

# A 10-Year Retrospective Review of the Nonsurgical Treatment of Infant Ear Anomalies

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**Background:** A review of a single surgeon's 10-year experience treating congenital ear anomalies using nonsurgical ear molding is presented. This study assesses the efficacy of treating a variety of anomalies in infants with age ranging from younger than 1 week to 22 weeks and identifies potential barriers to care.

**Methods:** A retrospective chart and photographic review of 246 consecutive infants treated with ear molding between 2010 and 2019 was undertaken. Data regarding patient demographics, anomaly classification, device selection, treatment duration, adverse events, and satisfaction with outcomes were collected.

**Results:** This study included 385 infant ear anomalies in 246 patients. Median age at initiation of treatment was 16 days and median treatment duration was 29.5 days. A median number of three devices was needed to complete bilateral treatment. Treated anomalies included mixed deformity, helical rim, prominent, lidding/lop, Stahl ear, conchal crus, cupping, and cryptotia. Complications occurred in 47 patients, with skin breakdown being the most common [26 patients (55.3 percent)]. Satisfaction rate was 92 percent in 137 surveyed parents. Median patient household income was approximately \$112,911, and treatment was covered by insurance for 244 of 246 patients.

**Conclusions:** The study outcomes demonstrate that ear molding can be effective in patients as old as 22 weeks without compromising treatment duration or complexity. In addition, in the authors' experience, molding is an effective treatment for the majority of infant ear deformities. Despite a steady increase in patient volume over the past 10 years and consistent coverage of treatment by insurance, the authors' catchment area continues to be largely limited to affluent households. (*Plast. Reconstr. Surg.* 150: 1049e, 2022.)

**CLINICAL QUESTION/LEVEL OF EVIDENCE:** Therapeutic, IV.

Infant ear molding enables the correction of congenital ear anomalies before both the window of eligibility for surgical intervention and the onset of teasing by peers.<sup>1-5</sup> This nonsurgical approach takes advantage of cartilage plasticity, believed to result from elevated levels of circulating maternal estrogens.<sup>6-8</sup> A 2008 systematic review determined that ear molding achieves results similar to those of otoplasty in both form and symmetry while eliminating the need for general anesthesia and risk of operative complications.<sup>9</sup> The EarWell Infant Ear Correction System (Becon Medical Ltd., Naperville, Ill.) and the InfantEar

Nonsurgical Ear Molding System (TalexMedical LLC, Malvern, Pa.) are two approved devices that mold the ear into a more normal anatomical shape.<sup>10</sup> The senior author (S.B.B.) has been using the EarWell since its introduction in 2010 and incorporated the InfantEar into his practice after it was developed in 2015. The approach to using these two prefabricated devices has been modified by the senior author over the past decade, enabling delivery of ear molding therapy to be customized for each patient.

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Ear anomalies are classified into deformations and malformations, as defined by Tan et al. in 1997.<sup>11</sup> Malformations are characterized by underdevelopment of cartilaginous or soft tissue components of the ear secondary to abnormal embryologic processes that occur between the fifth and ninth gestational weeks.<sup>7,12,13</sup> Deformations encompass irregularities in the external ear structure that develop after the ninth gestational week and are generally considered to be less severe than malformations.<sup>7,14</sup> Although this delineation is widely accepted, there is less consensus regarding classification of specific anomalies.<sup>15</sup> Based on descriptions of morphology in the literature, we classified presenting ear anomalies into eight groups: mixed deformity, helical rim, prominent, lidding/lop, Stahl ear, conchal crus, cupping, and

