EarWell Infant Ear Molding Device: Experience and Parent Survey

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Background: EarWell infant ear molding device is a noninvasive, nonsurgical option to treat ear deformities in early infancy. There are no studies involving the parents' perspective to the use of the EarWell.

Aim: To investigate our experience with EarWell infant ear molding device and to assess the parents' satisfaction.

Study Design: A retrospective case series study of infants with congenital ear deformities who were treated with EarWell device from October 2021 to November 2022. Demographic and clinical data were collected. Clinical photographs were obtained before, during, and after treatment. Parents' satisfaction level was assessed through telephone encounters and surveys, and issues associated with device application were identified. Clinical improvement of ear deformity was graded into poor, fair, good, and excellent.

Results: A total of 9 patients with congenital ear deformities were identified and included in this study (7 bilateral deformities and 2 unilateral deformities). The mean adjusted age of the initial treatment is 17 weeks (4–23 weeks), and the mean treatment duration is 5.7 weeks. The authors received full 8 responses from the parents' survey, and all parents were satisfied with post-treatment results (4 satisfied, 1 fully satisfied, and 2 very satisfied). Issues associated with device application were 3 superficial skin ulcers and 4 skin irritation. Clinical Improvement grades were: 5 excellent improvement, 2 good improvement, and 2 fair improvement.

Conclusions: On the basis of our experience, the EarWell device has shown a high success rate and a low complication rate. It is well accepted by parents, but it needs close follow-up to detect minor device-related issues. The device is safe for multiple skin types.

Key Words: EarWell, infant molding device, noninvasive

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Congenital ear deformity is a common cephalic deformity with an incidence of 11.5 per 10 000.[1] It affects not only children's appearance but also their psychological development, which may negatively impact their mental health and future social activities.[2] Infant auricular deformities are classified either as malformation or deformation, and malformations are characterized by a partial absence of the skin or cartilage, resulting in a constricted or underdeveloped pinna, whereas deformations are characterized by a misshaped but fully developed pinna.[3] Common deformations include helical rim anomalies, prominent ear, lidding/lop ear, stahl ear, conchal crus, and cryptotia,[4] whereas common malformations include constriction, cleft ear, and microtia.[5] According to statistics, significant factors might affect the risk of ear deformations; these factors include vaginal birth compared with cesarean delivery, premature rupture of membranes, abnormal pregnancy, and neonatal weight over 4000 g.[6]

Approximately 30% of newborns will have some degree of auricle anomaly,[7] out of which 15% to 20% will resolve spontaneously, and when diagnosed early, most ear deformations can be treated conservatively.[8,9] Studies have found that newborns have high levels of maternal estrogen circulating in their bodies. Within 72 hours after birth, circulating estrogen in the newborn reaches a significant peak, resulting in an increased concentration of hyaluronic acid in the cartilage and a corresponding increase in the ductility and plasticity of the cartilage.[1,10] Therefore, ear deformities can be corrected by initiating appropriate molding in the first week of life.[1,7] However, when treatment initiation is delayed, success rates decrease, and the length of treatment increases.[11] Neonatal molding reduces the need for surgical correction with results that often exceed what can be achieved with the surgical alternative.[7]

EarWell infant ear molding device is a nonsurgical modality that is best suited for deformations but is useful in cases of less severe malformation.[7] According to a recent meta-analysis study, the EarWell ear molding device can obtain complete correction with a high-efficiency rate (89.1%).[12]

Many research papers have addressed the efficiency and safety profile of using EarWell device in treating ear deformities; however, very few have focused on parents' perspectives regarding the use of this device. The aim of this study is to investigate our experience with EarWell infant ear molding device and to assess the parents' satisfaction.

METHODS

A retrospective chart and photograph review were conducted for a consecutive series of infants with congenital ear deformities who were treated with EarWell infant ear molding device in our department from October 2021 to November 2022; all included infants were seen and assessed in our clinic. Demographic and clinical data were collected, including age, sex, nationality, adjusted age at the initiation of treatment (in weeks), pretreatment deformation type, and relative risk factors.

Clinical photographs were obtained before, during, and after treatment. Parents' satisfaction and post-treatment review were obtained through telephone encounters and surveys. We used Microsoft Excel system and Cerner system (North Kansas City, MO) to collect and analyze our data.

