

One-Year Outcomes of Ear Molding for Infants with Constricted Ear

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Background: Ear molding is a noninvasive treatment that shows promising results for neonatal ear deformations. Little research has been reported evaluating 1-year outcomes or relapse after ear molding for ear malformations.

Methods: One-year molding efficacy for constricted ear, a common malformation that affects the aesthetic appearance of the auricle, was assessed during a single-center, prospective study conducted over a 3-year period (from May of 2017 to April of 2020). Infants with constricted ears were recruited and treated with the EarWell Infant Ear Correction System. Constricted ear classification, age at treatment application, duration of treatment, complications, and parental satisfaction were analyzed. Photographic documentation of the ears was performed before treatment, at treatment termination, and 12 months after treatment to evaluate treatment efficacy and relapse.

Results: Sixty patients with 91 constricted ears were recruited. The EarWell Infant Ear Correction System was initiated before 2 weeks of age for 75.0% of these patients. Successful correction was achieved in 85.8% of patients. Early molding initiation (before 14 days of age) resulted in a significantly higher success rate ($P = 0.017$). Class 1 and class 2 deformities achieved better outcomes than class 3 deformities ($P = 0.001$). Among the 91 auricles, 37 ears (40.7%) relapsed: 36.3% had mild relapse, 4.4% had moderate relapse, and 0% had severe relapse. The treatment duration for patients with relapse was shorter than for patients without relapse ($P = 0.035$).

Conclusion: Early ear molding is an effective treatment for constricted ear. Sufficient molding duration and consolidation periods are crucial in maintaining treatment effects. (*Plast. Reconstr. Surg.* 151: 159, 2023.)

CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, III.

Neonatal auricular anomalies are a major pediatric public health issue. The reported incidence of congenital auricular anomalies varies from around 6.0% to 57.5%.¹ Although ear deformities are not life-threatening, even

minor ear deformities can lead to psychological distress, social avoidance, and behavioral problems.²

Ear anomalies are classified into two major categories: deformations and malformations. Malformations are characterized by partial absence of the skin or cartilage, resulting in a constricted or underdeveloped pinna; deformations are characterized by a misshaped but fully developed pinna.³ The constricted ear is considered one of the major types of ear malformations, and it greatly affects the aesthetic appearance of the auricle. The term constricted ear, first used

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by Tanzer⁴ in 1975, refers to different degrees of helical and antihelical constriction, shortened auricular longitudinal axis, flattened or absent superior crus, decreased or obliterated scapha, and prominence.

Circulating maternal estrogen maintains high levels of hyaluronic acid in cartilage and potentiates the pliability of ear cartilage after birth; hence, ear molding makes it possible to correct ear anomalies without surgical intervention.⁵ The EarWell Infant Ear Correction System (Becon Medical Ltd., Naperville, IL) has been used since 2010 as an approved noninvasive device that optimizes cosmesis, avoids potential psychological morbidity, and mitigates the costs and risks of surgical correction for ear anomalies during the neonatal period.⁵⁻⁷

Ear molding has been gaining acceptance for various ear abnormalities; however, non-surgical treatment for ear malformations is controversial. The traditional belief is that constricted ear malformations require surgery and ear molding is ineffective and should not be attempted.⁸⁻¹⁰ A variety of surgical procedures for constricted ears have been described in the literature, such as the banner flap, D-flap, tumbling flap, and V-Y advancement of the helical root.¹¹ Regardless of the procedure used, otoplasty is performed typically at nearly 6 years of age, after the auricle has reached 90% or greater of its adult size.¹² Surgery presents potentially significant complications, including the risks of general anesthesia, residual deformity, and scar hypertrophy. Matsuo et al.¹³ recommended molding the constricted ear with a splint for several weeks, beginning at 1 week of age. Recent studies¹⁴ have shown that ear molding is a reliable treatment with good to excellent results for mildly to moderately constricted ears. Moreover, ear molding can downgrade the constriction severity of severely constricted ears to allow for easier surgical correction at a later date.

