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A Retrospective Review of Outcomes and Complications after Infant Ear Molding at a Single Institution

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Background: The purpose of this study was to evaluate outcomes and complications associated with infant ear molding at a single institution.
Methods: We conducted a retrospective chart review of all infants who underwent ear molding using the EarWell Infant Ear Correction System with pediatric plastic surgery from October 2010 to March 2021. Types of ear anomalies, age at initiation, duration of treatment, gaps in treatment, comorbidities, and complications were extracted for included patients. The primary outcomes assessed were degree of ear anomaly correction and incidence of skin complications. Parents were also sent a questionnaire regarding their long-term satisfaction with the ear molding treatment process.
Results: A total of 184 ears of 114 patients meeting inclusion criteria were treated during the study period. Mean age at treatment initiation was 21 days, and average duration of treatment was 40 days. Helical rim deformities (N = 50 ears) and lop ear (N = 40 ears) were the most common anomalies. A total of 181 ears (98.4%) achieved either a complete (N = 125 ears, 67.9%) or partial correction (N = 56 ears, 30.4%). The most common complications were eczematous dermatitis (N = 27 occurrences among 25 ears, 13.6%) and pressure ulcers (N = 23 occurrences among 21 ears, 12.5%). Infants who experienced a complication were 3.36 times more likely to achieve partial relative to complete correction ($P < 0.001$; 95% confidence interval 1.66–6.81).
Conclusion: Ear molding is an effective treatment strategy for infant ear anomalies, with most patients achieving complete correction. *(Plast Reconstr Surg Glob Open 2023; 11:e5133; doi: 10.1097/GOX.0000000000005133; Published online 24 August 2023.)*

INTRODUCTION

Congenital anomalies of the ear are common, affecting one out of three newborns.[1] Approximately one-third of these cases self-correct over the first few weeks of life, whereas the remaining two-thirds do not. If left unaddressed, persistent ear anomalies may lead to problems with self-esteem and mental health during the early school years and beyond.[2] Fortunately, a variety of treatment options are available for these patients. The first-line therapy for infants with mild-to-moderate anomalies is ear molding, a nonsurgical intervention that gradually reshapes the ear cartilage over the course of several days to weeks, through the application of continuous tension.[1,3] The treatment can be performed using a variety of tools, ranging from surgical tape to more sophisticated devices that grip onto the pinna. Reported outcomes in the literature are excellent, with 82%–90% of patients achieving favorable results.[1,3]

A variety of treatment-related and patient-related factors may potentially influence outcomes and complications during the ear molding process. One important variable is the timing of the treatment. Conventionally, ear molding is initiated as soon as possible after birth while the concentration of maternal estrogen in the infant bloodstream

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is at its highest level.[1] These circulating estrogens act on estrogen receptors expressed by auricular chondrocytes to elevate hyaluronic acid levels and pliability of the ear cartilage.[4–6] Byrd et al found superior outcomes and fewer complications among patients who initiated ear molding during the first week of life.[1] It has also been theorized that breastfeeding may extend the optimal time period for ear molding initiation due to the presence of maternal estrogens in breast milk.[1,7] However, it is unclear if concentration of estrogens in breast milk is sufficiently high, and this remains a topic of investigation.[1,7]

Another factor that may potentially influence outcomes is the type of ear anomaly, which is broadly categorized as deformities or malformations.[1,3] Deformities are characterized by fully developed but misshapen pinna. Examples of deformities include Stahl ear, helical deformity, lop ear, lidding, and prominent ear. In contrast, malformations are defined by the partial absence of skin and cartilage, leading to an underdeveloped pinna. Examples of malformations include cupped ear, constricted ear, and cryptotia. A previous study by Chan et al found a higher degree of successful outcomes after ear molding for deformities compared with malformations.[3]

First introduced to the literature by Byrd et al, the EarWell Infant Ear Correction System (Becon Medical Ltd., Naperville, Ill.) is one option for infant ear molding, used by many health-care providers.[1] The device consists of a cradle with adhesive that adheres to the skin around the ear, various size retractors that grip onto the helical rim, a conchal bowl former (as needed for conchal shaping), an optional foam piece that may overlay the conchal bowl former for additional pressure, and a lid that helps hold all the components in place (Fig. 1).

The objectives of this study were to (1) analyze the outcomes and complications associated with this ear molding system at a single institution over a 11-year period and (2) report long-term parent/patient-reported satisfaction with the ear molding treatment.