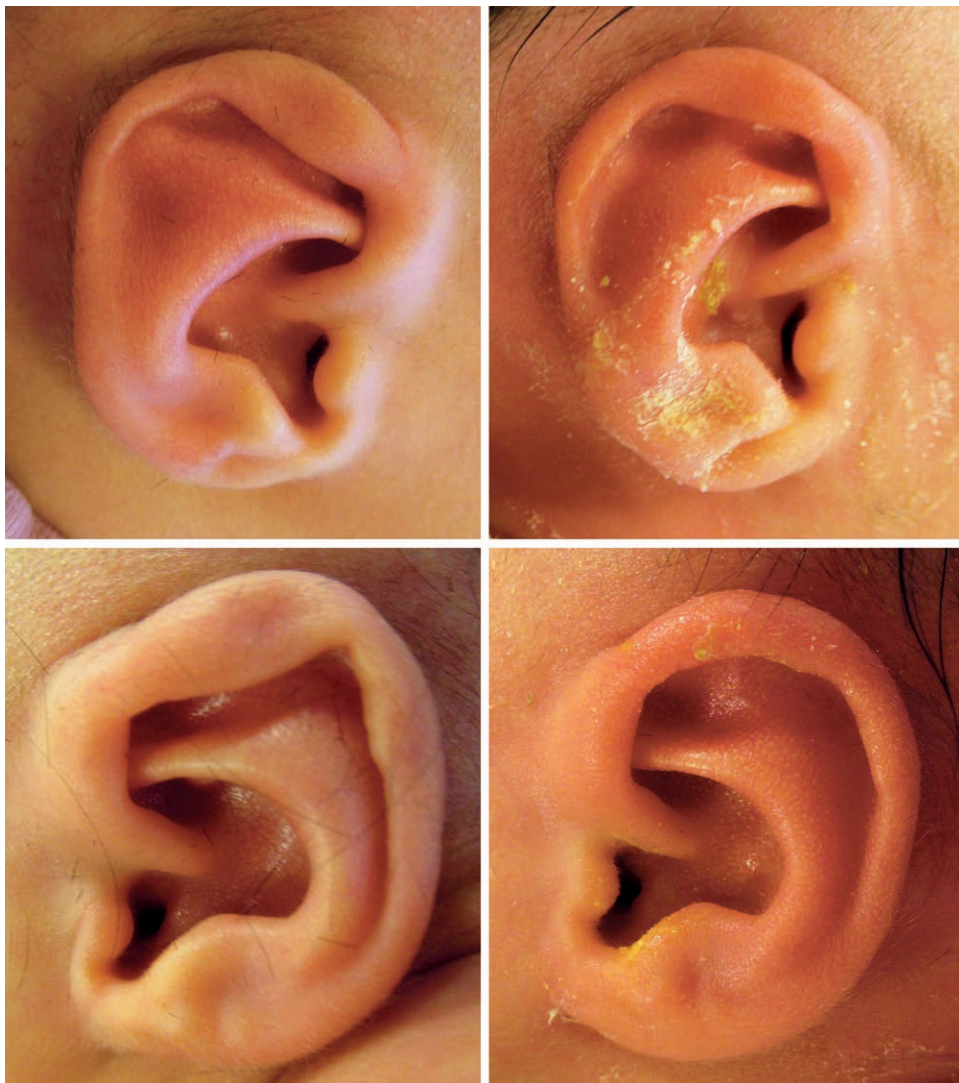
cryptotia.<sup>14</sup> A mixed deformity was defined as an ear having more than one identifiable anomaly (Fig. 1).

This article presents a single surgeon's (S.B.B.) 10-year experience treating consecutive infants with ear anomalies. Our sample is one of the largest to date and provides a unique opportunity to assess the outcomes of using ear molding to correct a variety of anomalies in patients ranging in age from less than 1 week to older than 22 weeks.

## PATIENTS AND METHODS

### Treatment Course

During the initial visit, the presenting ear anomaly was classified, and pretreatment



**Fig. 1.** Example of successful correction of bilateral mixed deformity (helical rim, hooding, Stahl ear) in a patient who presented at the age of 9 days. (Above) Right ear before and after 28 days of treatment with EarWell. (Below) Left ear before and after 28 days of treatment with EarWell.

