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The non-operative correction of ear anomalies in infants using the EarWell infant corrective system in the Netherlands

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Abstract *Background:* Congenital ear anomalies are regular but often overlooked occurrences. The golden standard of treatment has been to surgically correct these anomalies at a minimum age of 5 to 7 years. As of the last century, ear molding has developed to be a safe, reliable, and effective treatment method. Different treatment methods are still under investigation. This study aims to investigate the use of the EarWell Infant Corrective System in the Dutch population.
Methods: Children aged 0–12 weeks were included in the Zuyderland Medical Center to be treated with the EarWell Infant Corrective System in case of ear deformations. Every 2 weeks, the system was replaced and correction was evaluated by both physician and parents.
Results: Seventy-three participants were included, of whom 123 ears in total were treated. Age at initiation was 35.5 days on average; treatment lasted an average of 59 days. Parents and physicians both reported an amelioration of all ear anomalies after treatment, scoring the correction grade an 8.8. Overall satisfaction with the treatment method was 9 or higher for both groups.
Conclusions: The EarWell Infant Corrective System is a safe, reliable, and effective treatment method for the correction of ear anomalies in infants.

The human ear serves an esthetic purpose as one of the appendages of the human face. However, not every infant is born with anatomically correct ears. Congenital ear anomalies are one of the many congenital birth defects that may occur in the fetal or perinatal period. A distinction can

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be made between two different kinds of ear anomalies: malformations and deformations. Malformations are ear anomalies that have occurred during fetal ear development (weeks five to nine of gestation[1–3]), resulting in a chondrocutaneous defect. Deformations are ear anomalies, which developed during the perinatal period.[1] The exact pathogenesis of deformations is unknown, but they are believed to be caused by either external pressure or genetic predisposition.[4] Severe malformations have a lower incidence than deformations[5]. Although the incidence of ear anomalies is variable in literature,[6–10] congenital ear anomalies are widely known as one of the most consequential birth defects. While seemingly harmless, these anomalies may have a lasting psychosocial impact consequential to teasing during early childhood.[11,12] Because of these psychosocial consequences, parents might seek early treatment for this kind of anomaly. Otoplasty is currently the most acknowledged treatment, occurring at ages 5–7, when the ear is full-grown for at least 90% of its eventual size.[10,13,14] The success rate of otoplasty is 95.0%[15] based on the literature, but early surgical complications, such as bleeding and wound infection, may arise in 4.39% of the cases, while late surgical complications, such as asymmetry, suture extrusion, and scarring occur in 21.90%. Revision surgery is performed in 2.8% of the cases.[16] Furthermore, research has shown that the psychosocial consequences of being teased in early childhood due to congenital ear anomalies will be mitigated, but will not always fully disappear by performing an otoplasty.[11,12]

Ear molding was popularized in the 1980s[8,17–19] and has been an upcoming method of treatment. Due to this treatment being initiated at an early age, children are no longer exposed to the psychosocial consequences of having an ear anomaly. Furthermore, surgery will have psychosocial implications as well, whereas molding does not. Unfamiliarity about the technique, the duration of treatment, the age at which molding should be initiated and what kind of ear anomalies can be treated have long been the reason for a delay in the implementation of this technique as the standard treatment.[20–23]

There have been a multitude of molding techniques over the past few decades, with thought up variations ranging from things as simple as a paperclips with retention taping to systems with more complicated structures[2]. During the previous century and early in the 21st century, good results were accomplished with ear molding.[8,10,17–19,24–27] All studies, however, have different set-ups and different end-values, which makes it more difficult to find a consensus. Early rather than late diagnosis and treatment have been advised in earlier literature.[17,26,28] The general hypothesis as to why ear molding is an effective treatment method that relates strongly to the pliability of neonatal cartilage, which is hypothesized to be caused by circulating maternal estrogen. Estrogen has been known to have an increasing effect on hyaluronic acid and estrogen receptors have been found in the auricular cartilage.[29] This causes high levels of hyaluronic acid in the auricular cartilage during the neonatal period, making the ear more pliable.[30–33] The levels of estrogen peak after 72 h of birth and then steadily decline until normal levels have been reached at 6 weeks of age[2]. Some articles, however, have found molding to be effective up till 3 or 6 months of age.[24,28,34]

The EarWell Infant Corrective System TM is a silicone molding device developed by BeconMedical Ltd. (Tucson, Arizona), under the direction of Dr. Steve Byrd. This device aims to correct a multitude of the different kinds of congenital ear anomalies through simple application.