EarWell study survey was structured as follows: demographic data, satisfaction level, and issues associated with device application. Demographic data included patient name, date of birth, and date of application. Parents were given a scale of 1 to 5, where 1 is not satisfied, 2 is less satisfied, 3 is satisfied, 4 is fully satisfied, and 5 is very satisfied. On the basis of the previous scale, satisfaction level was rated. Issues associated with device application were either skin irritation or superficial skin ulceration. In addition, a hypothetical question was asked, stating that: if you have the option to choose this device again, will you use it again? (Fig. 1).

EarWell infant ear molding device was applied in our clinic by the treating physician. First, the scalp hair is shaved ~2 cm around the ear, and the area is prepared with alcohol to facilitate adherence of the posterior cradle against the skin. Then, an adhesive was used to hold the posterior cradle, which fits around the ear. The ear is then pulled through a central opening. To shape the conchal bowl, a conchal former is placed in the central cavity of the outer ear. The retractors are placed around the helix of the ear to gently mold it into the needed shape or position. The anterior shell attaches to the posterior cradle, allowing direct anterior forces to be applied, which aids in holding all device components securely in place[7] (Fig. 2).

Patients were examined every 2 weeks in our clinic for a total of 6 weeks duration for follow-up deformation correction, treatment adjustment, and to rule out any adverse events related to device application. In case of the presence of superficial skin ulceration (Fig. 3), treatment was stopped for a 1-week duration, and a topical antibiotic was applied, then the treatment was continued as planned. Clinical improvement was assessed based on the pretreatment and post-treatment photographs in addition to the clinician's observation during the follow-up period (2–17 wk). Clinical improvement was graded into 5 categories based on the degree of deformity correction: poor improvement (0%–25%), fair improvement (25%–50%), good improvement (50%–75%), and excellent improvement (75%–100%).


Earwell study
Survey

* Indicates required question

1. Name

2. DOB
Example: January 7, 2019

3. Date of application
Example: January 7, 2019

4. Are you satisfied with the result after earwell application *
Mark only one oval.
- Very satisfied
- Fully satisfied
- satisfied
- less satisfied
- Not satisfied

5. If you have the option to chose this devise again, will you use it again ?
Mark only one oval.
- Yes
- No

6. Did he/ she have complications after earwell application
Mark only one oval.
- Yes
- No

7. What kind of issues did your baby have?
Check all that apply.
- Skin irritation
- Skin sore
- Other:

FIGURE 1. EarWell parent survey.

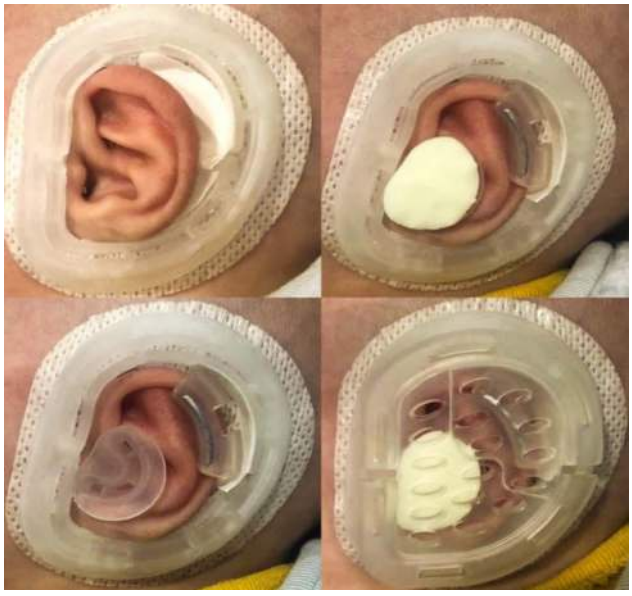

FIGURE 2. Steps of application of the EarWell device.