photographs were obtained. The benefits, risks, and alternatives to treatment were discussed with parents and consent was signed. Ear molding was typically initiated during the first visit with 2-week follow-up scheduled for most cases. Infants with malformations such as cryptotia require more aggressive treatment and were scheduled for weekly follow-up. [See **Figure, Supplemental Digital Content 1**, which illustrates successful correction of left-sided cryptotia, before (*left*) and after (*right*) treatment, <http://links.lww.com/PRS/F426>.] At every follow-up visit, the anterior shell (EarWell) or protective cap (InfantEar) was removed to evaluate progress and address adverse events necessitating device modification. If skin breakdown or ulceration occurred, the retractor was adjusted to redistribute pressure points. If the device was noted to be loose or separating from the skin, it was reinforced with adhesive tape or dermal glue or replaced. Correction of the anomaly was evaluated by the senior author with input from the parents before terminating treatment. After device removal, photographs were obtained and parental satisfaction was evaluated using a verbal survey that assessed overall satisfaction and whether, based on the outcome, they would pursue ear molding again. Responses to this verbal survey were recorded in the chart.

### Study Design

An institutional review board–approved (2018-173; MedStar Plastic Reconstructive Surgery Outcomes Registry) retrospective review of consecutive infants treated with ear molding by a single surgeon (S.B.B.) between 2010 and 2019 was performed. Demographic and clinical data collected included age, medical comorbidities, ear anomaly class, laterality of treatment, duration of treatment, device choice, number of device replacements, adverse events, length of follow-up, and decision to pursue adjuvant treatment. Ear anomalies were classified as follows: mixed deformity, helical rim, prominent, lidding/lop, Stahl ear, conchal crus, cupping, and cryptotia. [See **Figure, Supplemental Digital Content 2**, which demonstrates successful correction of a right-sided prominent ear deformity, before (*left*) and after (*right*) treatment with EarWell, <http://links.lww.com/PRS/F427>.] Parental zip code was also collected, and the US Census Bureau database was used to obtain values for median household income for each zip code.<sup>16</sup> These data were used to assess the socioeconomic diversity of our patient cohort and to determine whether it was representative of our catchment area.

### Statistical Analysis

Statistical analysis was performed using SAS version 9.4 (SAS Institute, Inc., Cary, N.C.). Continuous variables were described using means with standard deviations and medians with interquartile ranges. The Wilcoxon rank-sum test was used to examine differences in continuous variables between two groups. The Kruskal-Wallis test was used to examine differences among three or more groups. Categorical variables were described by frequencies and row percentages and chi-square and Fisher exact tests were used, as appropriate, to investigate differences between groups. Statistical significance was defined as a value of  $p < 0.05$ .

## RESULTS

This study included 385 infant ear anomalies in 246 patients; 106 (43 percent) were female and 140 (57 percent) were male. Family history of ear anomalies in at least one first-degree relative was positive in 22 patients. The average number of clinic visits during the course of treatment was four. Forty-nine patients (19.9 percent) were lost to follow-up and did not complete treatment for at least one ear. Median follow-up duration was 28 days (interquartile range, 21 to 42 days), with 43 patients returning to the clinic following treatment completion, with a median of one follow-up visit per patient. The demographics of our patient population are shown in **Table 1**. Median household income was \$112,911 (interquartile range, \$89,330 to \$125,508) with no statistically significant change in income identified over the 10-year study period ( $p = 0.943$ ).

### Presenting Anomalies

Treated anomalies included mixed (37.4 percent), helical rim (28.5 percent), prominent (10.6 percent), lidding/lop (9.3 percent), Stahl ear (3.6 percent), conchal crus (3.3 percent), and cupping (2.8 percent). Eleven patients were excluded from this analysis because no written or photographic documentation of their presenting anomaly could be obtained.

Treatment was bilateral in 139 patients (57 percent) and unilateral in 107 (43 percent). There was no statistically significant change over time in the decision to treat patients bilaterally versus unilaterally ( $p = 0.691$ ). There was no statistically significant relationship between laterality and treatment duration ( $p = 0.630$ ). Completion of bilateral treatment required the use of a median number of three devices (interquartile range, 2 to 4) per patient; unilateral treatment

