



Nonoperative Molding of Congenital Ear Deformities: The Impact of Birth-Initiation Delay on Correction Outcome

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Abstract: Ear molding can improve the majority congenital ear deformities when employed early after birth. However, the best time to initiate treatment remains debated. In describing one surgeon's experience over the past near decade, this study aims to highlight differences conferred by treatment timing. The authors hypothesize that auricular outcomes are superior when deformities are molded beginning in the first 3 weeks of life. A retrospective review (2010–2018) of 272 cases was performed to compare early initiation of molding (<3 weeks of birth) and delayed initiation (>3 weeks). The mean patient age was 20.4 days and the mean follow-up was 0.5 months. The overall treatment was approximately 31 days. The number of devices required was similar (2.3 versus 2.5) between early and delayed molding cases, but fall-outs (1.0 versus 0.7, $P = 0.02$) and replacements (0.9 versus 0.6, $P = 0.004$) were more common after delayed molding. Skin complications developed in 13.6% (37) of ears overall and did not differ by treatment timing. Follow-up surgery was reported in 2 (0.7%) ears. The 85% of families reported subjective satisfaction with the final outcome; satisfaction was significantly higher for early cases (97% versus 79%, $P = 0.03$). Ear molding of congenital ear deformities should begin within 3 weeks of birth. From our experience, setting realistic expectations helps limit discrepancies between expectation and outcome.

Key Words: Auricle deformity, congenital ear anomaly, ear molding, EarWell, InfantEar

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Nonoperative ear molding has been proven to be a safe, effective, and reliable method of correcting neonatal ear deformities.^{1–3} Molding not only spares operative morbidity but allows for much earlier correction compared to surgical options which usually can only address deformities after auricular cartilage maturation has commenced and the ear has approached adult size, usually between around age 6 and 7.⁴ Furthermore, cases managed surgically not uncommonly require operative revision, but are also frequently denied as cosmetic by insurance companies. The delayed correction and need for surgery burden patients who must already live with the deformity into the early grade-school years. Because ear molding during the infant period initiates mechanical alteration of deformed auricle during a time when maternally derived estrogen is present within the neonatal circulation, progressive correction is feasible. As a result of this organic restructuring, the incidence of residual deformities after molding is less than half the rate following otoplasty.² Additionally, it is the authors' experience that the results achieved with ear-molding are superior to those achieved through surgery. Ear molding creates a more normal-appearing ear that prevents the iatrogenic stigmata that may be associated with a surgical correction.

Traditionally, it purported that a notable majority (nearly 70%) of ear deformities would self-correct over time, but more recent studies show that a much higher percentage of ear anomalies do not improve with time and some deformities, such as protrusion, may progress after birth.^{5,6} Byrd has reported that optimal outcomes with molding are attained if correction is started within the first week of life, but Muraoka and Yotsuyanagi have reported excellent outcomes in patients between 6 months and 3 years old.^{3,7,8} The objective of this study was to evaluate outcomes after congenital ear-molding and investigate the relationship between treatment timing and outcomes. We hypothesize that when initiated within 3 weeks of birth, ear molding outcomes are most optimal.

MATERIALS AND METHODS

Ear Molding: Technique and Application

The patient presenting with an abnormally shaped ear is evaluated for ear molding using one of 2 systems: EarWell Correction System (Becon Medical Ltd, Tuscon, AZ) and InfantEar (Talex-Medical LLC, Philadelphia, PA).

For EarWell application, the area upon which the device is to be placed is first shaved. Then, using adhesive, the base of the device is applied to the head externally around the ear (Fig. 1A). Retractors are placed to mold the ear into the desired position and, if necessary, a conchal former is used to shape the concha (Fig. 1B). A cover is placed over the top, to avoid catching or snagging the retractors. InfantEar application begins with a base placed around the external surface of the ear (Fig. 2A). Retractors are oriented to maintain the desired corrective position, and a rim is then placed around the retractors to hold their position (Fig. 2B). Silicone gel is then applied onto and across the ear-device construct to adhere it in a static position (Fig. 2C). A cover cap is then placed (Fig. 2D).