Takeaways

Question: Can we determine success rate and complications with infant ear molding, using the EarWell Infant Ear Correction System?

Findings: Primary outcomes were correction of ear shape and incidence of skin complications. Long-term parent satisfaction was assessed. Complete correction occurred in 68% of ears. Partial correction was seen in 30%. The most common adverse issues were eczematous dermatitis (13.6%) and pressure ulcers (12.5%), which completely resolved. Parent satisfaction was high, and there were no psychosocial issues relative to ear shape when patients were older.

Meaning: Infant ear molding is an effective treatment for congenital ear anomalies with high success rates, low complications, and high parent satisfaction.

METHODS

This study was an institutional review board–approved retrospective review and prospective questionnaire study of infants who underwent ear molding at a single institution from October 2010 to March 2021. Patients were identified using Current Procedural Terminology codes related to nonsurgical ear molding through the Stanford Research Repository database, which enabled identification of patient medical record numbers. Data regarding types of ear anomalies, age at initiation, duration of treatment, temporal gaps in treatment, comorbidities, degree of correction, and details regarding any complications were extracted from patients' medical records.

Types of anomalies were classified as a deformity, malformation, or multiple anomalies (eg, constricted ear and cupped ear). Deformities included lop ear, lidding, helical rim deformity, antihelix deformity, prominent ear, and Stahl ear. Malformations included cupped ear, constricted ear, and cryptotia. Multiple anomalies were defined as two or more abnormalities, regardless of whether the

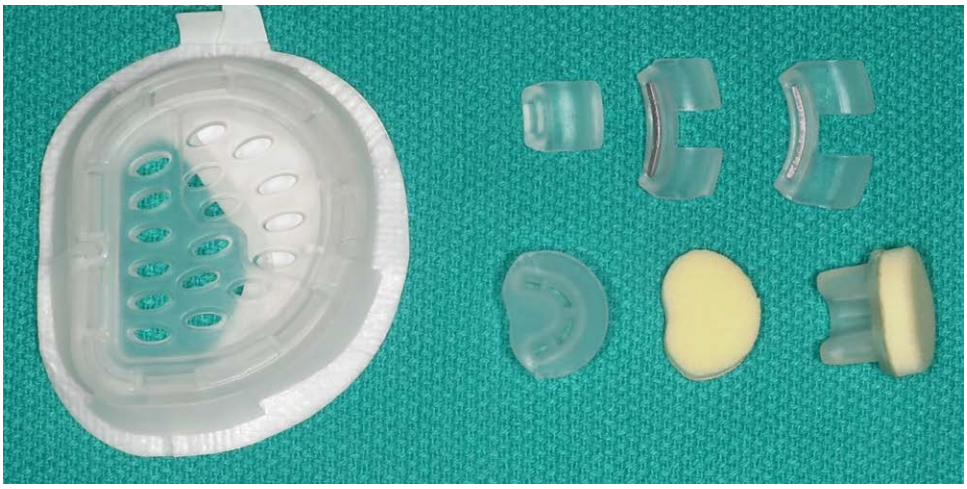

Fig. 1. EarWell infant ear molding device. The ear molding device consists of a series of retractors that grip onto the helical rim, an anterior shell that adheres to the face, a posterior cradle that holds the overall apparatus together (left), a conchal bowl former, and an optional foam piece that may overlay the conchal bowl former for additional pressure.

individual anomalies were deformities or malformations. The primary outcomes assessed were degree of ear anomaly correction (unsuccessful versus partial versus complete) upon treatment completion and incidence of skin complications during the treatment process.

The infant ear molding procedures were performed by one of three craniofacial plastic surgeons through the pediatric plastic surgery clinic at Lucile Packard Children's Hospital, Stanford Children's Health. Degree of ear correction was defined subjectively by the treating surgeon. Outcomes were deemed to be complete if the ear possessed all features of normal ear morphology, including a well-defined tragus, antitragus, crus, superior crus, lobe, concha, helix, and scapha, without evidence of the original anomaly.[8] In contrast, outcomes were deemed to be partial by the treating surgeon if there was some improvement in ear morphology without complete resolution of the original anomaly. Unsuccessful outcomes had no changes from the baseline morphology of the treated ear and were listed as failed correction. Patients who were lost to follow-up during the treatment period were excluded.

