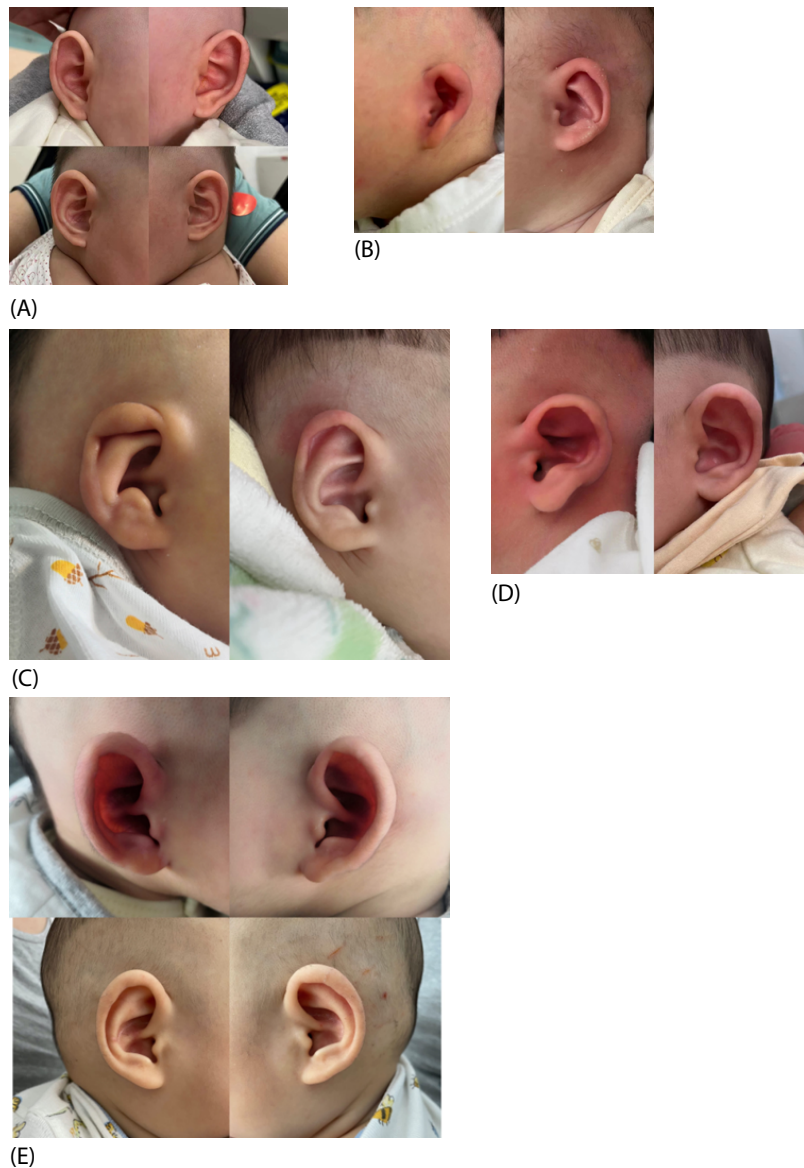


Figure 1. Comparison of different types of auricle deformities before and after treatment: (A) protruding ear deformity; (B) cup ear deformity; (C) lop ear deformity; (D) cup ear deformity; and (E) protruding ear deformity.

consolidate the ear auricle for about 2 months. When all treatment manipulations are completed, the patient education process enhanced parents' awareness to closely observe the condition of the affected ear. If there is any rebound, the correction process needs to be continued promptly.

No obvious complications are caused by the treatment of auricle deformities with the EarWell infant ear correction system, especially serious signs and symptoms such as perichondritis. The accompanying reactions, such as eczema and skin lesions, are relatively easy to manage.