In our experience, constriction caused by tissue deficiency can be reduced by the expanded use of ear molding. Evidence in the literature has shown promising results with ear molding for neonatal ear deformations. However, little research has described and evaluated the 1-year outcomes and relapse situations in detail, especially those of ear malformations. We present our experience treating 60 infants with constricted ear (91 ears) through nonsurgical methods using the EarWell Infant Ear Correction System and studying the 1-year effects and relapses.

This study aimed to explore whether ear molding is an effective and long-lasting treatment strategy for constricted ear malformations. Furthermore, it aimed to determine whether constricted ears tend to relapse after treatment and whether there is any difference in the treatment effects and relapse situations for different severity levels. Factors that may have affected the molding effects and relapse were analyzed. Parents' perspectives were evaluated to improve treatment strategies. Our study aimed to elucidate the indications for and limitations of nonsurgical treatment for constricted ear to assist in treatment refinement.

PATIENTS AND METHODS

Patients

A single-center, prospective study was conducted over a 3-year period from May of 2017 to April of 2020. A total of 60 children (91 constricted ears) were selected. The age of the patients ranged from 2 days to 107 days (average age, 19.2 days). In this study, 34.1% of children (31 ears) had mixed ear abnormalities (all had associated constricted ear), including constricted ear accompanied by cryptotia [four ears (4.4%)], Stahl ear [five ears (5.5%)], helical rim abnormalities [10 ears (11.0%)], and conchal crus [12 ears (13.2%)].

Patients were diagnosed and referred to our outpatient department by an obstetrician or pediatrician, or parents, who were unsatisfied with the auricle aesthetics and presented their children for outpatient treatment without a referral. Constricted malformations were divided into three classification groups based on severity (least severe, class 1; moderately severe, class 2; and most severe, class 3). (See **Table, Supplemental Digital Content 1**, which shows classification of constricted ears, <http://links.lww.com/PRS/F527>.)¹⁴ Exclusion criteria included microtia and age older than 6 months.

Treatment Course

The EarWell system was used to treat ear molding. This system consists of four main components: the posterior cradle, retractors, conchal former, and anterior shell (**Fig. 1**). The posterior cradle has a posterior conformer that is positioned in the antihelix and the proposed superior limb of the triangular fossa. The retractors are used to hold the helical rim in position. The soft compressible conchal former is placed