Parents of included patients were also prospectively asked to complete a survey of 14 questions regarding their long-term satisfaction with the infant's corrected ear(s) and the infant ear molding treatment process. The questionnaire consisted of dichotomous questions, Likert scale statements, and free-response questions. Specifically, outcomes assessed were satisfaction with four aspects of the ear's appearance (overall appearance, "natural" look, symmetry, prominence), each rated on a four-point Likert scale (1 = very dissatisfied, 2 = somewhat satisfied, 3 = somewhat satisfied, 4 = very satisfied) and summed for a cumulative maximum score of 16. Other possible outcomes included (1) issues with peers in social settings, (2) complications associated with the ear molding process, and (3) difficulties related to the operation or maintenance of the ear molding device. For these questions, Likert scale statements were rated on a 4–5 option scale, which ranged from "very dissatisfied"/"very difficult" to "very satisfied"/"very easy." Responses were divided into a "successful" group and an "unsuccessful" group, depending on whether respondents denoted the overall treatment outcome as successful or unsuccessful, respectively. Questionnaire data were distributed and collected using the REDCap Database Collection software. All statistical analysis was performed using SPSS (IBM SPSS Statistics for Mac, version 28.0; IBM Corp, Armonk, N.Y.). Statistical analysis was performed using the Mann-Whitney U test and logistic regression. Values of P less than 0.05 were considered significant.

RESULTS

A total of 184 ears of 114 infants meeting inclusion criteria underwent nonsurgical ear molding during the 11-year study period. Most of these ears (n = 167, 90.8%) were treated by the senior author (R.K.K.). The patient cohort included 77 (67.5%) male patients and 37 (32.5%) female patients. Mean age at treatment initiation was 21 days, and average duration of treatment was 40 days. By 32 days of life, 90% (N = 168) of the patients in our cohort had initiated the ear molding process (Fig. 2). Approximately 149 (81%) ears were classified as

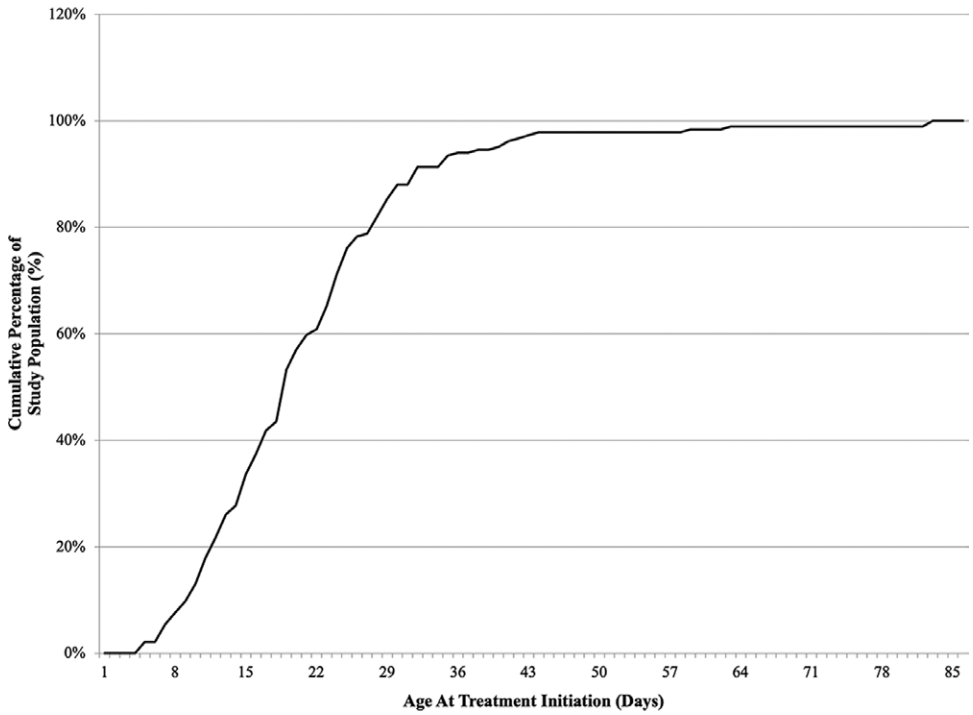

Fig. 2. Age at treatment initiation. Age (d) upon initiation of infant ear molding treatment. The mean age of treatment initiation was 21 days.

