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Newborn ear defomities and their treatment efficiency with Earwell infant ear correction system in China

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ABSTRACT

Introduction: Newborn ear deformity can be performed through Earwell infant ear correction system as a non-surgical treatment to avoid plastic surgery. In the newborn period, the auricle is soft and the cartilage is plastic, the deformed auricle shape can be treated by mechanical action.

Methods: From April 2016 to December 2018, we selected the patients who underwent Earwell non-invasive correction system in Eye & ENT Hospital of Fudan University for newborn ear deformities, and analyze the treatment age, treatment time, efficiency and complication of these patients.

Results: There were 105 patients with 141 ears underwent Earwell non-invasive correction system for newborn ear deformities. The average age for treatment is 2.16 ± 2.28 months (0.23–12.0 months). The average treatment time is 1.14 ± 0.57 months (0.33–4.0 months). The treatment outcomes show 109 ears get excellent results, 27 ears good results and 5 ears poor results. For complications, there were 6 patients had localized skin rash and 5 had skin lesion which were cured after 3–5 days. Nine patients had different degree of recurrence. The treatment age less than 6 weeks had a better results than treatment age old than 6 weeks ($\chi^2 = 4.48, p < 0.05$). Except 5 poor results patients, the treatment efficiency is 96.4% (136/141) in this study.

Conclusions: The Earwell infant ear correction system is proven to be a simple, non-invasive, high-efficiency, low-cost treatment method, which is more effective than traditional plastic surgery, and treatment efficiency of different types ear deformities can reach more than 95% in China. It is important to ensure the early treatment during the first 6 weeks.

1. Introduction

Newborn ear deficiencies mainly include two types, one is structural malformation accompanied by hearing loss, which require total auricular and hearing reconstruction surgery, the incidence of this type is lower [1]; the other type is ear deformity, usually without middle ear malformation or hearing loss, which can be treated by small plastic surgery or even without treatment, the incidence of this type is higher [2,3]. For this type of ear deformities, the traditional treatment is plastic surgery, but there were various complications after surgery [4,5]. In recent years, early treatment can be performed through infant ear correction system as a non-invasive treatment to avoid plastic surgery [6–9]. In the newborn period, the auricle is soft and the cartilage is plastic, the deformed auricle shape can be remodeling by mechanical action [8,10].

The author of the present study is the earliest institute to apply Earwell infant ear correction system for newborn ear deformities in China. We have accumulated rich experiences in auricle non-invasive correction, promote the application and standard treatment of this technique in China, a number of patients with ear deformities avoid surgical injuries. The present study analyze the treatment efficiency of these patients.

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2. Methods

2.1. Patient selection

From April 2016 to December 2018, we selected the patients who underwent Earwell infant ear correction system in Eye & ENT Hospital of Fudan University for newborn ear deformities, and analyze the treatment age, treatment time, efficiency and complication of these patients. The auricular cartilage has an unusual plasticity, because of circulating maternal estrogens; these hormones peak at day 3 and return to baseline during 6 weeks [11]. So the patients were divided into two groups, one is the treatment age less than 6 weeks, and the other is more than 6 weeks. The treatment efficiency were divided into three groups, excellent, good and poor result group. Excellent means normal ear shape with no appearance of original deformation; good means nearly normal ear shape or with mild yet nondistracting retention of original deformation; poor means improved but not a normal ear shape or no improvement or noticeable distracting retention of original deformation [12].

2.2. Treatment steps

The Earwell non-invasive correction system is composed of an anterior (cap) and posterior cradle, retractor, and a conchal former (Fig. 1) [13].

Step 1. Shave off the hair around ear before using Earwell non-invasive correction system (avoid damage to the skin), then wipe off the oil of skin with isopropyl alcohol to make the cradle adhere to the skin.

Step 2. Fix the cradle to the ear, then select appropriate size of the retractor to pull the helix to shape the auricle.

Step 3. The conchal former correct the upper part of the auricle to keep the shape of ear. Finally, using anterior cap to keep the shape. If necessary, using an elastic headband for external fixation.