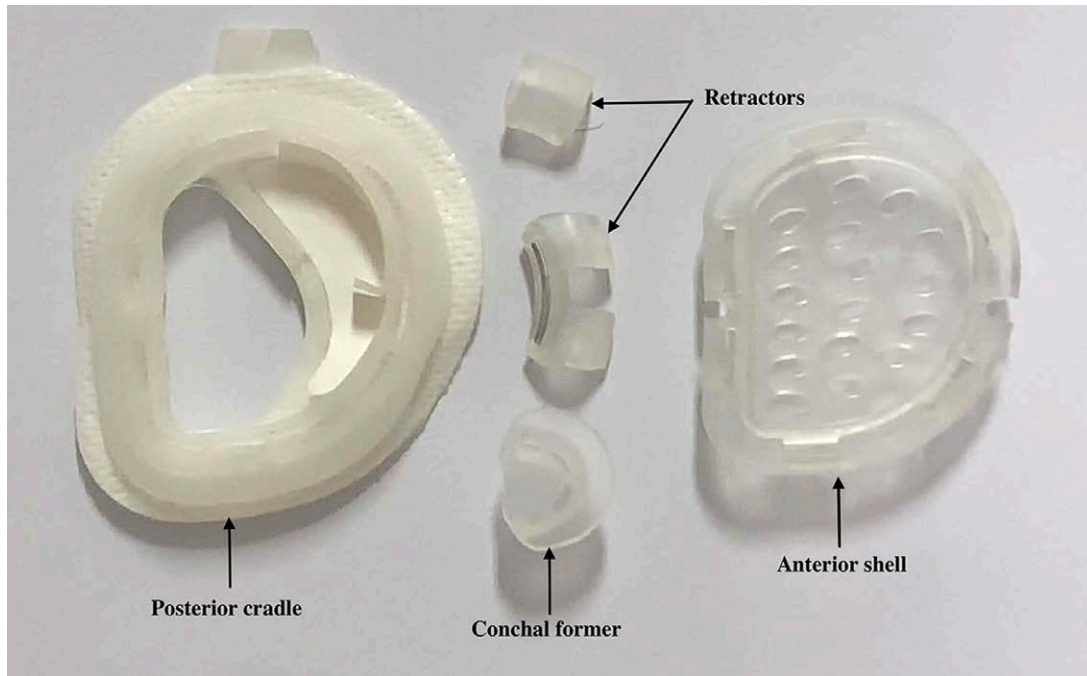


Fig. 1. The individual components of the EarWell Infant Ear Correction System.

within the conchal cavity and the anterior shell is attached to the posterior cradle, resulting in direct anterior forces applied to the conchal former and retractor system. The system was held in place by an adhesive surface.

Patients underwent molding at the outpatient clinic after informed consent and photograph collection information permission forms were signed and submitted. Our treatment course for constricted ear included two major periods: the ear expanding period and the consolidation period. After 6 to 8 weeks of expansion,

the appearance of the auricle was close to the optimal results that could be achieved with the molding treatment; however, continued use of the whole device or just the retractor (Fig. 2) for an additional 1 to 2 weeks was required to maintain the therapeutic effects. Patients were examined weekly for complications and shifting of the apparatus.

Data regarding the constricted ear classification, age at treatment application, and duration of treatment application were collected. Patients underwent a follow-up examination 12 months

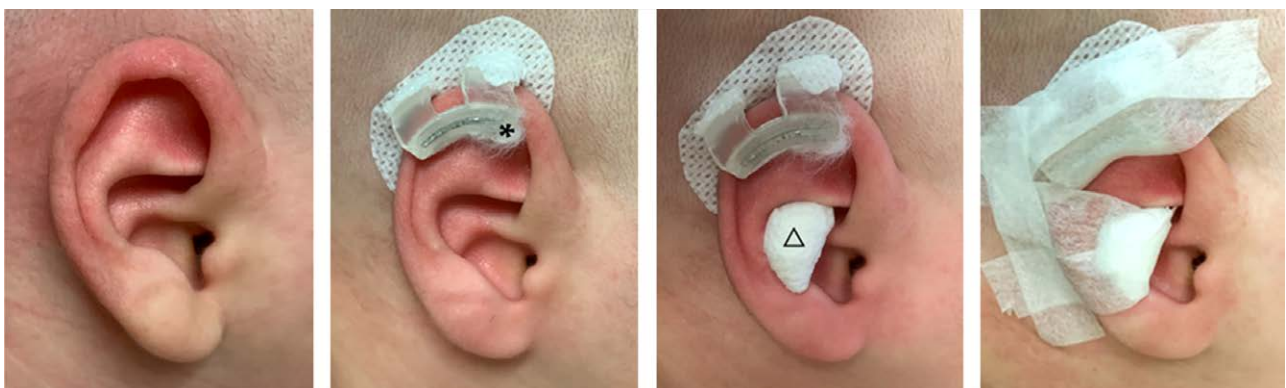


Fig. 2. Consolidation steps. After ear molding with the whole device and when the appearance of the ear is close to normal, we use a retractor to consolidate the treatment effects. Retractors expand and hold the helical rim in position. Cotton is used to protect the skin at the pressure point (*). The crescent-shaped soft plug (Δ) made of double-sided hypoallergenic tape is used to mold the conchal cavity.

after treatment. Photographic documentation of the ears was performed before treatment, at treatment termination, and 12 months after treatment. Photographs taken before and after treatment were assessed by three independent plastic surgeons who rated the treatment outcomes as poor, fair, good, or excellent.¹⁴ These surgeons also compared the treatment termination photograph and follow-up photograph to evaluate the relapse situation. The severity of the relapse was divided into four levels: none, mild, moderate, or severe. (See Table, Supplemental Digital Content 2, which shows the definition of different grades of relapse, <http://links.lww.com/PRS/F528>.) The parents of the patients were asked to score their impressions of the results of the EarWell system using a scale from 1 to 5 (1, extremely dissatisfied; 2, dissatisfied; 3, neutral; 4, satisfied; 5, extremely satisfied). The results of patients who did not attend the outpatient follow-up examination were collected by telephone interview and posttreatment photographs were sent electronically by the parents.

