Efficacy of Ear Molding in Infants using the EarWell Infant Correction System and Factors Affecting Outcome

Stephanie L. S. Chan, M.B.B.S., M.Med.
Gale J. S. Lim, F.A.M.S.
Yong Chen Por, F.A.M.S.
Ming Fang Chiang, B.N.
Shuxian Ho, B.N.
Seyed Ehsan Saffari, Ph.D.
Hui-Ling Chia, M.B.B.S., M.Med.

Singapore

Background: One-third of infants have ear anomalies, and less than one-third self-correct. Correction of ear deformities by molding exploits the plasticity of the auricular cartilage because of circulating maternal estrogen during infancy. In this study, the authors assess the efficacy of the EarWell Infant Correction System in the correction of ear deformities and determine the factors that affect its outcome.

Methods: The authors conducted a single-center prospective study over a 3-year period. Consecutive full-term infants who underwent ear molding with the EarWell system were recruited. Primary outcome was successful correction of ear anomaly. Secondary outcomes included complications and maintenance of ear shape. Factors identified included type of anomaly, age at application, duration of application, and breastfeeding.

Results: Sixty-seven patients with a total of 105 ears were recruited. The anomalies were classified into deformations (66.7 percent) and malformations (33.3 percent). The median age group at presentation was 0 to 7 days (67 percent). Average duration of application was 4.1 weeks. Successful correction was achieved in 86 percent of patients. Ear deformations achieved a significantly higher rate of successful outcome (98 percent) compared with malformations (64 percent) ($p < 0.001$). Skin complications were common (46 percent) and attributed to our tropical climate. Patients with complications were of a higher mean age (22.1 days) compared with patients with no complications (10.6 days) ($p = 0.037$).

Conclusions: The EarWell system is an effective nonsurgical option for the treatment of ear anomalies. The type of anomaly was the only predictor of successful correction, whereas age at application, duration of molding, and breastfeeding were not. Complications were more common in older infants. (*Plast. Reconstr. Surg.* 144: 648e, 2019.)

CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, IV.

It is estimated that one-third of infants have ear anomalies but only one-third of them self-correct.[1] Congenital ear anomalies are classified into malformations or deformations. Ear malformations refer to partial or complete absence of the skin and cartilage, whereas ear deformations are a result of misshapen cartilage with no deficiency of skin and cartilage.[2] Examples of ear deformation include lidding, Stahl ear, and prominent ears. Constricted ears, cryptotia, and microtia, in contrast, are common examples of ear malformations.

Before the advent of ear molding, surgical correction of ear deformities was advocated after the age of 5, when the ear has reached 90 percent of adult size.[3] Ear molding in infants may eliminate the need for future surgical correction, and many authors have reported the effectiveness of

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this intervention. Innovations included the use of foam,[4] tapes,[5,6] wires,[2,7–9] and putty.[10] Circulating maternal estrogen maintains high levels of hyaluronic acid in cartilage and potentiates the pliability of ear cartilage.[1] The presence of estrogen receptors in human auricular chondrocytes was demonstrated previously,[11] and animal models have verified that injection of estrogen into the auricle causes the ear to become soft and pliable.[5,12]

Byrd et al. introduced the EarWell Infant Ear Correction System (Becon Medical Ltd., Naperville, Ill.) for ear deformities.[1] They reported its success in attaining a good outcome in more than 90 percent of infants and concluded that the success of ear molding was directly related to the early age at initiation (before age 3 weeks). A total duration of 6 weeks of therapy using the EarWell system was recommended. Other authors have subsequently used the EarWell system for ear molding and reported similar success rates.[13–15] In this prospective study, we assess the effectiveness of the EarWell system and determine the factors that affect the success of ear molding.

PATIENTS AND METHODS

A single-center prospective study was conducted over a 3-year period from January of 2014 to December of 2016. The study was approved by the Singapore Health Service Centralised Institutional Review Board. Consecutive full-term infants, who presented to the Department of Plastic Surgery, KK Women's and Children's Hospital, Singapore, with ear anomalies and consented (by the parents) to ear molding with the EarWell system, were recruited into the study.

The EarWell system consists of four main components: the posterior cradle, retractors, conchal former, and anterior shell. The posterior cradle has a posterior conformer that is positioned into the antihelix and the proposed superior limb of the triangular fossa. The retractors are used to hold the helical rim in position. These retractors are held in place by the inner adhesive surface of the posterior cradle. Next, a soft compressible conchal former is placed within the conchal cavity. Lastly, the anterior shell is attached to the posterior cradle, resulting in direct anterior forces to be applied to the conchal former and retractor system[1] (Fig. 1).