Self-correction is generally underreported in the literature, although there have been statements that a third of ear anomalies might self-correct.[21] Control groups are seldom used in the investigation of ear molding and most studies are retrospective or prospective without a control group. There have been reports about the incidences of ear anomalies increasing during the first year of life,[35] which makes it more difficult to assess the self-correction grade of ear anomalies.

There is research available proving the effectiveness of the device. However, most studies are conducted in the USA. There are two European studies and still a couple questions remain, such as “till what age can ear molding start?” Most studies conclude that it is most effective if treatment is initiated before 3 weeks of age, but there are studies describing that the molding is still effective until 3 months.

The aim of this study is to thoroughly assess ear molding with the EarWell method in the Netherlands and to investigate the influence of breast feeding on treatment duration and efficacy.

Materials & methods

This is a single-centered, non-blinded, and non-randomized intervention trial affiliated with the Zuyderland Medical Center. Inclusion took place between April 2021 and February 2023. Participants were referred by their general practitioner, youth doctor, or other clients. Data were collected from patient data and photographs. All data were processed in a database and subjected to statistical analysis.

The research population was drawn from infants between the ages of 0–12 weeks who exhibited a certain congenital ear anomaly. The included anomalies were cryptotia, constricted ear, protruded ear, Stahl’s ear, helical rim deformities, lop ears, and cup ears. Exclusion criteria were an age of more than 12 weeks, certain malformations, such as anotia, microtia, and underlying pathology in need of urgent treatment.

Collected personal data included age at initiation of treatment, sex, family history, kind of ear anomaly, duration of pregnancy, and whether the infant was breastfed.

The EarWell Infant Corrective System TM was used to treat participants. This silicone device was developed by Becon Medical Devices in Tucson, Arizona, USA. It was created to treat a various amount of congenital ear anomalies using several separate parts which can be adjusted to accommodate each anomaly:

1. A posterior cradle adhered against the scalp for shaping the antihelix and superior crus;
2. A helical retractor, adhered to the posterior cradle;
3. A compressible conchal former;
4. A clear and perforated anterior shell, pressing on the conchal former and helical retractor.

To apply the EarWell device, an area of about 2–3 cm was shaved clean of hair around the ear of the infant upon

initiation of treatment. When applying the system, adhesive strips were used to keep the system in place for the following 2 weeks as an extra measure. Every 2 weeks or earlier in case of parent-reported issues, infants would return to the outpatient clinic to evaluate correction progress and renew the EarWell system, filling out questionnaires using VAS-scores and Likert scales contemporaneously.[36–39] Additionally, the treated ears were photographed in a standardized manner from lateral and anterior views, positioning the head in the Frankfurt Horizontal plane. Other facial features were left out of the photos and data were anonymized. The photos were taken with a digital camera in a secure digital environment with parental permission. Treatment was set to last at least 4–6 weeks. In case of prominent ears, correction was stabilized after treatment using only the helical retractor and adhesive strips, up until the infants were at least 4 months old. Complications and compliance were registered. Assessment of results was performed by an independent physician without any conflict of interests. Severity decline was measured as a relative decrease in severity score before and after treatment.

Treatment would be terminated if:

- Physician nor parents noticed any correction after 6 weeks of treatment;
- Complications arose that could not be treated through temporary relief of the system;
- Correction had stabilized for 2 weeks after a treatment duration of 4–6 weeks;
- A maximal treatment duration was reached that was agreed upon by both parents and physician before treatment initiation.