Neonates' personal conditions and wearing duration correlated with the symptoms of eczema. We applied 3M adhesive plaster for the fixation between the corrector and the tegumentary of the infant's auricle. When the wearing duration was prolonged, the occurrence of eczema at the position of the tape increased to a certain extent. Neonates with susceptibility to skin allergies had a significantly increased incidence of eczema due to increased sweat secretion in dry and hot weather. Another major factor affecting the occurrence rates of symptoms of eczema was the type of auricle deformity, and the lop ear and the protruding ear were the main

Types of auricle deformity	Initial time of diagnosis and treatment	Wearing duration
Panel A: protruding ear deformity	30 d after birth on October 30, 2020	119 d
Panel B: cup ear deformity	30 d after birth on July 12, 2021	114 d
Panel C: lop ear deformity	30 d after birth on November 18, 2021	110 d <i>Note:</i> Eczema occurs when the EarWell infant ear correction system is applied for prolonged duration.
Panel D: cup ear deformity	30 d after birth on February 14, 2022	104 d <i>Note:</i> Nursing education enhanced the family members' intervention skill during sleep for preferable clinical outcomes.
Panel E: protruding ear deformity	30 d after birth on July 15, 2022	91 d <i>Note:</i> Nursing education enhanced the family members' intervention skill and promoted continuous compliance.

Note: These pictures show the ears before treatment (left panels in each group) and after treatment (right panels in each group).

Table 1. Treatment initiation and wearing duration.

Deformity types	Cases (ears)	Correction effect, N (%)			Mean treatment duration (days; $\bar{x} \pm s$)	Complication		
		Excellent	Good	Poor		Rebound ratio, N (%)	Eczema, N (%)	Skin lesion, N (%)
Protruding ear	14	12 (85.71)	0 (0)	2 (14.29)	95.67 $\pm$ 20.33	4 (28.6)	3 (21.4)	0 (0)
Lop ear	19	15 (78.95)	3 (15.79)	1 (5.26)	87.56 $\pm$ 40.12	6 (31.6)	5 (26.3)	1 (5.3)
Cup ear	10	10 (100)	0 (0)	0 (0)	39.21 $\pm$ 16.28	0 (0)	1 (10)	1 (10)
Constricted ear	17	15 (88.24)	2 (11.76)	0 (0)	43.66 $\pm$ 8.37	0 (0)	1 (5.9)	1 (5.9)
Helix deformity	15	15 (100)	0 (0)	0 (0)	36.58 $\pm$ 6.34	0 (0)	1 (6.7)	0 (0)
Stahl's ear	8	8	0	0	34.35 $\pm$ 15.39	0 (0)	0 (0)	0 (0)
Cryptotia ear	10	10	0	0	38.94 $\pm$ 7.36	0 (0)	0 (0)	1 (10)

Table 2. Comparison of correction effect, mean treatment duration, and common complications in infant with different types of auricle deformity.

types corresponding to the occurrence of eczema in the course of this study. Meticulous and integrated education for patients' parents, continuous follow-up, and standardized guidance are the main solutions to reduce the occurrence of related symptoms. When the symptoms of skin eczema occur during the wearing of the ear correction system, the specific clinical treatment protocol is to apply mometasone furoate cream externally and reinstall the correction system 20 min after applying the ointment. For those with particularly severe symptoms, after being diagnosed by the otolaryngologist, mometasone furoate cream can be externally administered and then left to rest for 24 h until symptoms improved significantly and then the correction system can be reinstalled. The duration of intermittent wearing of the correction system is inversely proportional to the clinical outcome. Skin lesions are usually associated with the displacement of the traction hook when the adhesive tape is loosened. The displacement of the traction hook generates friction between the skin folds, consequently resulting in skin

lesions. Health-care providers' extra caution results in the close connection between the positions of the 2 ends of the traction hook. Wearing the correction system with the base component for long periods was related to the occurrence of skin lesions, and wearing a traction hook alone was significantly less associated with skin lesions. In the study, the entire correction system treatment duration is for 2–3 weeks. Subsequently, we initiated single traction hook correction for consolidation treatment, with rare occurrence of skin lesions. The treatment for skin lesions postcorrection is routine cleaning and disinfection with iodophor. The health-care provider applied external mupirocin ointment for serious conditions. The EarWell correction system may be reinstalled with medical cotton liner on the condition that the skin lesions do not affect the wearability or by using interrupted installations with 24- to 48-h intervals of recovery.