**Table 1. Demographic Characteristics of 246 Included Patients**

Variables	Values
Patients, no.	246
Ears, no.	385
Sex, no. (%) <sup>*</sup>	
Female	106 (43.1)
Male	140 (56.9)
Laterality of treatment, no. (%) <sup>*</sup>	
Right	61 (24.8)
Left	46 (18.7)
Bilateral	139 (56.5)
Age at presentation, days	
Mean ± SD	22.8 ± 19.5
Median (IQR)	16 (12–26)
Range	3–156
Family history, no. (%) <sup>*</sup>	
Yes	22 (8.9)
No	224 (91.1)
Type of auricular anomaly, no. (%) <sup>*</sup>	
Mixed deformity <sup>†</sup>	92 (37.4)
Helical rim and prominent	36 (39.1)
Helical rim and lidding/lop	19 (20.6)
Other combinations	37 (40.2)
Helical rim	70 (28.5)
Prominent	26 (10.6)
Lidding/lop	23 (9.3)
Stahl ear	9 (3.6)
Conchal crus	8 (3.3)
Cupping	7 (2.8)
Cryptotia	2 (0.8)
Not recorded	11 (4.5)
Device, no. (%) <sup>*</sup>	
EarWell	207 (84.2)
InfantEar	27 (10.9)
Both	12 (4.9)
Follow-up time, months	
Mean ± SD	1.7 ± 4.2
Median (IQR)	28 (21–42)
Range	0–46.5

IQR, interquartile range.

<sup>\*</sup>Frequency out of 246 total patients.<sup>†</sup>Frequency out of 92 patients classified as having mixed ear anomaly.

required a median number of two devices (interquartile range, 1 to 2). Both bilateral and unilateral treatment required a median of one device replacement. There was no statistically significant relationship between the type of presenting anomaly and the total number of devices needed to complete treatment ( $p = 0.097$ ).

### Device Selection

Patients were treated with the EarWell, InfantEar, or a combination of the two devices. A total of 207 patients (84 percent) were treated exclusively with the EarWell and 27 patients (11 percent) were treated using only the InfantEar. There was a statistically significant relationship between the age of patients at treatment initiation and the choice of device ( $p < 0.01$ ) (Table 2). Patients in whom treatment was started with the InfantEar (mean age,  $39.7 \pm 22.6$  days) were significantly older than patients in whom the EarWell

**Table 2. Relationship between Age at Initiation of Treatment and Choice of EarWell or InfantEar**

Variables	EarWell	InfantEar	<i>p</i>
Age, days			
Mean ± SD	20.9 ± 18.5	39.7 ± 22.6	<0.01 <sup>*</sup>
Median (interquartile range)	16 (12–23)	29.5 (24–47)	
Treatment duration, days			
Mean ± SD	31.4 ± 11.8	20.8 ± 9.5	<0.01 <sup>*</sup>
Median (interquartile range)	30 (21–41)	17.5 (14–28)	

<sup>\*</sup>Statistically significant ( $p < 0.05$ ).

was chosen (mean age,  $20.9 \pm 18.5$  days). [See Figure, Supplemental Digital Content 3, which illustrates successful correction of a right-sided mixed deformity (helical rim, lacking superior crus and definition of antihelix) in a patient who presented at the age of 23 days. Before (*left*) and after (*right*) 21 days of treatment with EarWell, <http://links.lww.com/PRS/F428>.] Treatment duration with the EarWell significantly exceeded that with the InfantEar ( $p < 0.01$ ) (Table 2).

Twelve patients (5 percent) were treated with a combination of the two devices. In most of these cases, treatment was initiated with the EarWell and patients were transitioned to the InfantEar as their ears grew. In a few cases, patients were started with the InfantEar because of the complexity of the deformity and switched to the EarWell when ear shape was normalized but maintenance molding was required. Interchanging between the devices allowed optimization of fit throughout the treatment course.

### Timing and Duration of Treatment

Mean age at treatment start was  $22.8 \pm 19.5$  days (range, 3 to 156 days) with a median treatment duration of 29.5 days (interquartile range, 14 to 37.25 days). Median age at initiation of treatment was 2 to 3 weeks (26 percent) when dividing patients into weekly age groups. A total of 152 patients (62 percent) initiated treatment before 3 weeks of age. [See Figure, Supplemental Digital Content 4, which displays successful correction of left-sided Stahl ear deformity in a patient who presented at the age of 12 days, shown before (*left*) and (*after*) treatment with EarWell, <http://links.lww.com/PRS/F429>.] Significantly more patients presented before 3 weeks of age in the second half of the study period (2015 through 2019) than in the first (2010 through 2014) ( $p < 0.01$ ). When comparing duration of treatment across age groups, there was no significant relationship between age at treatment start and duration of treatment ( $p = 0.653$ ) (Table 3). This finding