Results

Seventy-three participants were included in the study and 123 ears were treated, as 23 ears did not show any anomaly. Table 1 exhibits the patient characteristics.

The average duration of pregnancy was 39.8 weeks (SD 1.1), with 3 participants being born prematurely. Forty-four participants (60.3%) were breastfed.

Parents graded the understandability of treatment an average of 9.5 (SD 0.8).

The physician graded the application of the system an average of 9.0 (SD 1.5).

There was no significant difference in positive family history or kind of anomaly between the sexes, but a significant difference was seen in bilaterality, with males more often exhibiting bilateral anomalies than single-sided anomaly compared to females ($p = 0.010$). In females, bilaterality was 50%, while in males, ear anomalies were bilateral in more than 80%.

There was no significant relation between family history and kind of anomaly.

A variety of ear anomalies were seen in the study population (see Table 1), with prominent ears being the most frequently seen and treated anomaly (29.3%).

Two children were diagnosed with syndromes to which their ear anomalies could be attributed.

The comfort of the overall treatment was scored an average of 8.5 by parents (SD 1.7). The appearance of the system was scored 7.5 (SD 2.6).

Table 1 Patient characteristics.

Characteristics	Number/ average	Percentage (%)
Sex, (Male)	41	56.2
Ethnicity		
African	3	4.1
Asian	4	5.5
Arabic	3	4.1
Caucasian	61	83.6
Latin-American	2	2.8
Family history, (pos.)	37	50.7
Ear anomaly		
Conchal crus	8	6.5
Constricted ear	3	2.4
Cup ear	14	11.4
Helical rim deformity	19	15.4
Lop ear	15	12.2
Mixed	21	17.1
Prominent ear	36	29.3
Stahl's ear	6	4.9
Side		
Left	11	15.1
Right	12	16.4
Bilateral	50	68.5

Pos., positive.

Eight participants exhibited complications, of which 6 were pressure ulcers and 2 were skin dermatitis. Temporary alleviation of the system or replacement of the system while avoiding the pressure ulcers was performed as complication treatment and was effective in all cases. No leftover damage was seen afterward.

Eleven participants were non-compliant at some points in the research. All of these cases were related to early detachment of the system without notifying the research team.

Age at initiation and duration of treatment

The average age at initiation of treatment was 35.5 days (SD 18.9). The youngest child was 7 days old and the oldest was 80 days old. Treatment lasted an average of 59 days (SD 27.6), with a minimum of 27 days and a maximum of 154 days (Figures 1–3).

There was no significant correlation between sex and age at initiation or duration of treatment. There was no significant difference in age at initiation or duration of treatment dependent on a positive family history or gradation of positive family history (e.g., first-degree and second-degree). Breastfeeding did not significantly impact the duration of treatment ($p = 0.667$). Treatment duration did not significantly correlate with comfort during treatment. No significant correlation was found between age at initiation and total duration of treatment. The occurrence of complications did not significantly affect the duration of treatment and could not be significantly related to age at initiation of treatment. If treatment was initiated at a younger age, the compliance was significantly higher ($p = 0.017$). Duration of treatment was not significantly correlated with satisfactory rates of parents or the

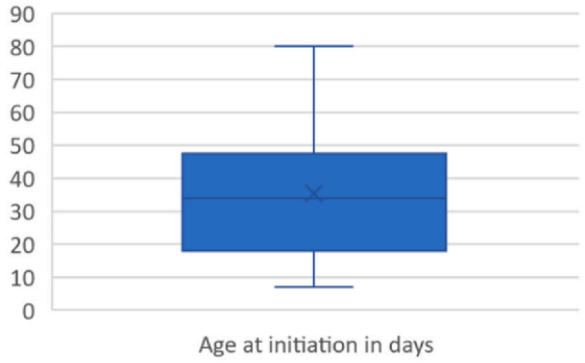

Figure 1 Box plot of age at initiation in days.