Table 1. Summary of Ear Anomalies

Anomaly	No. Ears (%)	%
Types of ear deformation		
Lop ear	40	21.7
Lidding	7	3.8
Helical deformity	50	27.2
Antihelix deformity	4	2.2
Prominent ear	13	7.1
Stahl ear	20	10.9
Total no. deformations	134	72.9
Types of ear malformation		
Constricted ear	19	10.3
Cupped ear	15	8.2
Cryptotia	7	3.8
Total no. malformations	41	22.2
Multiple anomalies		
Constricted ear and cupped ear	1	0.5
Lop ear and cup ear	4	2.2
Lop ear and constricted ear	1	0.5
Constricted ear and helical deformity	1	0.5
Cryptotia and cup ear	2	1.1
Total no. multiple anomalies	9	4.9

deformations, with helical rim deformities (n = 50, 27.2%) and lop ear (n = 40, 21.7%) representing the most common variants. In addition, 41 ears (22.2%) were classified as malformations, whereas nine ears (4.9%) possessed characteristics consistent with two different anomalies. A detailed summary of all anomalies is listed in Table 1. In total, 46 ears (25.0%) experienced a gap in treatment of at least 1 day during the molding process secondary to skin complications (19 ears, 10.3%) or the device falling off prematurely between clinic visits (27 ears, 14.7%). The average gap in treatment was 5 ± 3.8 days.

A total of 181 ears (98.4%) achieved either a complete (n = 125 ears, 67.9%) or partial correction (n = 56 ears, 30.4%) upon treatment completion (Table 2). One example of a complete correction is depicted in Figure 3. Three ears (1.7%) of two infants required early termination of molding secondary to eczematous dermatitis in the periauricular skin due to the adhesive, thus receiving insufficient duration of treatment. These are classified as failure of treatment (Fig. 3). These three ears with failed correction were excluded from the advanced data analysis below due to the limited sample size in this group.

One or more skin complications occurred in 49 ears (26.6%). The most common complications were eczematous dermatitis (n = 27 occurrences among 25 ears, 13.6%) and pressure ulcers (n = 23 occurrences among 21 ears, 12.5%). Examples of each are shown in Figure 4. Further analysis examined the relationship between ear molding outcomes and ear molding procedural characteristics. There was no statistically significant association between age at initiation ($P = 0.314$), duration of application ($P = 0.198$), or type of anomaly ($P = 0.469$) and degree of correction. However, there was a statistically significant difference in achieving a partial versus complete correction in infants who experienced a complication ($P < 0.001$). Moreover, infants who experienced a complication were 3.36 times more likely to achieve a partial correction ($P < 0.001$; 95% confidence interval 1.66–6.81) compared with infants with an uncomplicated treatment course. Age at application ($P = 0.269$), duration of application ($P = 0.238$), and type of anomaly ($P = 0.361$) were not associated with the incidence of one or more complications.

Questionnaires were sent to all the caregivers of infants included in the study. Responses were received for 24 of 114 patients, achieving a 21.1% response rate. Most respondents (70.8%) indicated that the overall duration of treatment was "reasonable," whereas seven (29.2%) respondents felt that it was either "moderately" or "very time-consuming." Three quarters (75%) of parents and guardians felt that ease of use and maintenance of the ear molding system was "somewhat easy." Most respondents (95.8%) indicated that their child "almost never" experienced issues concerning their ears in social situations, whereas one individual (4.2%) indicated that their child experienced issues in "some social situations." Nineteen participants (79.2%) felt that the ear molding device was "somewhat," "moderately," or "very" irritating to their child's ear, whereas five individuals (20.8%) responded that the process was "not irritating at all." All respondents (100%) indicated no additional procedures were performed on the corrected ear(s) after ear molding

Table 2. Types of Anomalies and Outcomes

	Outcomes			
Anomaly	Complete Correction	Partial Correction	Failed Correction	No. Ears
Deformation				
Lop ear	31	9	0	40
Lidding	4	3	0	7
Helical deformity	33	17	0	50
Prominent ear	7	5	1	13
Stahl ear	19	5	0	24
Malformation				
Constricted ear	13	6	0	19
Cupped ear	7	6	2	15
Cryptotia	7	0	0	7
Multiple anomalies	4	5	0	9
Total no. ears (%)	125 (67.9)	56 (30.4)	3 (1.7)	184 (100)