Each device was applied for a duration of 2 weeks. Molding using the EarWell system was continued for a further 2 weeks after the anomaly was corrected. Patients were reviewed weekly for complications and treatment interruptions, such as shifting of the apparatus.

Data collected included the type of anomaly, family history of ear anomalies, age at application, duration of application, whether the infant was breastfed, grading of outcome, complications, and maintenance of ear shape. Photographic documentation of the patients' ears before, during, and after treatment was taken and stored in

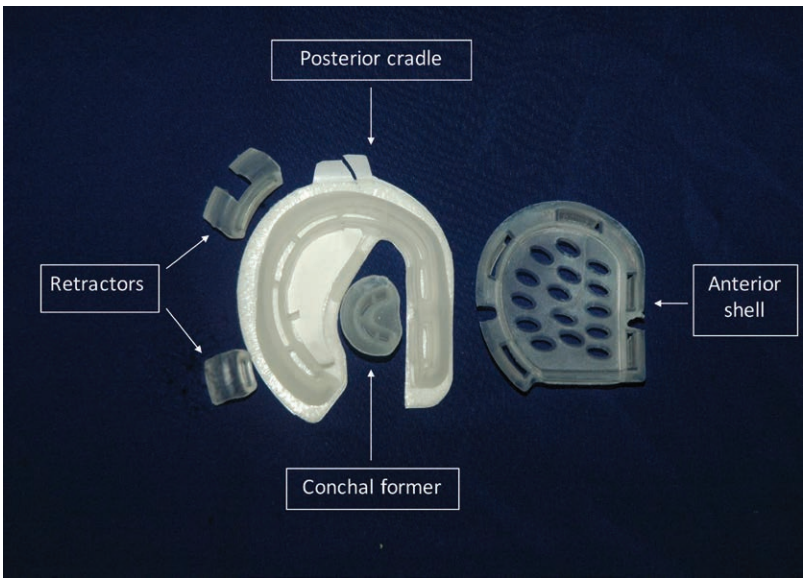

Fig. 1. The EarWell Infant Ear Correction System showing the individual components: the soft compressible conchal former, posterior cradle, anterior shell, and retractors.

Table 1. Photographic Grading for Ear Anomalies*

Grade	Shape	Deformation/Malformation
Excellent	Normal ear shape	No appearance of original deformation/malformation
Good	Nearly normal ear shape	Mild yet nondistracting retention of original deformation/malformation
Fair	Improved but not a normal ear shape	Noticeable, distracting retention of original deformation/malformation
Poor	No improvement	Abnormal ear shape with retention of original deformation/malformation

*From 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.

a secure server. The patients were followed up at 1, 3, and 6 months after completion of treatment. The pretreatment and 6-month posttreatment photographs were assessed by three independent plastic surgeons, who rated the outcome as poor, fair, good, and excellent. The agreement test was applied. Definitions of grading are explained in Table 1. Parents of the patients were asked to rate their satisfaction with the EarWell system on a scale of 1 to 5, with 1 being extremely dissatisfied, 2 being dissatisfied, 3 being neutral, 4 being satisfied, and 5 being extremely satisfied. The data were analyzed on IBM SPSS Version 23 (IBM Corp., Armonk, N.Y.). Variables were analyzed using Fisher's exact test, two-sided two-sample *t* test, Mann-Whitney *U* test, two-sided one-sample *t* test, and one-sample Wilcoxon signed rank test where appropriated. Values of $p < 0.05$ were taken to be statistically significant.

Patients who did not attend follow-up reviews were also included in our analysis. Their information was collected by means of telephone interview, and posttreatment photographs sent by the parents electronically.

RESULTS

We recruited 67 patients, with a total of 105 ears. Thirty-seven infants (55 percent) were female and 30 (45 percent) were male. Four patients had a positive family history of ear anomalies, all of whom were first-degree relatives with a history of prominent ears. However, only half of these infants also had prominent ears. Unilateral and bilateral deformities were noted in 43 percent and 57 percent of patients, respectively. The commonest deformity was constricted ear (32.4 percent), followed by lidding (28.6 percent) (Table 2).

Table 2. Summary of Ear Anomalies

Anomaly	No. of Ears (%)
Types of ear deformation	
Lidding	30 (28.6)
Stahl ear	19 (18.1)
Helical deformities	10 (9.5)
Prominent ear	5 (4.8)
Lop ear	5 (4.8)
Conchal crus	1 (0.95)
Total no. of deformations	70 (66.7)
Types of ear malformation	
Constricted ear	34 (32.4)
Cryptotia	1 (0.95)
Total no. of malformations	35 (33.3)

Of the 67 patients who were recruited, 45 completed treatment, with a total of 71 ears. The mean length of follow-up was 12.7 months (range, 6 to 32 months). The average number of clinic visits during the course of EarWell treatment was 3.4. Twenty-two patients did not complete treatment, and the reasons are summarized in Figure 2. Eighty percent of the patients had the EarWell system initiated before 4 weeks of age (Fig. 3). When divided into weekly age groups, the median age group of application was within the first week of life (67 percent).