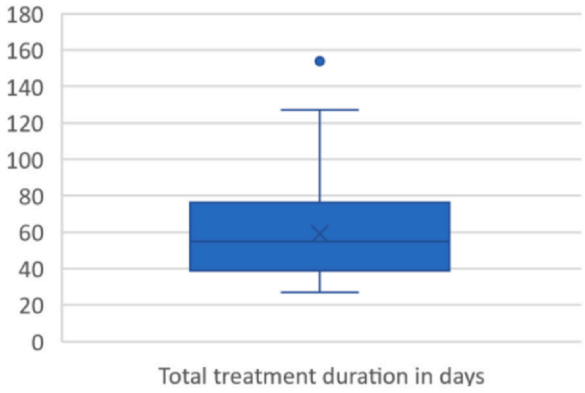

Figure 2 Box plot of total treatment duration in days.

physician. There was no significant correlation between age at initiation and easiness of system application. There was no significant correlation between age at initiation of treatment and success rate, nor in parent- or physician-reported satisfaction. There was no significant correlation between duration of treatment and success rate, nor in parent-reported satisfaction. There was, however, a significant negative correlation between duration of treatment and physician-reported satisfaction ($p = 0.020$).

Table 2 Treatment duration in days by ear anomaly.

Anomaly	Treatment duration, days	SD
Conchal crus	59.4	31.8
Constricted ear	90.7	54.8
Cup ear	71.0	31.9
Helical rim deformity	51.0	18.1
Lop ear	35.3	8.4
Mixed	53.0	27.3
Prominent ear	75.4	25.5
Stahl's ear	50.0	14.3

SD, standard deviation.

Table 2 shows the average duration of treatment per ear anomaly. The duration of treatment was significantly shorter for lop ears than for prominent ears, helical rim deformities, and cup ears ($p < 0.001$, $p = 0.044$, and $p = 0.018$, respectively). Duration of treatment was significantly shorter for helical rim deformities than for prominent ears ($p = 0.004$). The age at initiation was significantly higher for participants with a constricted ear anomaly compared to those with other anomalies ($p = 0.010$).

Treatment was terminated because of sufficient correction in 82.2% of cases. Other reasons for treatment termination included having reached a maximal treatment duration (11%), parental request (5.4%), and fine motor development of the child (1.4%).

Success rate

The mean decrease in severity of the ear anomalies was 81.0% (SD 24.5). The mean satisfaction with the treatment on a scale from 0 to 10 was 9.0 for the physician (SD 1.7) and 9.2 for the parents (SD 1.4). The average score given for the

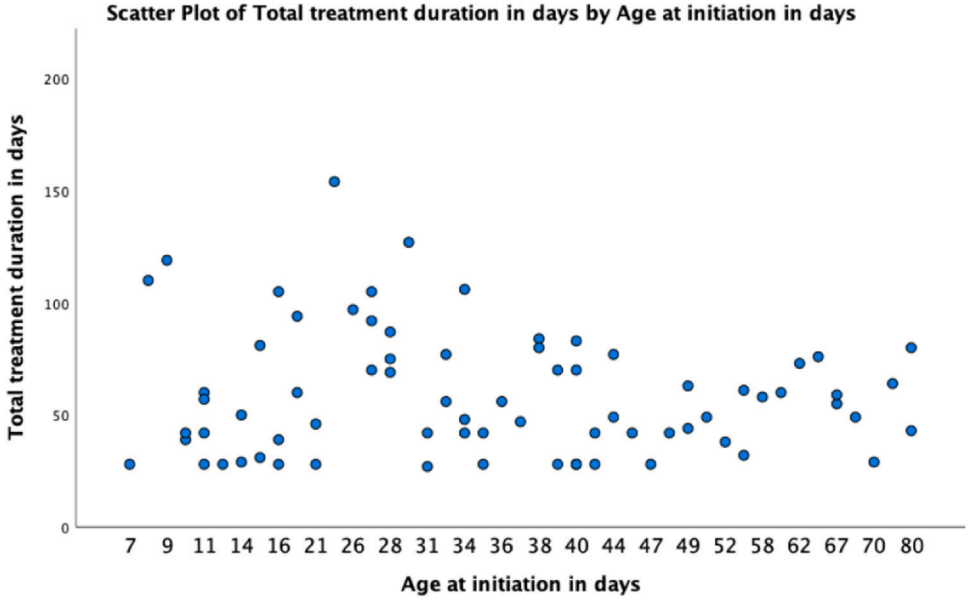

Figure 3 Scatter plot of treatment duration in days by age at initiation in days.