**Table 3. Comparison of Treatment Duration across Age Groups**

	Age at Presentation, Treatment Duration, Days			<i>p</i>
	<3 Weeks	3–5 Weeks	≥6 Weeks	
Mean ± SD	30.7 ± 11.7	30.2 ± 12.6	28.3 ± 14.3	0.653
Median (interquartile range)	28 (21–40.5)	29.5 (19.8–40)	26 (20–28)	

persisted when stratifying patients who presented later. Median treatment duration was 29.5 days (interquartile range, 14 to 37.3 days) for patients presenting before the age of 9 weeks and 23.5 days (interquartile range, 18.8 to 28 days) for those presenting at or after 9 weeks with no statistically significant difference between groups ( $p = 0.109$ ).

### Complications

Forty-seven of 246 patients (19 percent) experienced complications during treatment, which included skin irritation, skin breakdown, ulceration, and infection (Table 4). The most common complication was skin breakdown [26 patients (55 percent)], which usually occurred at pressure points under the retractors. There was no correlation between the presenting anomaly class and incidence of complications ( $p = 0.229$ ) and no statistically significant relationship between the incidence of complications and treatment duration ( $p = 0.894$ ). No patient required treatment cessation secondary to complications; all patients experienced resolution of symptoms after device adjustment and pressure point modification.

### Long-Term Outcomes

Only 43 patients returned to the clinic after completion of ear molding, with the number of follow-up visits ranging from one to five (median, 1). Of these 43 patients, 35 patients returned for only one follow-up visit after treatment completion; in all 35 cases, parents were satisfied with outcomes and cited their reason for return as “general follow-up.” Of the remaining eight patients, three returned for consultation regarding soft-tissue redundancy that could not be corrected with ear molding. For

these three patients, immediate intervention was not necessary and recommendations were made to observe how the soft tissue evolved as the patient grew. These three patients had no further recorded follow-up for surgery or consultation. Two patients returned to the clinic for unrelated concerns: one patient needed referral to otolaryngology for excision of skin webbing in the external ear canal and the other underwent preoperative planning for excision of a benign upper lip nodule. Three parents endorsed minor recurrence during follow-up, including one patient with a mild recurrence of scaphal flattening. This patient had stable antihelical folds that were significantly improved from baseline; the parents were satisfied with the overall result and decided against further treatment. In the other two cases of recurrence, device reapplication was requested, with both families endorsing satisfaction with their final outcomes.

Two patients required adjuvant surgery following the completion of ear molding. One required surgery at the age of 3 months to remove a strip of redundant cartilage for an unresolved Stahl ear deformity. The second patient had a diagnosis of VACTERL (vertebral defects, anal atresia, cardiac defects, tracheo-esophageal fistula, renal anomalies, and limb abnormalities) in association with right radial bone aplasia and history of ostomy placement. After initial treatment with ear molding, this patient underwent lop ear correction using polydioxanone foil as an internal splint.

### Parent Satisfaction

Of the 137 parents who rated their experience with ear molding, 126 (92 percent) expressed satisfaction with the appearance of their child’s ears after treatment. Of the 11 parents who expressed dissatisfaction, incomplete correction of shape was the most commonly cited reason. There was no statistically significant difference in rates of satisfaction in parents of infants who presented before the age of 3 weeks versus those who presented later ( $p = 0.416$ ). Parental satisfaction rates did not vary significantly when compared across the individual types of ear anomalies ( $p = 0.524$ ).

**Table 4. Incidence of Complications**

Complication	No. (%)
Total patients with complications*	47 (19.1)
Skin breakdown	26 (10.6)
Skin irritation	12 (4.8)
Ulceration	5 (2.0)
Infection	4 (1.6)

\*Percentage reflects a denominator of 246 patients; all other percentages reflect a denominator of 47 patients with complications.