Outcome Grading and Successful Correction

Pretreatment and 6-month posttreatment photographs were reviewed by a plastic surgeon and graded according to standardized criteria.[15] Successful correction was defined as patients who were rated as having good and excellent outcome grading. Sixty-one of 71 ears (86 percent) were successful in correction of ear anomaly. Forty ears (56 percent) were graded excellent, 21 (30 percent) were graded good, 10 (14 percent) were graded fair, and none were graded poor (Table 3). Successful correction was attained in 16 of 25 ear malformations (64 percent) compared with 45 of 46 ear deformations (98 percent), as shown in Table 4. The difference was statistically significant between ear deformations and ear malformations ($p < 0.001$). Examples of successful correction are illustrated in Figure 4 (malformation) and Figure 5 (deformation). An example of unsuccessful correction of constricted ear (malformation) is shown in Figure 6.

Age at Application

The mean age at application was 15.7 days (range, 0 to 97 days). Within each outcome

<table>
<tr><td colspan="3">Total number of patients recruited
N = 67
(No. of ears = 105)</td></tr>
<tr><td colspan="2">Did not complete treatment
n = 22
(No. of ears = 34)</td><td>Completed treatment
n = 45
(No. of ears = 71)</td></tr>
<tr><td>Dropped out due to complications
n = 3</td><td>Withdrawn due to treatment futility as ear cartilage already hardened n = 2</td><td rowspan="4"></td></tr>
<tr><td>Parents already satisfied with ear shape
n = 4</td><td>Defaulted follow up
n = 10</td></tr>
<tr><td>Passed away during course of treatment from an unrelated cause
n = 1</td><td>Inability to retain device n = 2</td></tr>
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Fig. 2. Summary of the patient population.

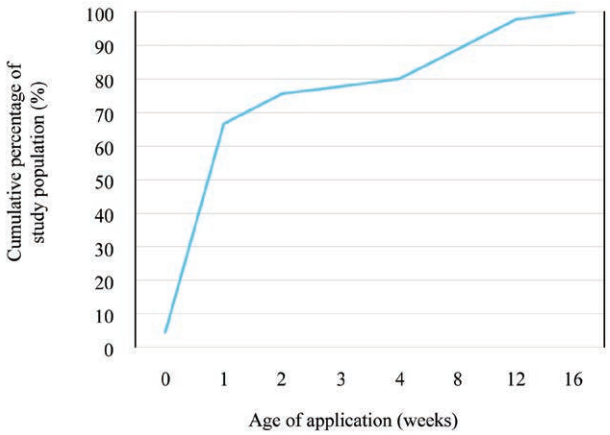

Fig. 3. Age at application of the EarWell system. Eighty percent of patients started the EarWell system before 4 weeks of age.

group, the average age at initiation of the EarWell system was 19.7 days in the excellent group, 16.7 days in the good group, and 12.5 days in the fair group (Table 5). This was not statistically significant ($p = 0.723$). Successful correction (as earlier defined to be those rated to have good and excellent grading) was also unrelated to the age at application of the EarWell system ($p = 0.491$), as shown in Table 4.

Duration of Application

The mean duration of application for all patients was 4.1 weeks (range, 1.5 to 6 weeks), with an average duration of application of 3.6 weeks in the group with excellent grading, 4.4 weeks in the group with good grading, and 4.0 weeks in the

Table 3. Types of Anomalies and Outcomes

Type of Ear Anomaly	Outcomes (%)				No. of Ears
	Excellent	Good	Fair	Poor	
Deformation					
Lidding	15	5	0	0	20
Stahl ear	8	4	0	0	12
Helical deformities	3	1	1	0	5
Prominent ear	2	1	0	0	3
Lop ear	4	1	0	0	5
Conchal crus	0	1	0	0	1
Malformation					
Constricted ear	7	8	9	0	24
Cryptotia	1	0	0	0	1
Total no. of ears (%)	40 (56)	21 (30)	10 (14)	0 (0)	71 (100)

Table 4. Analysis of Successful Correction of the Total Patient Population*

Variable	Correction		*p*†
	Successful (*n* = 61)	Unsuccessful (*n* = 10)	
Type of ear anomaly			<0.001‡
Deformation	45 (98)	1 (2)	
Malformation	16 (64)	9 (36)	
Age at application, days			
Mean ± SD	18.7 ± 26.9	12.5 ± 20.0	0.491
Median (range)	5 (0–97)	4 (1–60)	0.771
Duration of application, wk			
Mean ± SD	3.84 ± 1.43	4.00 ± 1.24	0.746
Median (range)	4 (1–6)	4 (1–6)	0.703

*Mean ± SD and median (range) for continuous variables; frequency (%) reported for categorical variable.
†Fisher's exact test for categorical variable; two-sided two-sample *t* test and Mann-Whitney *U* test for continuous variable.
‡Statistically significant.