Statistical Methods

Data analysis was performed using SPSS 22.0 statistical software (IBM Corp., Armonk, NY). The qualitative indicators are described as percentages and the quantitative indicators are described as mean \pm standard deviation or median (range). Variables were analyzed using the chi-square test, Fisher exact test, independent two-sample *t* test, and Mann-Whitney *U* test, when appropriate. Logistic regression was used to analyze the treatment effect. All statistical tests were two-sided and $P < 0.05$ was considered statistically significant.

RESULTS

We recruited 60 patients with unilateral or bilateral constricted ears (91 ears); 25 (42%) were female patients and 35 (58%) were male patients. Twenty-nine infants (48%) had unilateral constricted ears and 31 (52%) had bilateral constricted ears. Of these patients, 75% underwent treatment initiation with the EarWell system before 2 weeks of age. The 91 ears were classified as follows: class 1, 34 ears (37.4%); class 2, 37 ears (40.7%); and class 3, 20 ears (22.0%).

Treatment Outcomes

Successful ear molding with treatment effects graded as excellent or good were achieved for 78 ears (85.8%), fair results were achieved for 11 ears (12.1%), and poor results were achieved for two ears (2.2%) (Table 1). Photographs for each class were selected before and after molding to evaluate typical treatment outcomes. (See Figure, Supplemental Digital Content 3, which demonstrates class 1, class 2, and class 3 constricted ears before treatment, at treatment termination, and at the 1-year follow-up examination. All three patients achieved excellent treatment outcomes; the class 3 patient had a mild relapse, <http://links.lww.com/PRS/F529>.)

The ages at initial application for successful correction and unsuccessful correction were 7.0 days (range, 2 to 76 days) and 17.0 days (range, 5 to 107 days), respectively. The age at initial treatment for those in the successful correction group was younger than that of patients in the unsuccessful correction group (Mann-Whitney *U* test; $P < 0.01$) (Table 2). Early molding initiation (before 14 days) resulted in a significantly higher success rate than later initiation (91.2% compared

Table 1. Comparison of Treatment Effects of Different Constricted Ear Classifications

Classification	Treatment Effect Grade, n (%) of Ears				<i>P</i> ^a
	Excellent	Good	Fair	Poor	
Class 1	23 (67.6)	9 (26.5)	2 (5.9)	0 (0)	
Class 2	15 (40.5)	19 (51.4)	3 (8.1)	0 (0)	
Class 3	6 (30.0)	6 (30.0)	6 (30.0)	2 (10.0)	
Total	44 (48.4)	34 (37.4)	11 (12.1)	2 (2.2)	<0.01

^aFisher exact test was used to compare the treatment effect grades of the different classifications.

Table 2. Treatment Effect and Posttreatment Relapse of Ear Molding for Constricted Ears^a

Variable	Successful	Unsuccessful	<i>P</i> ^b	Relapse	Nonrelapse	<i>P</i> ^b
Age at application, days	7 (2–76)	17 (5–107)	<0.01	10(2–107)	7 (2–76)	0.121
Duration of application, weeks	10.9 \pm 3.31	7.31 \pm 2.39	<0.001	9.42 \pm 3.32	10.96 \pm 3.42	0.035

^aValues presented as mean \pm SD for normal distribution and median (range) for non-normal distribution.

^bTwo-sided two-sample *t* test for normal distribution and Mann-Whitney *U* test for non-normal distribution.