RESULTS

A total of 9 patients with congenital ear deformities were identified and included in this study (5 females and 4 males); patients are from different ethnicities and social backgrounds (6 Emirati, 1 Jordanian, 1 Kazakhstani, and 1 Pakistani). We had 16 ears in total, 7 patients had bilateral ear deformities, and 2 had unilateral ear deformity. Pretreatment deformation types were as follows: 2 lop ears, 1 conchal crus, 3 constricted ears, 1 prominent ear, 2 cup ears, and 3 convex conchae. Relative risk

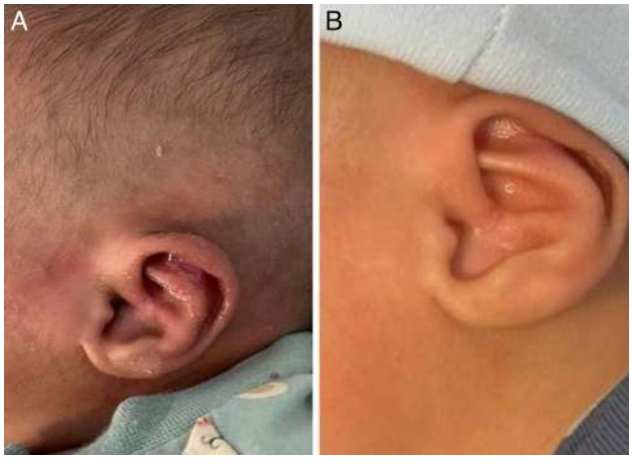

FIGURE 3. Minor complication related to the use of the EarWell device. (A) left ear of one of our patients with conchal crus deformity who developed a superficial skin ulcer 2 weeks after EarWell device application. (B) Significant improvement after 1 week of stopping treatment and applying topical antibiotics.

factors for having ear malformation were regarded as prematurity and other associated anomalies. We had a total of 3 infants with documented risk factors, all of them were preterm, and 1 of them had associated anomalies (ectopic kidney and cardiac anomalies).

The adjusted age at initiation of treatment ranged from 4 to 23 weeks (Supplemental Table 1, Supplemental Digital Content 1, http://links.lww.com/SCS/F288), the calculated mean age at treatment initiation is 17 weeks, and the mean duration of treatment application is 5.7 weeks.

We had full 8 responses from the parents' surveys. All parents were satisfied with the results after the device application; satisfaction levels were as follows: 4 satisfied, 1 fully satisfied and 3 very satisfied (Fig. 4). When parents were asked if they had the chance to use this device again, half of them said they would like to use it again. Reported issues associated with device application were 3 superficial skin ulcers and 4 skin irritation. In case of developing a skin ulcer, the device was removed for a 1-week duration, fucidin was applied topically, and the usual treatment was continued once the healing occurs.

Most cases had excellent improvement and complete correction of the ear malformation (Fig. 5). Improvement grades were as follows: 2 patients with fair improvement, 2 patients with good improvement, and 5 patients with excellent improvement.

DISCUSSION

In this study, we focused on the parents' perspective to the use of EarWell infant ear molding device, making our study one of the first studies to have parents' perspective incorporated and clearly addressed. We contacted all parents through telephone encounters and online surveys. Out of the 9 included patients, we have got full 8 responses from these surveys. Our survey has focused on the parents' satisfaction level in addition to their willingness to use or recommend this device. We addressed parents' concerns of using this device as we asked them regarding any issues associated with the EarWell device application. Issues associated with device application were skin irritation, significant discomfort of the patient, and, in some cases, superficial skin ulceration. In addition, we have pointed out the strengths and weaknesses of using this device from the parents' perspective. One of the weaknesses of this device, as reported by one of the parents is the loosening of the adhesive tape that is used in EarWell ear correction kit. We have noticed

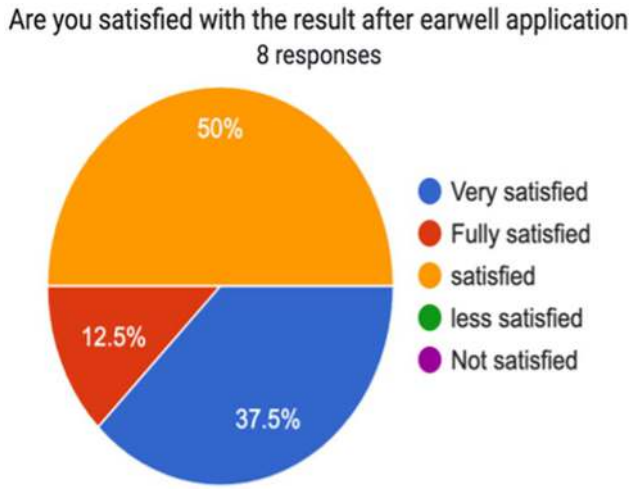

FIGURE 4. Parents satisfaction rate (percentage).