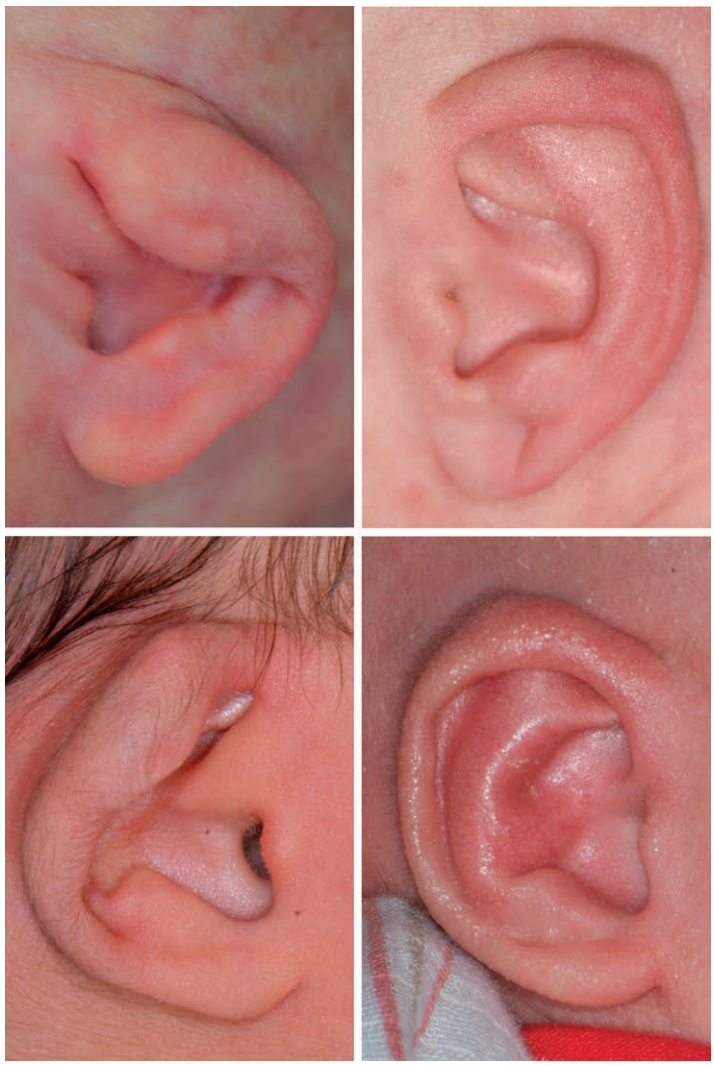

Fig. 4. Examples of successful correction of ear malformations (constricted ears). Before (*left*) and after (*right*) treatment.

group with fair grading (Table 5). The difference in duration of application between the groups was not statistically significant ($p = 0.087$). There was also no difference in the duration of application between patients with successful and unsuccessful correction ($p = 0.746$), as shown in Table 4.