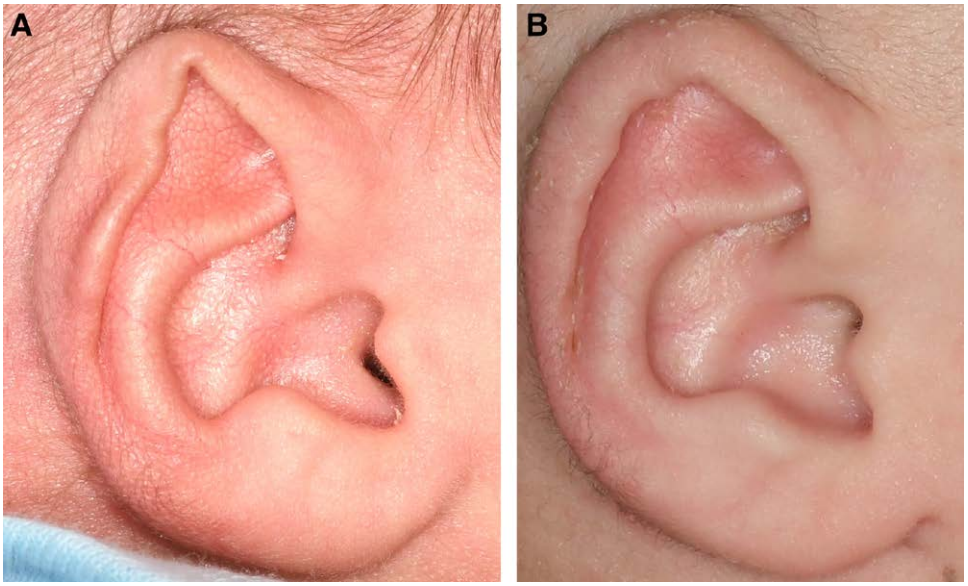

Fig. 3. Complete correction of helical rim deformity. A, Helical rim deformity before treatment. B, Complete correction of deformity following infant ear molding.

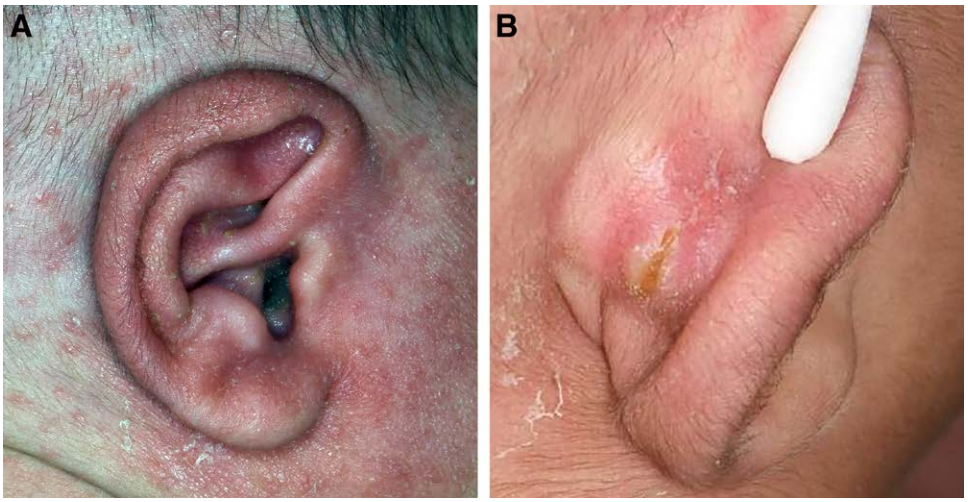

Fig. 4. Complications. Eczematous dermatitis (A) and pressure ulcer (B) were the most encountered complications during infant ear molding.

treatment completion. Questionnaire responses are summarized in Figure 5.

Further analysis divided responses based on whether the overall treatment outcome was considered successful or unsuccessful. The successful group consisted of 21 respondents (87.5%), and the unsuccessful group consisted of three respondents (12.5%). The mean cumulative appearance score demonstrated a statistically significant difference, with an average score of 11 ± 2.6 for the unsuccessful group and 15.4 ± 1.6 for the successful group ($P = 0.002$) (Fig. 6). Analyzing whether individuals would perform the procedure again revealed a statistically significant difference between groups, with an average score of 2 ± 0.0 for the unsuccessful group and 3.86 ± 0.36 for the successful group ($P < 0.001$).