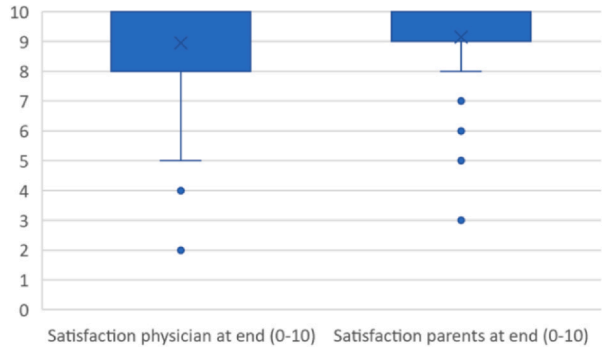

Figure 4 Boxplots of satisfaction of physician and parents at the end of treatment.

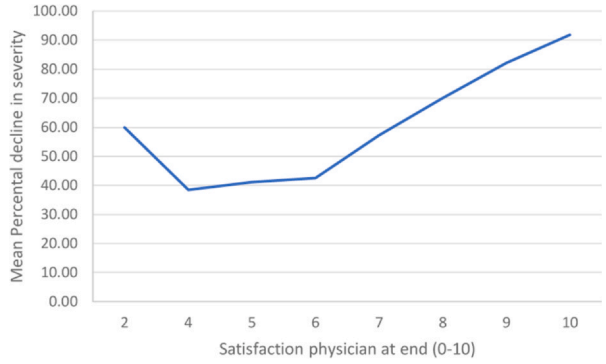

Figure 5 Graph exhibiting satisfaction of physician against percentual decline in severity.

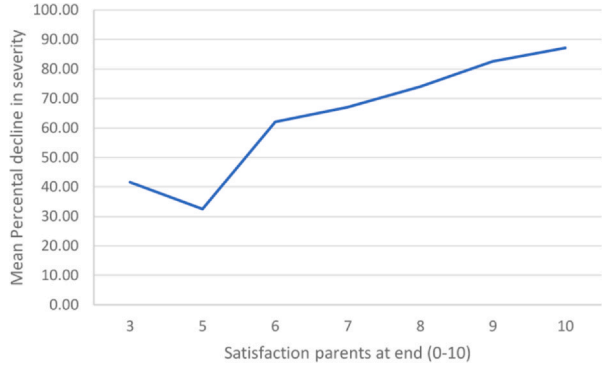

Figure 6 Graph exhibiting satisfaction of parents against percentual decline in severity.

accomplished result was an 8.8 and was equal for both the physician and the parents (SD 1.4 and 1.5, respectively; Figure 4). There was a significant positive correlation between success rate and parent- and physician-reported satisfaction and correction score ($p < 0.001$ for all cases; Figures 5-8). Table 3 shows a Likert scale of the ear anomalies pre- and post-treatment. There was no significant difference in satisfactory rate for different kinds of ear anomalies. All average satisfactory rates per anomaly were above 7 on a scale from 0 to 10. No significant difference in decline in severity between the different anomalies was found. There was no significant sex-related difference in success rate. The relative decrease in severity was 75.6% in the group that was not breastfed, it was 83.1% in the group