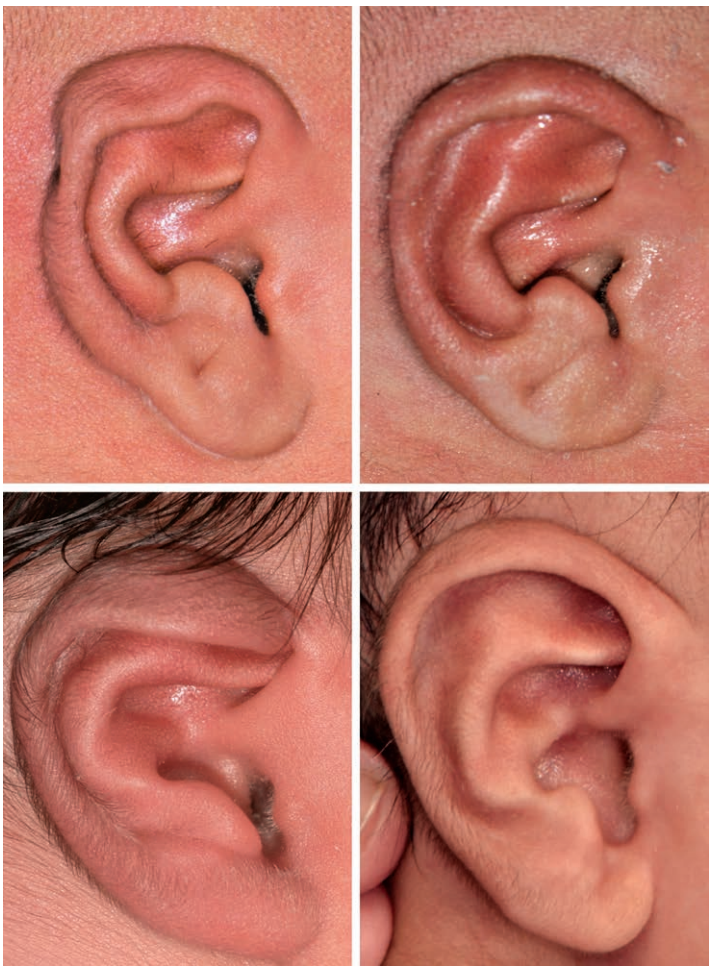

Fig. 5. Examples of successful correction of ear deformations. Before (*left*) and after (*right*) treatment. (*Above*) Helical rim deformity. (*Below*) Lidding.

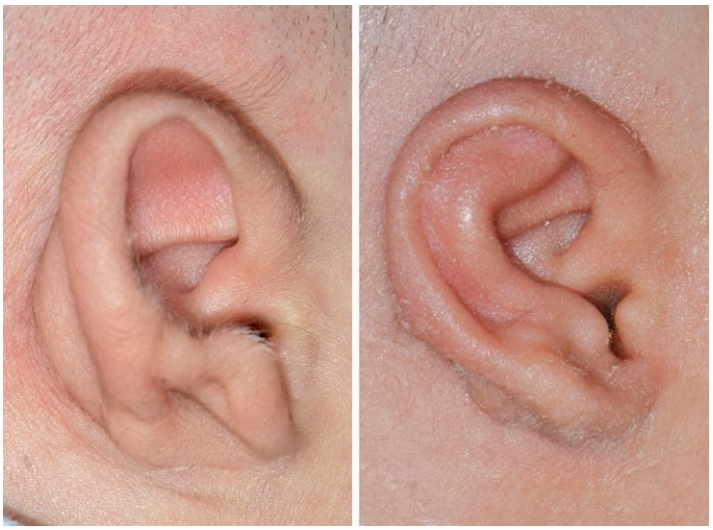

Fig. 6. Example of fair outcome in a patient with right constricted ear malformation. (*Left*) Pretreatment photograph at 1 day of age. (*Right*) Fair outcome after molding, with incomplete expansion of helix.

Table 5. Comparison of Outcome Grading with Duration and Age at Application

Variable	Outcome Grading				*p**
	Excellent	Good	Fair	Poor	
Age at application, days					
Mean ± SD	19.7 ± 27.1	16.7 ± 27	12.5 ± 20		0.723
Median (range)	5 (0–90)	4 (1–97)	4 (1–6)	NA	0.834
Duration of application, wk					
Mean ± SD	3.6 ± 1.4	4.4 ± 1.4	4.0 ± 1.3		0.087
Median (range)	4 (1–6)	4 (1–6)	4 (1–6)	NA	0.053

NA, not applicable.
*Two-sided two-sample *t* test and Mann-Whitney *U* test for continuous variables.

Table 6. Types of Complications

Complication	No. (%)
Pressure ulcers/excoriation	18
Dermatitis	2
Total no. of patients	20 (46)

Complications

Twenty of 45 patients (46 percent) experienced complications during the treatment period, which included dermatitis and skin excoriations or pressure ulcers (Table 6). Ulcers and excoriations are distributed at pressure points under the retractors (scapha and helical rim) and conchal conformers (conchal crus). Adhesive and intertriginous dermatitis are common under the adhesive tapes and along the posterior auricular crease, respectively (Fig. 7). These skin complications healed with conservative management and did not require surgical intervention.

The average age at application in patients with complications was 22.1 days (range, 0 to 97 days). In contrast, the average age at application for patients with no complications was younger, at 10.6 days (range, 2 to 52 days). This difference was found to be statistically significant ($p = 0.037$). Neither the type of ear anomaly nor duration of application of the EarWell system showed correlation with the incidence of complications (Table 7).