The patient education content of the infants' family members mainly focuses on the prevention of complications and specific nursing knowledge. The fixed part

of the correction system needs to be free of moisture; the other point is to prevent sweating. The more the sweating, the higher is the incidence of eczema and the possibility of displacement of the traction hook, which is accompanied by an increased risk of skin lesions.

The innovation of this research: There are many types of auricle deformities, and the current treatment methods through nonsurgical means have been increasingly accepted by physicians and patients' parents. Meanwhile, it is necessary to evaluate the general safety and performance of physical orthopedic treatment methodologies. The Earwell correction system is beneficial for clinicians to assess the effect, process, and clinical path of complications in the diagnosis and treatment process. Furthermore, the research results show the benefit in terms of clinical outcomes and patient safety with patient education supported by evidence-based medical data. The research shows that parents developed comprehensive understanding of the type of auricle deformity, treatment process, and prognosis of the infant patients, and compliance and physician–patient relations are significantly improved.

The limitation of this research: The current research conclusions are based on small-sample studies. In the future, research models with larger sample sizes need

to be considered to further clarify its clinical significance and to support clinical practice.

In conclusion, the EarWell infant ear correction system's effectiveness on auricle deformities is clinically significant. Compared with other types of auricle deformities, protruding ears and lop ears rebound and the probability of skin lesion occurrences remarkably increase. The significance of this clinical study is that it has realistic clinical path guidance for postcorrection care, especially after the education of the patient's family members, for prolonging the wearing time of orthotics for protruding and lobe ears, and for more-targeted nursing details, which can better prevent and manage the complications with better clinical results.

Ethical approval

This study was approved by the ethics committee of Guangzhou Women and Children's Medical Center. All patients' guardians were well informed and signed the consent form.

Conflicts of interest

All contributing authors declare no conflicts of interest.

References

1. Fu YY, Xie YZ, Guo Y, Zhang JL, Zhu YD. Classification and treatment of congenital auricular deformation. *Chin J Otol*. 2018;18:310–313 (in Chinese).
2. Byrd HS, Langevin CJ, Ghidoni LA. Ear molding in newborn infants with auricular deformities. *Plast Reconstr Surg*. 2010;126:1191–1200.
3. Zhang TY. Comments on the classification and treatment of congenital auricular deformation. *Chin J Otol*. 2018;18:314–315 (in Chinese).
4. Zou F, Li Q, Zhuang QE, Zhang Y. Auricular orthosis for newborns and infants Observation on the curative effect of deformity. *Chin J Otol Integ Trad Chin Western Med*. 2017;25:355 (in Chinese).
5. Wu SL, Qi XD, Zhao H, Qin JZ, Zhong SZ. Preliminary study on the morphological classification of neonatal auricles. *Chin J Clin Anat*. 2013;31:384 (in Chinese).
6. Zhou X, Zhang QG, Xie YC, et al. Selection and application of ear reconstruction surgery for Chinese microtia. *Chin J Otorhinolaryngol Head Neck Surg*. 2015;50:192–196 (in Chinese).
7. Daniali LN, Rezzadeh K, Shell C, Trovato M, Ha R, Byrd HS. Classification of newborn ear malformations and their treatment with the EarWell infant ear correction system. *Plast Reconstr Surg*. 2017;139:681–691.
8. Matsuo K, Hayashi R, Kiyono M, Hirose T, Netsu Y. Nonsurgical correction of congenital auricular deformities. *Clin Plast Surg*. 1990;17:383–395.
9. Jiang DW, Geng J, Li H, Hu XY. Microtia of I degree retroauricular flap combined with autologous rib cartilage primary transplantation of auricular reconstruction for correcting and repairing microtia of I degree. *J Pract Med*. 2016;33:401–403 (in Chinese).
10. Leonardi A, Bianca C, Basile E, et al. Neonatal molding in deformational auricular anomalies. *Eur Rev Med Pharmacol Sci*. 2012;16:1554–1558.
11. Cao J. Establishment of auricular database of newborns and analysis of the factors correlated with auricle deformities. *Med Inf*. 2015;28:262–263 (in Chinese).