DISCUSSION

This study represents a large retrospective analysis of outcomes after infant ear molding at a single institution, with the majority (90.8%) of patients treated by a single surgeon (R.K.K). We found that 67.9% of our patients achieved complete corrections, whereas an additional 30.4% achieved partial corrections with improvement in their baseline anomalies. This overall success rate of 98.3% is consistent with other studies in the literature: Byrd et al reported a success rate of 90% using a similar

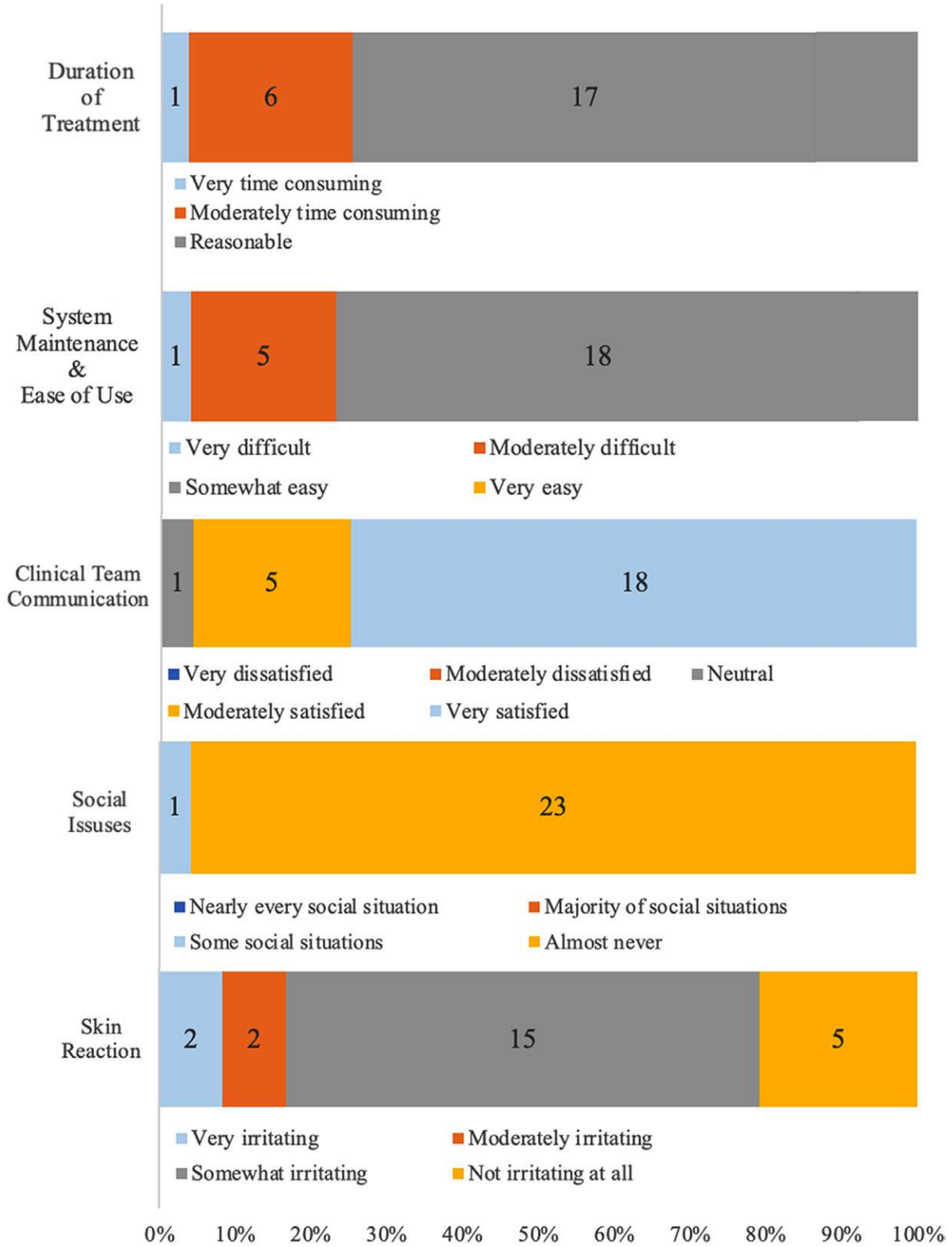

Fig. 5. Ear molding questionnaire long-term satisfaction and outcomes. Questionnaire responses from parents of treated patients regarding their satisfaction with duration of treatment, ease of use, clinical team communication about the treatment process, skin reactions, and whether any social issues have occurred with their children due to ear appearance since treatment.