Table 3. Logistic Regression of the Treatment Effects for Constricted Ear by Age, Treatment Duration, and Classification^a

Independent Variable	Odds Ratio (95% CI)	P
Age at application	0.95 (0.91–0.99)	0.01
Treatment duration	1.62 (1.14–2.30)	<0.01
Classification		
Class 1	19.95 (2.04–194.78)	0.01
Class 2	6.67 (1.03–43.13)	0.04
Class 3 ^b	1	

^aThe dependent variable was the treatment effect (variable assignment: success = 1; no success = 0); independent variables included classification of constricted ear, age at application, and treatment duration.

^bCategorical variable: class 3 for reference category.

with 69.6%; Fisher exact test, $P = 0.017$). The mean overall duration of application for successful correction was 10.9 ± 3.1 weeks; that of unsuccessful correction was 7.13 ± 2.39 weeks. Patients with successful correction had a longer treatment duration (independent sample t test; $P < 0.001$) (Table 2).

In addition, we conducted a logistic regression model for treatment outcomes by classification, age, and duration (Table 3). The result of omnibus test of model coefficients was $\chi^2 = 32.18$ ($df = 4$, $P < 0.001$). An evaluation of the goodness of fit of the model was performed using the Hosmer and Lemeshow test ($\chi^2 = 6.51$, $df = 8$, $P = 0.59$). For a unit change in age, the odds were expected to change by a factor of 0.95 (0.91 to 0.99) while holding all other variables constant. For a unit change in treatment duration, the odds were expected to change by a factor of 1.62 (1.14 to 2.30) while holding all other variables constant. Meanwhile, the treatment success rates for classes 1 and 2 were 94.1% and 91.9%, respectively, which were significantly better than the rate of 60% observed in class 3 (Fisher exact test, $P < 0.01$) (Table 1). Compared with class 3, the treatment effect of class 1 displayed an odds ratio of 19.95 (95% CI, 2.04 to 194.78; $P = 0.01$) and class 2 displayed an odds ratio of 6.67 (95% CI, 1.03 to 43.13; $P = 0.04$) (Table 3).

Relapse after Treatment

Among the 91 auricles, 54 ears (59.3%) did not experience relapse and 37 ears (40.7%)

experienced relapse; 36.3% had mild relapse, 4.4% had moderate relapse, and 0% had severe relapse. [See Figure, Supplemental Digital Content 4, which shows mild relapse of constricted ear after treatment. (Left to right) Before treatment, at treatment termination, and at 1-year follow-up examination, <http://links.lww.com/PRS/F530>. See Figure, Supplemental Digital Content 5, which shows moderate relapse of constricted ear after treatment. From left to right: before treatment, at treatment termination, and at 1-year follow-up examination, <http://links.lww.com/PRS/F531>.]

The average ages at the time of treatment application for patients with and without relapse were 10 days (range, 2 to 107 days) and 7 days (range, 2 to 76 days), respectively. There was no statistically significant difference between these groups (Mann-Whitney U test, $P = 0.121$) (Table 2).

The average treatment duration for patients who experienced relapse and those who did not were 9.4 ± 3.3 weeks and 11.0 ± 3.4 weeks, respectively. The difference between these two groups was statistically significant. Patients with relapse had a shorter treatment duration than patients without relapse (independent samples t test, $P = 0.035$) (Table 2).

Relapse rates after treatment were significantly different among the different classifications (chi-square test, $P < 0.001$) (Table 4). Patients with class 2 and class 3 constricted ear were more likely to experience posttreatment relapse than patients with class 1 constricted ear (Bonferroni correction, $P < 0.05$). However, there was no statistically significant difference in the recurrence rates of those with class 2 or class 3 constricted ear. It is worth noting that in our study, relapses were mild to moderate; no case of severe relapse occurred.