Maintenance of Result

Ninety-one percent of patients reported maintenance of ear shape after treatment. Four patients (9 percent) reported mild recurrence, but parents did not seek further treatment because they were satisfied with the improvement in ear form. Of these four patients, three had constricted ears.

Breastfeeding

Breastfeeding did not affect the outcome of molding. All four patients who were not breastfed had successful correction (100 percent), compared with 45 of 51 patients who were either partially or fully breastfed (88 percent). The difference was not statistically significant ($p = 0.266$), as shown in Table 8.

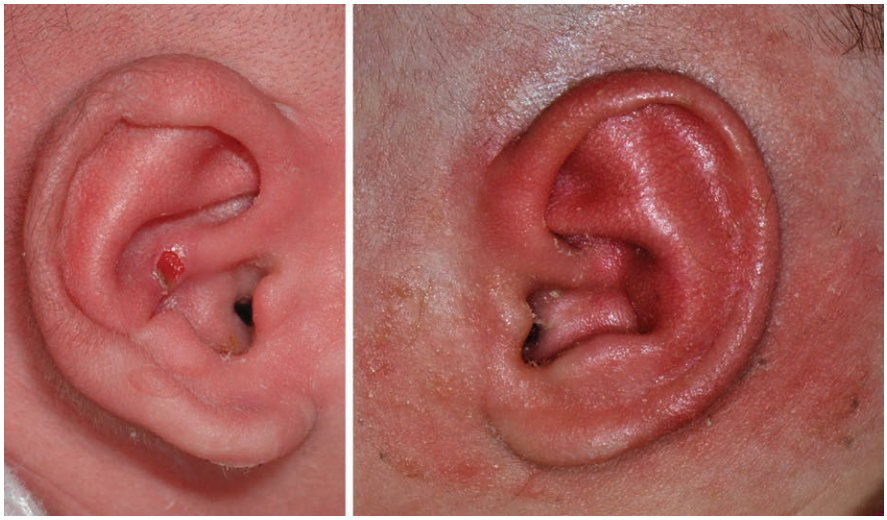

Fig. 7. Complications of the EarWell system. (*Left*) Ulcer at conchal crus. (*Right*) Auricular and periauricular dermatitis.

Table 7. Complications and Mean Age at Application*

Variable	Complications		*p*†
	Yes (%)	No (%)	
No.	20	25	
Type of ear anomaly			0.783
Deformation	12 (43)	16 (57)	
Malformation	8 (47)	9 (53)	
Age at application, days			
Mean ± SD	22.1 ± 30.8	10.6 ± 15.3	0.037‡
Median (range)	5 (0–97)	3 (1–52)	0.545
Duration of application, wk			
Mean ± SD	4.18 ± 1.25	4.12 ± 1.24	0.883
Median (range)	4 (1.5–6)	4 (2–6)	0.930

*Mean ± SD and median (range) for continuous variables; frequency (%) reported for categorical variable.
†Fisher's exact test for categorical variable; two-sided two-sample *t* test and Mann-Whitney *U* test for continuous variables.
‡Statistically significant.

Table 8. Breastfeeding and Successful Correction

Breastfeeding	Successful Correction		Total	*p**
	No	Yes		
No	0	4	4	0.266
Partial	0	13	13	
Full	6	28	34	
Total	6	45	51	

*Fisher's exact test for categorical variable.

Parent Satisfaction

Forty-one of 67 parents responded to the post-treatment interview. The majority of parents (85 percent) were either satisfied or extremely satisfied (Fig. 8). Poor correction of shape and the cost of the EarWell system were the reasons for dissatisfaction.

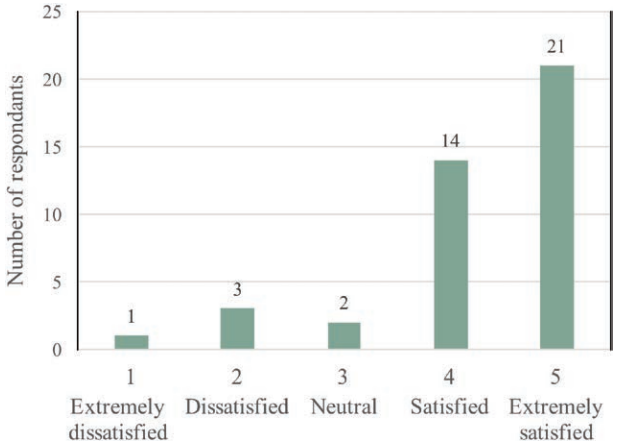

Fig. 8. Parent satisfaction rated on a scale of 1 to 5. Eight-five percent of parents were either satisfied or extremely satisfied with the EarWell system.