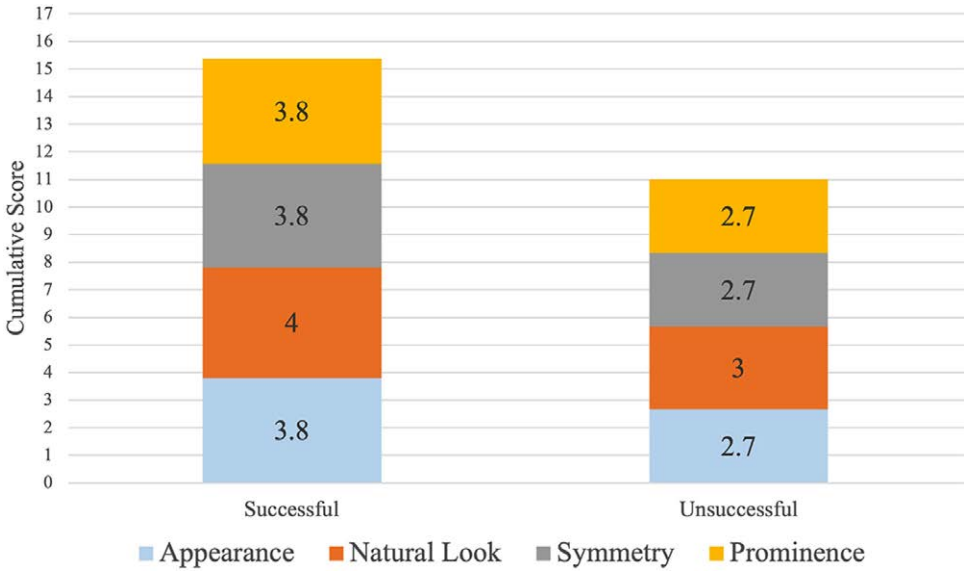

Fig. 6. Cumulative appearance scores. Cumulative appearance score was significantly higher among parents who reported their child's treatment was a success (n = 21) when compared with parents who did not believe the treatment was a success (n = 3).

three-tier grading system of "excellent" (normal shape), "good" (near normal shape with some degree of abnormality), and "poor" (slight or no improvement).[1] Chan et al found that 86% patients achieved a "good" or "excellent" outcome on a four-tier scale, and Doft et al reported a correction of 96% deformities.[3,9]

Interestingly, we did not find a significant difference in the degree of correction between deformations and malformations in our cohort. This result is a departure from recent literature that demonstrated deformities tend to achieve a greater degree of correction. For instance, Daniali et al reported "excellent" to "good" outcomes in 97% of deformation anomalies, whereas only 88.2% of malformation anomalies achieved "excellent" to "good" outcomes.[10] Similarly, Chan et al had a significantly higher rate of successful outcomes with deformities compared with malformations.[3]

Consensus on the timing of ear molding initiation remains uncertain: proponents of earlier timing cite greater malleability of auricular cartilage due to high levels of maternal estrogens, which decline by 6 weeks of age, whereas proponents for later timing suggest that spontaneous correction may occur.[4,5,11–15] Our study did not demonstrate a significant association between the age at treatment initiation and the degree of correction. Similarly, Chan et al and Daniali et al did not find a significant association between the overall success of correction and the degree of correction in comparison with age at treatment initiation.[3,10] On the other hand, Byrd et al reported that only approximately half of the infants who initiated ear molding after 3 weeks from birth had a favorable response.[1] Further investigation is needed to clarify the importance of timing on ear molding outcomes and to better understand the potentially distinct importance of maternal estrogens on outcomes between deformities and malformations.

Although several studies, including ours, may have demonstrated a nonsignificant association between age and correction, it does not seem practical to delay ear molding treatment. Self-correction rates vary between studies and among ear anomalies, and additional factors, including duration of treatment, tolerability of therapy, compliance, and psychosocial interaction with peers, also need to be considered.[3,16,17] Moreover, initiating ear molding later results in a longer duration of treatment and lower treatment compliance.[9,16,18] Patients who begin treatment after 3 weeks of age also have increased rates of device fall-off and replacements, which are detrimental to treatment success.[19]

Based on these factors, we recommend referral to an infant ear molding specialist as soon as possible to initiate infant ear molding. Importantly, families should be made aware that a single device application will not last the entire treatment duration, and visits are required every 1–2 weeks for device replacement for a total treatment duration of 4–8 weeks. Treatment duration beyond 8 weeks is unlikely to make further improvements due to the decreased estrogens, treatment fatigue by parents leading to poorer compliance, as well as increased adhesive loosening and device fall-off as infants become more active and at older ages.