Complications

Complications during the treatment period included dermatitis (10 of 91 ears) [see Figure, Supplemental Digital Content 6, which demonstrates dermatitis after use of the EarWell Infant Ear Correction System; (left to right) before

Table 4. Comparison of Treatment Success and Relapse Rates of Different Constricted Ear Classifications

Class	Treatment Effect, n (%) of Ears			Posttreatment Relapse, n (%) of Ears		
	Successful	Unsuccessful	P ^a	Relapse	Nonrelapse	P ^b
1	32 (94.1)	2 (5.9)		5 (14.7)	29 (85.3)	
2	34 (91.9)	3 (8.1)		18 (48.6)	19 (51.4)	
3	12 (60.0)	8 (40.0)		14 (70.0)	6 (30.0)	
Total	78 (85.7)	13 (14.3)	<0.01	37 (40.7)	54 (59.3)	<0.01

^aFisher exact test.

^bChi-square test.

treatment, auricular and periauricular dermatitis, and complete resolution of the complication, <http://links.lww.com/PRS/F532>], skin excoriations (6 of 91 ears), and pressure ulcers (3 of 91 ears) [see **Figure, Supplemental Digital Content 7**, which demonstrates pressure ulcers after use of the EarWell Infant Ear Correction System; (*left to right*) before treatment, ulcer at the conchal crus, and complete resolution of the complication, <http://links.lww.com/PRS/F533>]. The overall complication rate was 20.9%. The rate of tissue excoriation was 9.9%. All skin complications resolved after treatment without residual symptoms. Two patients experienced posttreatment head asymmetry that was not a direct result from the ear molding but was attributable to improper parental care during device wearing.

Parent Satisfaction

Parents of 83.5% of the patients (76 ears) indicated that they were extremely satisfied or satisfied with the posttreatment effects. (See **Table, Supplemental Digital Content 8**, which shows evaluation of parents' satisfaction, <http://links.lww.com/PRS/F534>.) Poor correction effects and the cost of the molding system were reasons for dissatisfaction. Dissatisfied parents had children with class 2 or class 3 constricted ear and children who were older at the time of treatment application; these factors were related to relatively poor correction.

DISCUSSION

Ear malformations, which are accompanied by inherent tissue deficiencies and less pliable auricular cartilage, have significantly lower successful molding rates compared with ear deformations.¹⁵ Successful ear molding was achieved for 85.8% of the constricted ears in our study. Continuous long-term follow-up of the treatment effect is important; our follow-up duration was 1 year. The importance and significance of the 1-year follow-up are as follows. First, the shape of the ear already has a certain degree of stability at 1 year of age, as approximately 90% of the eventual adult ear width and 75% of its destined length are already achieved.¹⁶ Second, we found that some constricted ears have the tendency to relapse at different degrees after 1 year of treatment, which is much different than other ear deformities, such as lidding ear, Stahl ear, and cryptotia, which can maintain a large degree of stability. This phenomenon can provide doctors and patients with more

reasonable treatment expectations and a guide to optimize the treatment process such as the extension of the treatment duration.

Age at Treatment Application

Several studies reported that outcomes were clearly better when molding was initiated during the first 5 to 7 days of life; outcomes were less favorable when treatment was initiated after 3 weeks of age.^{5,14,17} In our study, molding before 2 weeks of age resulted in a significantly higher success rate (91.2%) than molding initiated later (69.6%). These results suggest that early molding can improve the treatment effects for constricted ear.

Approximately one-third of the deformations showed a tendency for self-correction; however, the remaining deformations and all malformations required immediate treatment.^{18,19} Watchful waiting may eliminate the opportunity for non-surgical correction of constricted ears that do not experience self-correction because of the strong tension caused by deficiencies of the skin and cartilage.

Duration of Treatment Application

The average treatment duration reported in the literature is 2 to 6 weeks, depending on the type of abnormality. Our research indicated that the total treatment duration for constricted ears was 10.33 ± 3.44 weeks; this treatment period included the expanding duration (8.54 ± 2.98 weeks) and consolidation duration (1.67 ± 1.56 weeks), which were much longer than those required for other deformities.^{9,14,15} This prolonged treatment duration is required mainly because constricted tension caused by skin and cartilage deficiencies necessitates a prolonged treatment duration for long-lasting expansion.