FIGURE 1. Application of the EarWell Device. A. The EarWell base is applied with adhesive onto the head immediately outside and around the ear. B. The ear is molded into the desired position according to the placement of the retractors. If necessary, a conchal former is used to shape the concha.

Case Selection

An Institutional Review Board-approved, single-surgeon (SBB), single-institution retrospective review of a prospectively maintained database was performed. Ear molding cases performed between July 2013 and November 2018 were identified using the Current Procedural Terminology (CPT) code 21086. Collected variables included demographics (age, race, family auricle history), birth history and congenital conditions (syndromes, associated anomalies, medical comorbidity), procedure-related information (device type, length of molding (d), fall-out events), skin complications (irritation, ulceration, infection), and case outcomes (progression to surgery, subjective family satisfaction, total office visits, total treatment cost).⁹ Irritation was defined as erythema without disruption of the epidermis. Ulceration was defined as a breakdown of epidermis revealing dermis.

Cases were stratified according to molding initiation (defined as days from birth to application of the first device) within 3 weeks of birth or after 3 weeks of birth. The primary outcomes of interest were procedural variables, complications (skin, cartilage, infection), and progression to surgery. A secondary subgroup analysis was performed to assess subjective family satisfaction with final molding outcomes. Cases with post-procedural documentation of (subjective) family-reported satisfaction were pooled and similarly stratified by early and late initiation.

Statistical Analysis

Absolute and mean results were characterized using descriptive statistics and measures of central tendency, respectively. Continuous variables were reported as mean (std. dev.). Student's *t* tests



FIGURE 2. Application of the InfantEar Device. A. Once the InfantEar base (white) is placed around the external ear, retractors (blue) are placed to mold the ear into the desired shape. B. A rim (pink) is placed around the retracted ear construct. C. Silicone gel is applied to adhere the construct in position. D. Once the gel has settled, a cover cap is placed superficially to hold the device in place.

were used to investigate binary differences. Pearson Chi-square test and Fisher Exact test were used to compare proportions. The unit of analysis was 1 ear. All statistical analyses were performed using SPSS Statistics for Mac OS, version 25 (IBM, Armonk, NY). Significance was defined as $P < 0.05$.

RESULTS

Two-hundred seventy-two deformities were identified in 175 consecutive patients (102 males and 73 females) who underwent nonoperative ear molding. Overall (mean) follow-up was 0.5 months. Medical insurance covered the costs of treatment for 98.6% (173) of patients. Descriptive information is shown in Supplementary Digital Content, Table 1, <http://links.lww.com/SCS/B361>. The mean patient age at the time of molding initiation was 20.4 (18) days. Nearly 60% (161) of the deformities were in males. The 80.6% (83) of those with known race were Caucasian. The 6.2% (17) of deformities were associated with coexisting comorbidity, and 6.2% (17) were associated with family auricular defect histories.

The 71.1% (194) of deformities presented bilaterally. Examples of the presenting deformities before and after correction by ear molding are shown in Figures 3–7. The most common deformity, affecting 35.3% (96), was the mixed deformity (conchal crus with prominent/cup deformity). There was no difference in the deformity laterality (right ear 50.9% (139) versus left ear 48.7% (133), $P = 0.4$). The mean treatment length was 30.9 (16.3) days. Adjunct techniques were used in roughly 10% (26) of cases. The overall



FIGURE 3. A. Mixed deformity before correction and B. after molding.

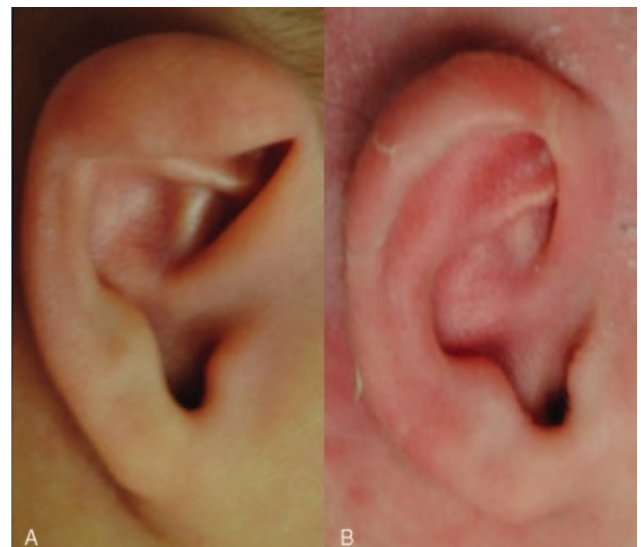


FIGURE 4. A. Cup deformity before correction and B. after molding.