DISCUSSION

Comparably to previous studies on ear molding using the EarWell system,[1,13–15] we achieved a high success rate in the correction of ear deformities. Among the factors studied, our results demonstrated that that the type of anomaly is the only predictor of successful correction, where ear malformations had significantly lower success rates (64 percent) compared with deformations (98 percent). Inherent tissue deficiencies, together with less pliable auricular cartilage, a common finding in malformations, account for the lower success rates.

Accordingly, this information is relayed to parents during counseling to manage their expectations. In our experience, despite the lower success rate, most parents proceed with ear molding because the morphology of malformations is more severe, and parents often desire some improvement. In addition, a partially corrected form has the potential to simplify definitive reconstruction in the future.

Both age at application and duration of molding were not correlated to the outcome ($p = 0.491$ and $p = 0.746$, respectively) (Table 4). Subgroup analyses within ear deformations and malformations also did not demonstrate a correlation (Table 9).

It has been suggested that starting EarWell treatment in infants younger than 3 weeks is more effective. Infants older than 3 weeks required a longer period of molding that often exceeded 3 months for successful correction.[1] We were not able to demonstrate that initiating EarWell treatment before age 3 weeks yields a better outcome. Table 10 shows that success rates between patients starting before and after age 3 weeks were comparable, regardless of the type of deformity.

Traditionally indicated for deformations, the application of the EarWell system is expanded to include ear malformations, such as cryptotia

Table 9. Analysis of Successful Correction in Each Group of Ear Deformations and Malformations*

Variable	Successful Correction		*p*
	Successful	Unsuccessful	
Deformation			
No. of ears	45	1	
Age at application, days			
Mean ± SD	20.8 ± 29.4	2.0 ± NA	0.531†
Median (range)	5 (0–97)	2 (2–2)	0.386†
Duration of application, wk			
Mean ± SD	3.72 ± 1.57	4.0 ± NA	0.862†
Median (range)	4 (1–6)	4 (4–4)	0.937†
Malformation			
No. of ears	16	9	
Age at application, days			
Mean ± SD	12.7 ± 17.5	13.7 ± 20.8	0.901‡
Median (range)	3 (2–60)	5 (1–60)	0.589‡
Duration of application, wk			
Mean ± SD	4.19 ± 0.83	4.00 ± 1.32	0.667‡
Median (range)	4 (3–6)	4 (1–6)	0.946‡

NA, not applicable.
*Mean ± SD and median (range).
†Two-sided one-sample *t* test and one-sample Wilcoxon signed rank test.
‡Two-sided two-sample *t* test and Mann-Whitney *U* test.

Table 10. Analysis of Successful Correction with Relation to Age at Application

Age at Application	Successful Correction		*p**
	Successful (%)	Unsuccessful (%)	
Total patient population			0.719
No.	61	10	
≤3 wk old	44 (85)	8 (15)	
>3wk old	17 (89)	2 (11)	
Deformation			1.000
No.	45	1	
≤3 wk	32 (97)	1 (3)	
>3 wk	13 (100)	0 (0)	
Malformation			1.000
No.	16	9	
≤3 wk	12 (63)	7 (37)	
>3 wk	4 (67)	2 (33)	

*Fisher's exact test.

and constricted ears, because of its capability to distract and expand the constricted helix.[15] In cryptotia, the superior helix is abnormally buried under the temporal skin, because of anomalous anatomy and insertion of auricular muscles.[16,17] The molding process for cryptotia is carried out in two stages, first to distract the buried helix, and second to mold the superior helix, which is underdeveloped in all cases of cryptotia. [**See Figure, Supplemental Digital Content 1**, which demonstrates the molding process for cryptotia. This patient attained an excellent outcome. (*Left*) Pretreatment photograph at 40 days of age. (*Second from left*) Retractor applied to distract the buried auricle and expand the constricted helix in the first stage. (*Center*) Two weeks after distraction and before initiation of EarWell treatment in the second stage. (*Second from right*) Immediate posttreatment photograph after 4 weeks of EarWell treatment. (*Right*) Six months after completion of treatment, ***http://links.lww.com/PRS/D710***.] In constricted helices, the retractors serve not only to shape the helix but also to expand the constriction by distraction (Fig. 9).

The ear cartilage remains pliable and amenable to molding because of high circulating levels of maternal estrogen. Physiologic studies have shown that estrogen levels in neonates and infants decrease over time.[18] Despite the presence of maternal estrogen in breast milk, we found no molding benefit if the child is breastfed during the treatment period. Moreover, all four infants who were not breastfed had successful correction (Table 8).