Step 4. The type of ear deformity is different, sometimes it is necessary to shear the retractor or the cradle according to the shape of ear, to meet the personal treatment and reduce complication.

2.3. Statistical analysis

Chi squared test was preformed to see the treatment efficiency of Earwell non-invasive correction system. All analyses were performed using SPSS software (version 20.0; IBM, New York), and a p value of < 0.05 was used as the cut-off point for statistical significance.

Table 1
The deformity types of 141 ears.

	< 6 weeks	> 6 weeks	Total
Cryptotia	10	14	24
Lidding	14	15	29
Cup ear	20	11	31
Helical rim	23	18	41
Stahl's ear	1	0	1
Mixed	8	7	15
Total	76	65	141

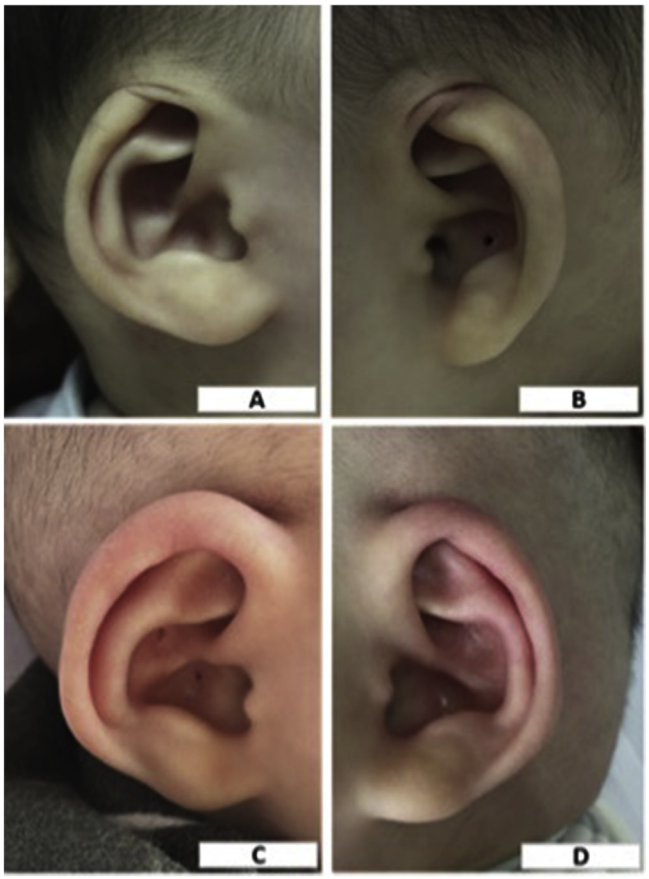

Fig. 2. Earwell non-invasive correction for one 6-months old boy with bilateral cryptotia. A and B, before treatment. C and D, after correction for 1month. The treatment outcome of both ears were excellent.

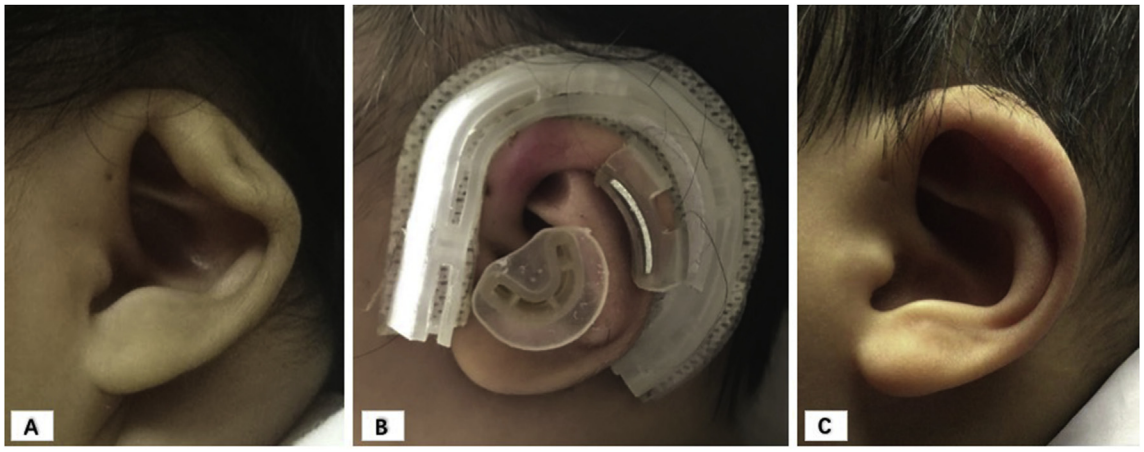

Fig. 1. Earwell non-invasive correction for one 2-months old girl with cup ear. A, before treatment. B, during treatment. C, after correction for 1month.