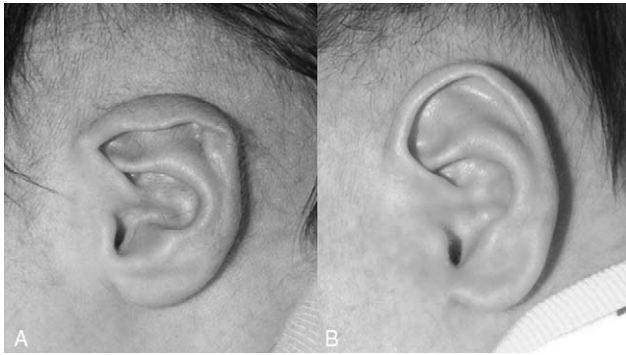


FIGURE 5. A. Helical rim deformity before correction and B. after molding.

mean number of device fall-out events 0.81 (1). The overall mean number of replacement devices was 0.69 (0.9). The mean number of devices used during a molding course was 2.4 (1.7).

Thirty-seven total skin complications occurred, including breakdown in 6.6% (18), irritation in 5.1% (14), ulceration in 1.1% (3), and infection in 0.7% (2). Follow-up surgery occurred after 0.7% (2) of cases. The mean number of total office visits was 4.6 (1.9). Subjective reports of family satisfaction were documented in 100 cases; 85% (85) of responses reported positive satisfaction, while 15% (15) reported dissatisfaction.

Early Versus Delayed Molding: Univariate Comparison

Univariate comparison of outcomes between cases of early treatment (<3 weeks of birth) (n=176) and delayed treatment (≥3 weeks of birth) (n=96) is shown in Supplementary Digital Content, Table 2, <http://links.lww.com/SCS/B361>. The mean age at initiation between the 2 groups was significantly different (10.6 versus 28.5 days, $P < 0.001$). Both groups were similar demographically (race, gender) and medically (family auricle history, present comorbidity, associated anomalies). The type of deformity did not correspond with the timing of treatment ($P = 0.74$).

The EarWell device was used similarly in both groups, while InfantEar devices were used exclusively in delayed cases ($P < 0.001$). The mean length of treatment was similar for both groups (34.8 days versus 32.4 days, $P = 0.41$). A significantly



FIGURE 6. A. Stahl ear deformity before correction and B. after molding.

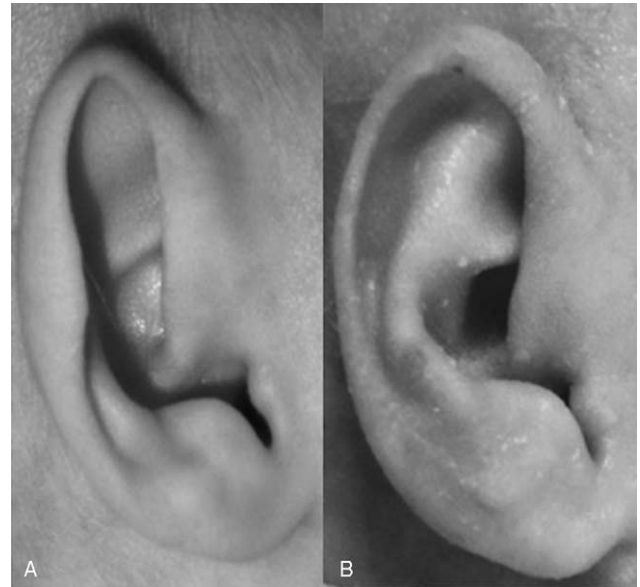


FIGURE 7. A. Prominent deformity before correction and B. after molding.

higher fall-out incidence was seen with delayed treatment (1.04 versus 0.69, $P = 0.02$). Reapplication was required similarly across cases, but significantly more replacement devices were needed for delayed treatments (0.9 versus 0.6, $P = 0.004$). Skin complications occurred similarly regardless of treatment timing. One case each from the early and late groups underwent follow-up surgery. The average number of total office visits did not differ by treatment timing (4.6 versus 4.5, $P = 0.86$). The incidence of satisfaction after molding was significantly higher in patients treated sooner after birth (97% versus 79%, $P = 0.03$).