Infants who developed complications started ear molding at an older mean age (22.1 days),

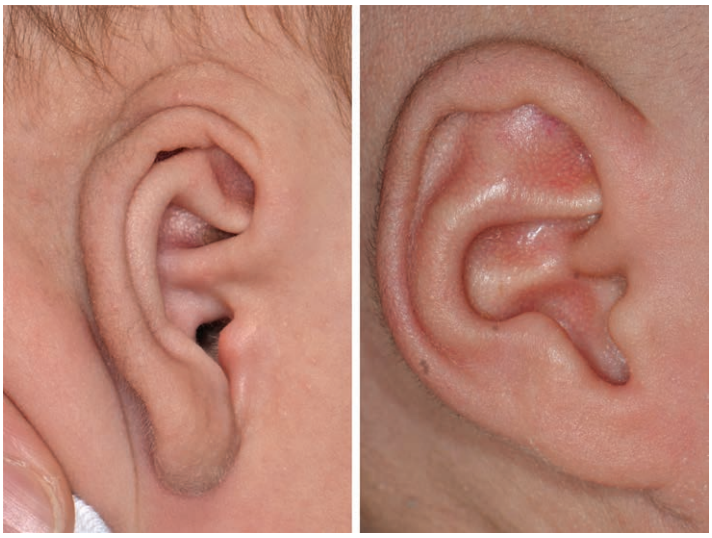

Fig. 9. Application of the EarWell system in a patient with right ear cryptotia. This patient attained an excellent outcome. (*Left*) Pretreatment photograph at 40 days of age. (*Right*) Six months after completion of treatment.

compared with those with no complications (10.6 days). Possible explanations include, first, as circulating maternal estrogen levels decline with age, the ear cartilage hardens. The risk of pressure ulcers increases when retractors are applied against rigid cartilage. Second, the patient's immune system may play a role in the development of dermatitis, with older infants having a greater propensity to develop a dermatitic response. It is known that the innate immune system of neonates is muted as a result of fetal tolerance to maternal antigens.[19] Furthermore, the adaptive immunity system has been proven to be blunted, with a decreased affinity for maturation of antibodies in infants younger than 2 months.[20] As the child becomes older, the immune system becomes more hyperreactive, resulting in heightened responses to new antigens.

We recommend, in patients at risk, that silicone dressings are placed at pressure points under retractors and conformers to protect these areas from pressure ulcers and chafing (Fig. 10). After initiation of these measures, we noted a reduction in our rate of complications.

Compared with previous studies carried out in temperate climates,[1,13–15] a higher incidence of skin complications is noted in our study. This is attributed to the high humidity and temperature of the local tropical weather. The annual averages for relative humidity in Singapore range throughout the day from 64 to 96 percent, and the average high temperature ranges from 30 to 32°C. Skin dampness attributable to the humidity and perspiration contributes to skin maceration, excoriations, dermatitis, and device loosening.

We encourage parents of the patients to keep their child in a cool, dry environment, maintained by air-conditioning system or fans, during treatment. This helps to reduce perspiration and humidity and increase the patient comfort level. We found it necessary to review patients weekly to monitor for skin complications and treatment interruptions caused by device loosening.

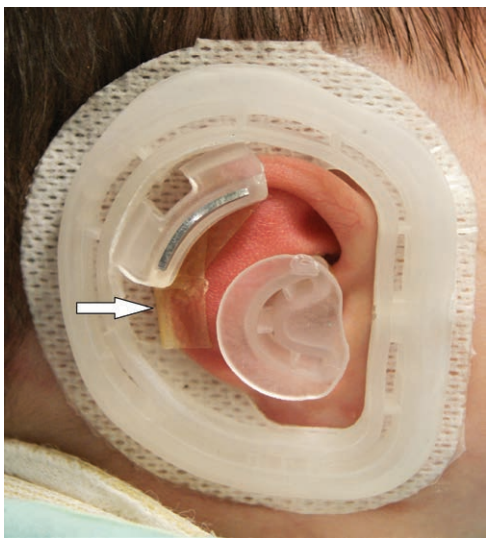

Fig. 10. Measures taken to prevent formation of excoriations and pressure ulcers. Silicone tape is placed at the scaphoid fossa before retractors are applied.

CONCLUSIONS

Ear molding is an effective nonsurgical treatment for ear anomalies—in particular, ear deformations—and should be readily available and offered to parents. Interspecialty collaboration is crucial to facilitate early identification and initiate prompt treatment.

Hui-Ling Chia, M.B.B.S., M.Med.
Department of Plastic, Reconstructive, and Aesthetic Surgery
KK Women's and Children's Hospital
Level 5, Women's Tower
100 Bukit Timah Road
Singapore 229899
chiahuiling@gmail.com

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