## DISCUSSIONS

### Treating the Late-Presenting Patients

This study presents one of the largest consecutive series to date of infants with congenital ear anomalies undergoing molding using a standardized treatment protocol. Initiating ear molding in infants before the age of 3 weeks has been suggested to decrease treatment duration, but our study did not support this finding.<sup>7,17,18</sup> Our results show that age at treatment initiation is not a significant factor in dictating duration of treatment ( $p = 0.653$ ) (Table 3). This finding persisted when patients younger than 9 weeks were compared with very late-presenting patients older than 9 weeks ( $p = 0.109$ ). Delayed initiation of treatment was also not associated with higher rates of complications ( $p = 0.775$ ). These findings contrast with the existing literature and are likely a result of the senior author's approach to treatment. By encouraging patients to follow up every 1 to 2 weeks, patients are closely monitored for not only skin complications but also appropriate progress. The senior author assesses the ear form, including symmetry, at every visit and makes necessary modifications. A commitment to treating the ear dynamically and making constant adjustments may help improve outcomes and standardize treatment duration for all patients, including those who present later.

In the 137 parents surveyed, there was no statistically significant difference in satisfaction rates between parents of patients who presented before 3 weeks of age and of those who presented later ( $p = 0.416$ ). Given that it is felt that parent satisfaction correlates with the ability of the surgeon to meet expectations, the senior author informs parents that treatment may be less effective when started after 3 weeks of age. Thus, the lack of a statistical difference in outcomes may reflect our ability to meet a different set of parental expectations rather than objectively similar treatment outcomes. Table 2 demonstrates a significant trend toward choosing the InfantEar for older-presenting patients because of the better fit of the device for larger ears.<sup>19</sup> This finding suggests that although parental expectations must be taken into account, our ability to plan treatment based on patient age and presentation may have an independent positive effect on outcomes.

### Applying Lessons Learned

Compared with previous studies, a lower incidence of complications (19 percent) is noted in our cohort. We attribute our relatively low rate of

complications to the fact that patients were assessed for adverse events at every weekly or biweekly visit. If ulceration was noted, the retractor was repositioned or a modification was made to relieve pressure points. By the end of the study period, it is estimated that prefabricated systems were modified for at least 30 percent of patients.<sup>19</sup> The use of additional supplies or modification of technique improved fit of the device for each unique ear, especially in older patients. These modifications assisted with offloading pressure, minimizing rates of skin breakdown and ulceration to 11 percent and 2 percent, respectively (Table 4). This approach to improving device fit helps explain our finding that complication rates did not significantly differ among the different classes of anomalies ( $p = 0.229$ ). All patients in whom adverse events occurred were treated with conservative management; none required treatment cessation or surgical intervention.

When ear molding was first introduced as a nonsurgical treatment for congenital ear anomalies, the focus was on treating just the more misshapen ear if the contralateral ear was only mildly affected. However, parents were often more satisfied with the appearance of the corrected ear than of the contralateral ear, leading to concerns regarding asymmetry. Our practice has evolved to recommend bilateral correction even in cases of only mild deformity on the contralateral ear. The bilateral approach not only corrects the deformity but also improves symmetry, which can be difficult to achieve with unilateral treatment. Because our practice only adopted this approach to bilateral treatment within the last 3 years, the data do not show a statistically significant preference toward choosing bilateral treatment over the past 10 years ( $p = 0.691$ ). Of the 43 patients who returned to the clinic after completing treatment, 25 underwent bilateral molding. For these 25 patients, 23 parents were satisfied with treatment whereas two requested device reapplication to correct minor recurrence. Symmetry was not cited as a concern in either of these two cases and parents of both patients were satisfied with final outcomes. The ability to customize therapy for each ear in a single patient allows for a minor deformity to be corrected on one side while concurrently correcting a more severe contralateral deformity or malformation. The results observed during long-term follow-up suggest that improved symmetry resulting from bilateral treatment persists as patients mature.