DISCUSSION

This study presents an expanded understanding of how the management of pediatric ear deformities has evolved during the clinical practice of the senior author. As our experience with ear molding continues to grow, we have not only adapted the groundwork laid by seminal authors in this field, but also come to understand the importance of early, cohesively managed multidisciplinary care. The foremost aspects of multidisciplinary coordination for auricular deformity care entail clear two-way communication between pediatricians and plastic surgeons or otolaryngologists. As efforts are required to make sure this occurs as soon as possible after birth, we hope our paper helps bridge communication and knowledge gaps between the nonsurgical pediatric specialists and surgeons. While the surgeon bears the onus of responsibility to coordinate the multidisciplinary team, an early referral from the pediatrician is crucial for an optimal ear molding experience. Additionally, we hope our paper helps inform the same multidisciplinary team of physicians of the demographic disparities and trends regarding this treatment. As indicated by our population, there is a tilt in demographics of treated patients; the significant majority are Caucasian, which begs us to ask the question of why health care equity for auricular deformity correction is lagging. We hope that by shedding light on the breakdown of who is treated, we begin the discussion about how to minimize disparities in auricular deformity care across patient populations. A significant majority of our patients' treatments were covered by insurance plans (98%), leading us to be optimistic that barriers and access to care can be absolved with adequate effort from neonatal doctors, pediatricians, obstetricians, and plastic surgeons.

Congenital ear deformities occur in 5% to 15% of infants, with estimates concluding one-third may self-correct.³ Studies have shown that psychosocial outcomes are improved in children and adolescents who have a successful molding experience.¹⁰ Considering that untreated congenital pathology often implicates psychological effects that persist beyond childhood, it is imperative to understand how the utility of a procedure intended for neonates, like ear molding, can be altered by unavoidable demographic considerations like age of treatment. Ear molding not only spares operative morbidity, but also allows for much earlier correction compared to surgical options, which usually address deformities only after the auricle has reached its adult size.⁴ Furthermore, cases managed surgically may require surgical revision and considering surgical patients are already burdened with the deformity into the early grade-school years, revisional surgery only prolongs deformity resolution, even if the best result is obtained. Because ear molding initiates correction of the congenital ear during a time of enhanced cartilage pliability secondary to maternally derived estrogen within neonatal circulation, natural, progressive correction ensues. As a result of this organic restructuring, residual deformities are nearly 6 times less common after ear molding compared to otoplasty.² In the senior author's opinion, nonoperative molding results in superior outcomes compared to surgery in patients who are older. It should be noted that the preference for nonoperation goes beyond the surgeon's experience and is justified by the embryologic and pathophysiologic basis of auricular deformities. Unlike malformations in which the expected anatomy is lacking due to improper intrauterine morphogenesis (ie, microtia), deformations are indicative of complete, yet abnormal, anatomy.¹¹ In the context of this study, molding can help reposition the deformed ear elements to normalcy, while surgery is unnecessary in that is invasive enough to enable reconstruction of missing anatomic elements (ie, malformations).