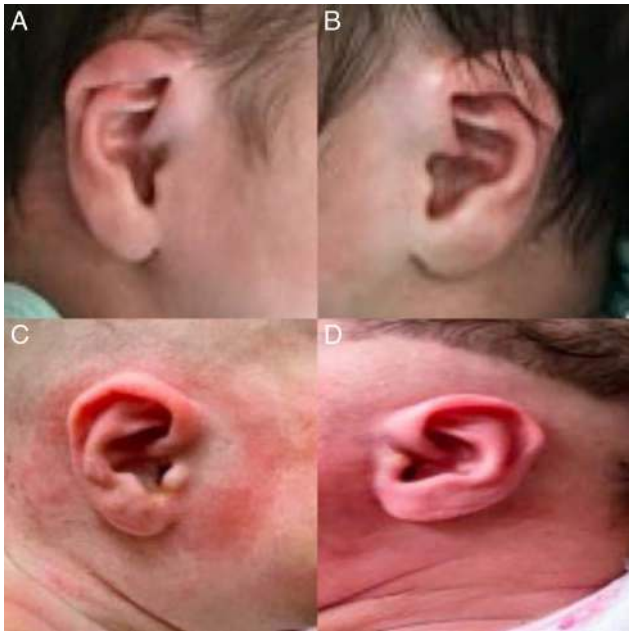

FIGURE 5. Excellent improvement in bilateral auricular deformity after EarWell device application. (A) Left lop ear deformity before treatment. (B) Right lop and constricted ear deformity before treatment. (C and D) Complete correction of bilateral ear deformities 6 weeks post-treatment.

that the level of awareness and knowledge about ear deformities and the possible treatment options among the public and general community is low; we recommend increasing the level of awareness toward congenital auricular deformities and the use of EarWell infant ear molding device, especially among pediatricians and family physicians since they have significant contact with the parents during the early infancy period.

Our patient selection is an international multicultural encompassing all skin types. This demographic study has shown that the use of EarWell infant ear molding devices is safe, effective, and widely accepted. Our patients' nationalities were as follows: 6 Emirati, 1 Jordanian, 1 Kazakhstani, and 1 Pakistani. Skin type and patient ethnicity were not directly related to the efficiency rate of the EarWell device.

Neonborns have a significant number of maternal estrogen in their circulation; this in return increases the concentration of hyaluronic acid in ear cartilage, giving its good plasticity.[1] The EarWell infant ear molding device uses the plasticity of ear cartilage to correct congenital ear deformations.[13] The timing of the application of the EarWell infant ear molding device for the treatment of congenital auricular deformity is very critical. Byrd et al[7] found that efficiency rate of the EarWell ear molding device in correcting congenital ear deformities was higher than 90% within the first week of birth, but the efficiency rate of the EarWell ear molding device in treating congenital ear deformities has dropped significantly to lower than 50% in children over 3 weeks of age. Our data has shown that the best results of EarWell infant ear molding device application is in the early infancy before 4 months of age; however, some improvement can be expected in patients after 4 months, but in this case, the degree of improvement can be unpredictable. Therefore, careful patient counseling and case selection is required before its application.

One of the limitations in this study was finding a control group. Another limitation is patient compliance with the device application, the recommended duration of device application is 6 weeks; however, some parents are applying it inconsistently;

possible reasons include skin irritation, compliance issues related to the child, and patient discomfort. This has subsequently affected the post-treatment results in some patients. Last but not least, a significant limitation in this study was establishing a grading scale for the clinical improvement of ear deformity correction after the use of EarWell device; unfortunately, there is no standardized scale to grade the degree of improvement in congenital auricular deformities after the use of infant ear molding devices. In our case, the grading was done by the senior author (D.M.) based on his observation during the treatment period, along with comparing pretreatment and post-treatment clinical photographic documents.

In summary and based on our experience, EarWell infant ear molding device has shown high success rate and low complication rate. It is safe and effective and can be applied to all types of congenital auricular deformations. It is well accepted by parents but needs close follow-up to detect minor device-related issues. The device is safe for multiple skin types. We recommend the EarWell device for any child with ear anomaly as early as possible, ideally before the age of 4 months.

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