### Increasing Awareness and Expanding Access

Over the course of the past 10 years, the success of ear molding at our practice has served as the

impetus for a regional public education campaign that included letters sent to pediatricians, grand rounds presentations, and articles published in both the American Academy of Pediatrics newsletter and local parenting magazines. The number of cases performed by the senior author tripled from the first half of the decade (55 cases) to the second (191 cases), likely secondary to our effort to increase local public awareness of the benefits and relatively low risks of ear molding. In addition, the number of patients presenting before 3 weeks of age increased significantly from the first half of the decade to the second ( $p < 0.01$ ). We attribute this rise in parents seeking early intervention for their children to the emphasis placed on the benefits of early ear molding compared with surgery later in life in the literature and in the materials we circulated. [See Figure, Supplemental Digital Content 5, which displays an adult with right-sided Stahl ear deformity before (*left*) and after (*right*) undergoing in-office surgical correction with suboptimal results, <http://links.lww.com/PRS/F430>.] Although we continue to encourage parents to initiate treatment early, our data support that age should not be a significant deterrent given that parents have been consistently satisfied with outcomes, even in patients as old as 22 weeks.

Despite the greater than threefold increase in cases from the first to the second half of the 10-year study period, our study indicates that the income distribution of our patient population has not changed significantly over time ( $p = 0.943$ ). Median household income approximated by zip code using the United States Census Bureau database was \$112,911, placing our patients in the middle-to-upper income tier of the area surrounding our practice.<sup>16</sup> Measures of parent-reported patient ethnicity demonstrated that 75 percent of our cohort identified as White. When considered within the context of the high socioeconomic diversity in the census tracts in the patient catchment area, these findings show that despite our efforts to increase awareness of ear molding as a nonsurgical treatment typically covered by insurance, we have not yet breached existing barriers to health care. Given the demonstrated potential of ear molding to significantly improve the ear form and to prevent appearance-related bullying, we argue that it is essential to increase both awareness of and accessibility to this treatment option.

Only by understanding our current patient population can efforts be targeted toward underrepresented portions of our catchment area. To increase access to ear molding for all families, we encourage increasing awareness of all

pediatricians, not only those associated with academic institutions, regarding ear molding as a treatment option. We strive to ensure that all pediatricians are aware of ear molding and have the resources to broadly discuss the basics of treatment as well as insurance coverage options. Our institution is currently channeling efforts into a related study aiming to assess local pediatrician awareness of ear molding in order to evaluate the efficacy of the senior author's educational campaign.

Increased recognition and diagnosis of congenital anomalies are also essential. A recent study found that use of a standardized assessment protocol for ear anomalies during the newborn hearing screening was associated with increased frequencies of both identification of ear anomalies and referral for treatment consultation.<sup>4</sup> Although circulation of literature, lectures, and referrals are effective ways to educate the public about the option of ear molding, the use of universal newborn screening can expedite time to consultation visit and initiation of treatment. As plastic surgeons, we are in a position to urge further study and implementation of these types of screening techniques. By increasing collaboration with pediatricians and by making ear anomaly screening routine for all newborns, ear molding can be made more consistently and widely available.

### Limitations

Although the major limitation of this study is its retrospective design, every attempt was made to minimize bias by relying exclusively on clinical details in the medical record during data collection. When review of photographs was needed to confirm diagnoses, all diagnoses were made by the senior author to maintain consistency. All cases of ear molding were performed by the senior author, limiting technical variability in technique.

### Future Directions

As the body of literature supporting the efficacy and safety of ear molding grows, an emphasis should be placed on expanding access. The senior author has worked to increase awareness of nonsurgical molding in his catchment area through national and local presentations and publications. Educational campaigns should aim to highlight that ear molding represents an opportunity for early intervention that optimizes results, bears minimum risk, and is most often covered by insurance. As highlighted in our socioeconomic assessment, we encourage providers who perform ear molding to assess their own catchment areas and to work toward increasing accessibility.

## CONCLUSIONS

This study demonstrates that ear molding achieves successful outcomes with high satisfaction and low complication rates for a wide range of patient ages and presentations. There has been a rise in the number of ear molding cases performed by the senior author over the past 10 years, indicating increasing interest in nonsurgical correction of ear anomalies. The large majority of patients in this study were insured and of high socioeconomic status, suggesting the need for broadening awareness and increasing access to ear molding as a treatment option.

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