Initial ear molding had indicated success with splinting or tape up to a few months of life.^{12,13} Thus far, however, studies in patients treated after the early months of life indicate a longer duration of molding required (≥ 3 months) for less (consistent) corrective outcomes.^{4,8,14-17} Since studies from Byrd et al group and Bartlett's group, who first reported experience with EarWell and InfantEar systems, respectively, consensus shifted to beginning molding as early as possible (< 3 weeks and < 1 week, respectively) due to a direct correlation between early treatment initiation and superior deformity correction.^{1,3,10,13} The conclusions were congruent with limited prior case reports suggesting an association between poor outcomes and initiation at older ages (> 3 months).¹⁵ More recently, Doft et al conducted a prospective study of 158 ears in 96 consecutive infants treated with the EarWell system. The 95% of treatments were initiated within 2 weeks of birth, the average treatment duration was 14 days, and parents were surveyed at 3 points: immediately, 6 months, and 12 months after the completion of treatment.² The 96% of deformities were corrected and 99% of parents stated they would choose ear molding again, if needed, driving the authors to conclude 2-weeks an appropriate duration of treatment given newborns with deformities are identified and referred for treatment by 2 weeks old. Woo et al described using the EarWell system on 33 ears in 21 consecutive patients beginning at an average 22.6 days after birth. Sixteen ears were treated within 3 weeks of birth. The 89% of all deformities achieved improvement, with 46% judged as "good or excellent" and 43% as "fair." While all cases treated within the first 3 weeks of life resulted in favorable outcomes, unfavorable outcomes ("very poor" or "poor") were seen in only cases that had been treated after the first 3 weeks of life ($n = 3$).¹⁸ Recently in 2019, Chan et al published in 2019 a 3-year prospective study of 105 ears in 67 consecutive infants in Singapore treated with the EarWell system.¹⁹ The 67% of

patients were treated within the first week of life. The average treatment duration was 4.1 weeks. The 98% of deformities were corrected and complications occurred significantly greater in patients treated at an older median age (22.1 days versus 10.6 days, $P = 0.037$). When outcomes were subjectively assessed by plastic surgeons and categorized as "excellent, good, fair, and poor," the average duration of treatment was less for "excellent" outcomes (3.6 weeks) compared to "good" (4 weeks) or "fair" (4.4 weeks) outcomes. Current recommendations for auricular deformity management advocate for referral to a plastic surgeon within 3 weeks of birth. Our data demonstrate no increase in complications when ear-molding correction is first attempted after the first 3 weeks of life, widening the age range for successful ear molding. Our data also indicate, however, that earlier treatment may be a smoother process for parents and families and confer greater satisfaction.

The ultimate goal of ear reconstruction is to restore as normal an auricle as possible while maintaining symmetry with the contralateral ear. The major principles of ear molding address development of a posterior inclined axis, 0.6:1 width to height ratio, and smooth curved lines for the tragus, antitragus, and concha.²⁰ The currently available ear molding devices work to address these ideals, but the process is dynamic. Proper ear molding often requires multiple devices and adjunctive therapy, as well. Our data indicate similarities in the rate of reapplication and the total number of devices used for early and delayed moldings. No matter the age of the patient, ear mold requires frequent follow-up and device manipulation. Truly successful auricular correction may require assessment and management of both ears, even when one ear is more affected than the other. The assessment of both ears is crucial because successful molding entails not only a corrected deformity, but also a symmetrical facial appearance. Thus, both ears frequently must be managed to ensure the corrected deformity mirrors the natural maturation process of the contralateral ear. Although molding kits are useful for basic anomalies, the senior author has readily achieved optimal results using adjunct techniques like scaphal molding and impression-material encasement of molding devices. Obtaining the ideal result requires 4 to 6 weeks of continuous reassessment.

Even though ear-molding devices offer a viable nonsurgical option for addressing congenital ear deformities and malformations, the process is not without risk. However, minor reactions are uncommon, and significant complications are exceedingly rare. Known rare complications include skin breakdown, cartilaginous breakdown, and excoriation. Our data indicate it is unlikely that skin complications are related to treatment timing. Skin complications can be sufficiently managed with topical antibiotic treatment and repositioning of the molding device one centimeter from the initial area of contact.

Ear molding is ideally advocated for the treatment of congenital ear deformities within three weeks of birth. Uncommon complications include allergy, skin breakdown, and failure to meet expectations. From our experience, setting realistic expectations helps limit discrepancies between expectation and outcome. This study provides important updates to the understanding of ear molding in infants up to five weeks of age, but it is not without limitations. Our study intervention was predominantly the EarWell system. While this provides consistency across age groups, we could benefit from analyzing additional ear molding devices. Future research will be dedicated to the types of adjunctive treatment and their effect on patient outcome and satisfaction.

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Volcanic eruption