Because constricted ears are accompanied by prominence and conchal crus, which may contribute directly to forward tension and increased conchal–mastoid angle, there is a tendency for constricted ears, especially class 2 and class 3, to curl and constrict again after treatment termination. In our study, patients who experienced relapse had a shorter treatment duration than patients who did not; however, the ages at treatment application for patients with and without relapse were not significantly different, suggesting that maintaining sufficient molding time is more important for achieving stable treatment effects.

We found that a relatively stable treatment effect requires 8 weeks of use of the entire molding

system to expand and shape the ear and 2 weeks of consolidation. Consolidation is critical after the constricted ear reaches a normal appearance. Insufficient treatment durations will reduce the treatment success rates and increase the possibility of recurrence after treatment. Not all goals for treatment of class 2 and 3 constricted ears are to obtain normal appearance. In some serious cases, after the treatment duration of 12 to 14 weeks, if obvious improvements are observed, but no further treatment progress is noted, the treatment can be suspended.

Treatment Effects and Relapse for the Different Constricted Ear Classes

Our research showed that the treatment effects for class 1 and class 2 were significantly better than those for class 3 (Tables 3 and 4); these results are consistent with those of a previous study.¹⁴ The relatively poor treatment effects for class 3 constricted ears mainly occurred because of the severity of skin and cartilage defects, thereby increasing the auricle tension.

Compared with class 1 constricted ears, class 2 and class 3 constricted ears are more likely to experience relapse (Table 4). The auricle cartilage is less extensible than the skin and the expansion ability of ear molding for patients with serious tissue deficiency is limited; the residual tension results in relapse after molding. Based on the physical molding principle that continuous physical stretching before hardening of the auricle cartilage can maintain the treatment effects, we suggest the consolidation time be extended appropriately for these patients. Because of the different hardness, tension, and plasticity of each ear, the prolonged consolidation time is individualized, which can begin in 1 week and then after 3 days of short suspension; if there is no relapse, the treatment can be terminated, and observation continued.

Complications

Complication rates of tissue excoriations and breakdown range from 3% to 7.6% for molding of ear abnormalities.^{5,9,11,14} In our study, this rate was 9.8% and included skin excoriations and pressure ulcers. The relatively higher rate of tissue excoriations and dermatitis [11% (10 of 91)] may have been associated with the tissue tension and a relatively longer treatment time. All complications resolved after treatment.

Three patients in our study with conchal crus deformity developed pressure ulcers. Conchal

crus deformity often is associated with prominent ear and cup ear. The conchal crus frequently appears as the continuation of the helical rim across the concha. This was referred to as a prolonged crus helicus by Matsuo et al.²⁰ The molding system allows anterior forces to be applied to the concha that would flatten the conchal crus and correct the conchal–mastoid angle; however, the anterior forces can lead to pressure ulcers.⁵ Therefore, we replaced the conchal former with a crescent-shape soft plug made of double-sided tape to reduce the pressure in some cases (Fig. 2) to avoid pressure ulcers at the conchal crus.

Head asymmetry, which is not caused directly by ear molding, mainly occurs because infants tend to lie opposite to the molding side or sleep in the supine position when using a bilateral treatment system. The sleep position is considered the leading risk factor for the development of positional plagiocephaly, which appears to be age-dependent; the peak of its prevalence occurs within the first 6 months of life and decreases until age 2 years.²¹ Head orientation asymmetry can be prevented by enhancing parental awareness of side preferences while sleeping and ensuring the infant is sleeping on alternating sides.

CONCLUSIONS

Early ear molding was an effective nonsurgical treatment for constricted ear malformation, particularly class 1 and class 2 cases. Severely constricted ears achieved partial improvement, thus allowing for easier surgical correction in the future. Skin and auricular deficiencies resulted in constricted tension, which led constricted ears, especially class 2 and class 3, to curl and constrict again after treatment termination. Early application of treatment increased the therapeutic effects. Sufficient molding time was crucial to treatment efficacy and reduced the relapse rate.

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