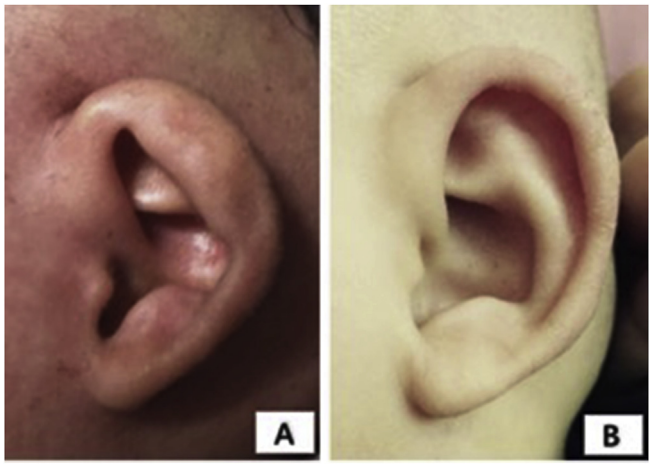

Fig. 3. Earwell non-invasive correction for one 1-months old boy with cup ear. A, before treatment. B, after correction for 1month. The treatment outcome of left ear was excellent.

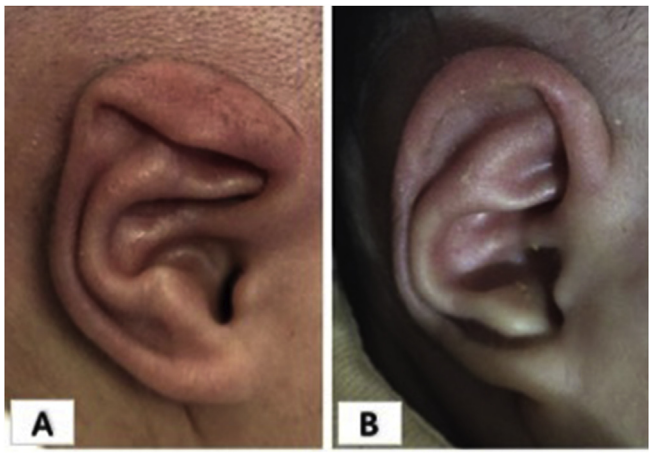

Fig. 4. Earwell non-invasive correction for one 3-weeks old girl with lidding ear. A, before treatment. B, after correction for 2 weeks. The treatment outcome of right ear was excellent.

3. Results

From April 2016 to December 2018, there were 105 patients with 141 ears underwent Earwell non-invasive correction system for newborn ear deformities (Table 1). There were 70 right and 71 left ears. The average age for treatment is 2.16 ± 2.28 months (0.23–12.0 months). The average treatment time is 1.14 ± 0.57 months (0.33–4.0 months), the age old than 6 weeks group treated with longer time than age less than 6 weeks group. The treatment outcomes show 109 ears get excellent results (Figs. 2–4), 27 ears good results (Fig. 5) and 5 ears poor results (Fig. 6). For complications, there were 6 patients had localized skin rash and 5 had skin lesion which were cured after 3–5 days. Nine patients had different degree of recurrence. To compare the excellent results with other outcomes, the treatment age less than 6 weeks had a better results than treatment age old than 6 weeks ($\chi 2 = 4.48$, $p < 0.05$) (Table 2). Except 5 poor results patients, the treatment efficiency is 96.4% (136/141) in this study.