This study also provides important insights regarding the complications that may occur during the ear molding process. Eczematous dermatitis and pressure ulcers were the most frequently encountered complications in our cohort, and similar complications are described in the literature.[3] Experiencing one of these complications was significantly predictive of achieving a partial correction or failed outcome rather than complete correction, underscoring the importance of preventing and promptly managing skin complications to minimize gaps in treatment. In our experience, pressure ulcers tend to

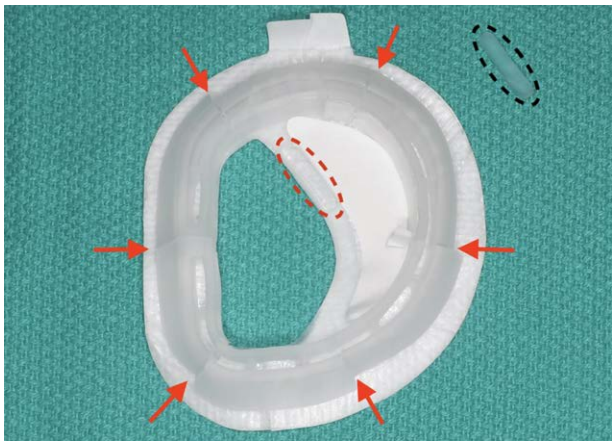

Fig. 7. Modifications to the EarWell device. The device may be modified by trimming down the antihelix-shaping post (red circle) of the posterior shell. The removed piece is depicted in the photograph (black circle). Red arrows indicate full-thickness cuts in between lid insertion slots to improve cradle flexibility and reduce tension to prevent loosening of the adhesive backing from the skin.

form in three main regions: the border of the antihelix and scapha where superior aspect of the retractor grips onto the skin, the conchal bowl where the conchal bowl former rests, and the postauricular skin where the antihelix-shaping post of the posterior shell presses against the back of the ear. Pressure injury in these regions can be mitigated through simple modifications, such as avoiding the addition of foam on top of the conchal former when this piece is utilized and trimming down the height of the antihelix-shaping post of the posterior shell of the ear molding device (Fig. 7). Pressure ulcers may be managed through small adjustments such as repositioning retractors, further trimming down the antihelix-shaping post, temporarily removing the conchal former or retractor until the skin has healed, or pausing treatment for a few days. Loosening of the adhesive from the skin can also occur frequently, causing the device to fall off prematurely in between visits, and may lead to lengthy pauses in treatment. The device can be changed more frequently to avoid such problems. In addition, the device can be modified by cutting slits in between the lid insertion slots (Fig. 7) to create more flexibility in the cradle construct and avoid pulling the adhesive backing away from the skin.

Lastly, our study included a comparative analysis of the parent's perspective of correction outcomes following infant ear molding. Based on our survey results, parents and guardians who deemed the treatment successful felt that the molded ear had a better overall appearance and a more natural look, symmetry, and prominence. Although most parents rated the duration of treatment, ease of use and maintenance of the ear molding system, and the lack of issues with peers or complications favorably, the treatment's success was primarily determined by the final appearance of the ear. Although 87.5% of survey respondents in our cohort felt that the outcome was successful, it is important to manage the expectations of parents before and during treatment. Emphasizing treatment compliance, regardless of perceived outcome, is critical because even a partial correction may reduce adverse psychosocial outcomes due to an ear anomaly.

LIMITATIONS

This study comes with several notable limitations. Foremost, the information collected on patients was restricted to their medical records due to the study format as a retrospective chart review. Additionally, results were graded in a subjective manner because there are no established objective measurements for morphology in infants. The advent of convolutional neural networks capable of detecting ear anomalies from 2D images represents a more objective method by which results might be graded in the future.[20] Even though objective measurements are not performed in our protocol, we feel it is valuable to gauge long-term success by the presence or absence of psychosocial issues due to ear shape during adolescence. There was a limited survey response rate (21.1%), which should be considered when interpreting the aggregate responses to the questionnaire sent to parents of the included cohort studied. Moreover, although more than 90% of the ears in this study were treated by the senior author, the remaining ears were treated by two other attending providers at our institution, leading to a small degree of variability in treatment administration and outcome grading.

CONCLUSIONS

Infant ear molding is an effective treatment strategy for infant ear anomalies, with most patients achieving complete correction. Dermatitis from the adhesive can occur, which quickly resolves after cessation of the treatment. Pressure ulcers may occur, which heal quickly once adjustments are made without permanent sequelae. Close monitoring of the progress and managing complications early during treatment will help optimize outcomes.

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DISCLOSURE

The authors have no financial interest to declare in relation to the content of this article.

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