4. Discussion

4.1. Pre-treatment care

(1) Psychological: in-depth communicate with parents before treatment, so that they can fully understand the whole process and efficiency of treatment, especially for the relatively older patients (the best therapeutic time window is 1–6 weeks after birth) [3], and patients with mixed deformities (Fig. 6) [14]. The auricular cartilage has an unusual plasticity, because of circulating maternal estrogens; these hormones peak at day 3 and return to baseline during 6 weeks [11]. We can show comparison of the therapeutic effects of similar cases, these will increase the confidence of the treatment. (2) Record image data: record the contrast photos before and after treatment, in order to compare the outcomes.

4.2. Nursing during treatment

(1) Keep the skin around the ear clean and dry: to avoid the occurrence of milk spillage, if it happens, remove the cover for local cleaning and keep it dry; excessive metabolism, secretions, long-term closure of local tape will lead to discharge with the formation of odor, we should intensify care and clean the ear. Therefore, each parent must be taught to remove the cradle cover properly for cleaning the ear. (2) Prevent the correction system falling off: pay attention to the posture when holding or sleeping, avoid the repeated rubbing of the ear cradle; control the indoor temperature, reduce the sweating of the child, pay attention to the bath water, do not soak the cradle. The correction system falls off will affect the therapeutic effect. (3) Follow-up: the patients should return to clinic 1–2 weeks later, if there were degumming, skin lesions, ulceration and other abnormal status, the patients should get back as soon as possible to ensure the treatment efficiency [11].

4.3. Treatment of complications

4.3.1. Skin redness and lesions

This is the most common complication caused by local traction and friction, the incidence is related to the treatment age of non-invasive correction and the skin basic conditions of the newborn patient. Most of the lesions occurred at the force part of the auricle, such as helix and the cavity of concha. If the skin lesion occurs, the cradle should be took off temporarily. If the skin lesion or the exudate is severe, it should be disinfected with 75% alcohol and then applied with antibiotic ointment [12]. In this study, only 5 cases lead to local skin lesions, three patient occur as the reason of the ear armor compression, and another 2 patients due to retractor fixed to the helix. After remove the retractor and ear mold, all patients recovered 3–5 days after cleaning and disinfection (Fig. 5).

4.4. Skin allergy

The skin allergy occurred mainly as allergic to tape or silica gel, manifested as rash, secretions around the ear. We can remove the correction system if the skin allergy is mild, thoroughly clean and disinfect the external ear. After observed for 2 h, if the skin redness disappeared, we can wear it again. For those severely allergic condition, in addition to remove the Earwell system and clean the external ear, it is necessary to suspend correction treatment. Do antianaphylactic treatment until the symptoms disappear and then re-wear the Earwell system. In this study, there were 6 cases of allergic reactions manifested as rash, the symptom was mild and the correction treatment was not suspended. Pay attention to weekly skin assessment and cleaning until the end of the treatment.

5. Conclusion

The Earwell infant ear correction system is proven to be a simple, non-invasive, high-efficiency, low-cost treatment method, which is more effective than traditional plastic surgery. The treatment efficiency of different type ear deformities can reach more than 95% in China. It is important to ensure the early treatment during the first 6 weeks.

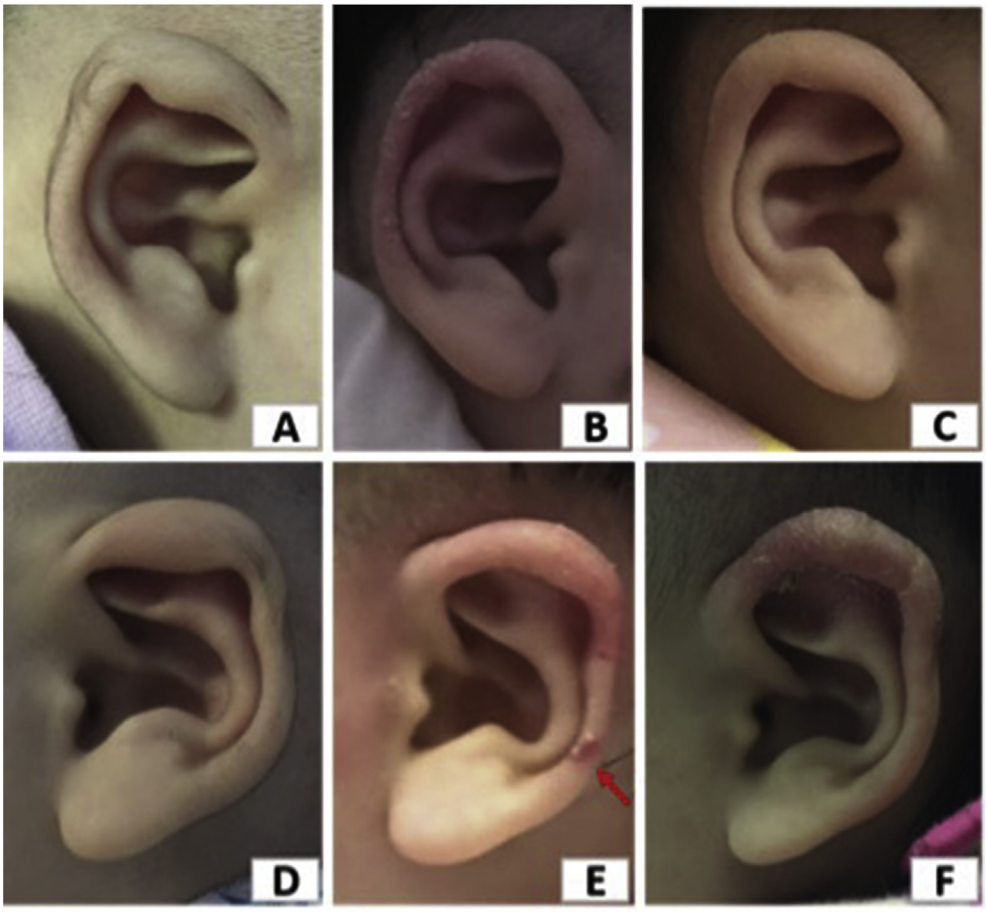

Fig. 5. Earwell non-invasive correction for one 3-months old girl with bilateral lidding ear. A to C, there was a little recurrence after took off the Earwell system, the treatment outcome of right ear was good. D to F, 4 days after took off the Earwell system, the skin redness and lesions recovered after cleaning and disinfection (arrow). The treatment outcome of left ear was good.

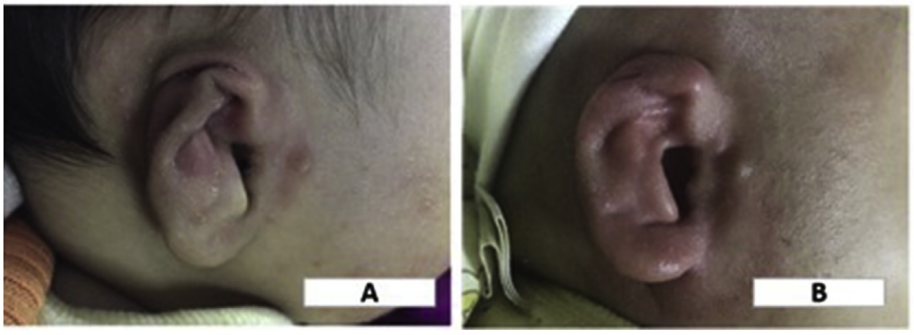

Fig. 6. Earwell non-invasive correction for one 2-month old boy with mixed deformity. A, before treatment. B. after Earwell non-invasive correction for 1month. The treatment outcome was poor, but there were still some improvement.

Table 2
Treatment efficiency of 141 ears.

	< 6 weeks	> 6 weeks	Total
Treatment age (months)	0.78 ± 0.42	3.77 ± 2.52	2.16 ± 2.28
Treatment time (months)	1.08 ± 0.58	1.23 ± 0.55	1.14 ± 0.57
Treatment efficiency			
Excellent	64	45	109
Good	10	17	27
Poor	2	3	5
Complication			
Skin lesion	2	3	5
Skin rash	5	1	6
Recurrence	5	4	9

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Conflicts of interest

All authors declare that they have no conflict of interest.

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