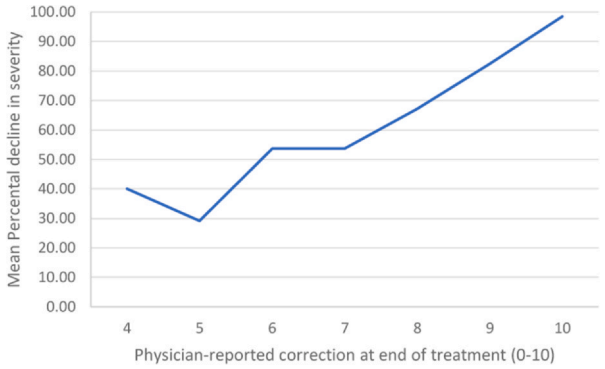

Figure 7 Graph exhibiting physician-reported correction against percentual decline in severity.

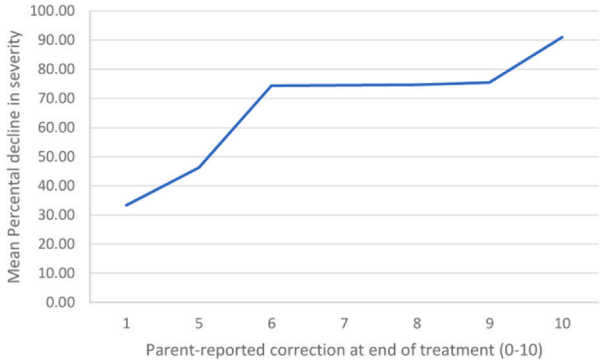

Figure 8 Graph exhibiting physician-reported correction against percentual decline in severity.

that was breastfed. This difference was insignificant. The difference in parent- or physician-reported satisfaction between these groups was insignificant as well. Appearance of the system was not significantly correlated with parent- or physician-reported satisfaction. Comfort of treatment was significantly positively correlated with the success rate ($p = 0.002$), parent-reported satisfaction ($p < 0.001$), and physician-reported satisfaction ($p < 0.001$). There was no significant difference in success rate or physician- and parent-based satisfactory rate, based on a positive family history.

Discussion

This study shows that the EarWell Infant Corrective System is an easily applicable, easily understandable, and widely effective treatment method for ear anomalies in the Dutch population. All treated ears improved after treatment, which shows that if treatment did not fully correct an anomaly, it was either no longer bothersome according to both parents and physician or optimized for later surgical treatment. Only minor and few complications were seen, and parents reported that the comfort and appearance were not as bad as initially assumed. In conversations with parents, the shaving of the head and the lack of color of the treatment system were mostly reported as being bothersome. Comfort did significantly impact the treatment evaluation, as both parents and physician felt uncomfortable

Table 3 Likert scale of severity of anomaly before and after treatment.

Moment	0 *(0)*	1 *(0.1-2)*	2 *(2.1-4)*	3 *(4.1-6)*	4 *(6.1-8)*	5 *(8.1-10)*
At start	0	30	47	33	9	4
At end	65	46	10	2	0	0

when faced with lesser comfort for the children. This research included participants up to the age of 12 weeks, which is higher than that recommended in earlier studies.[40] However, it could be seen that this did not impact the results, satisfaction, or duration of treatment. It was seen that compliance was higher for the younger children, which can be attributed to fine motor development. Parents often reported that as children grew older, they would start picking at the systems more often. Duration of treatment was also longer in this study than that in other studies, which can mostly be attributed to a prolonged stabilization period (see Figure 9).[40] It should be noted that relapse was not included in this article and that follow-up data are still being collected. Furthermore, this study does not indicate that the maximum age of initiation of treatment is 12 weeks, as older ages have not been included in this study.

Especially in the case of cup ears and prominent ears, stabilization was prolonged as recurrence was seen to likely occur when children were lying supine. Effect of treatment was often already seen after 2 weeks (see Figure 10).

Prominent ears were the most common anomaly in the study population, making up almost a third of all treated ears. Literature has shown that the prevalence of prominent ears in the Caucasian population is about 5%. As most of the study population is Caucasian, it may indicate that the prevalence of all ear anomalies in the Caucasian population is about 15%. This indicates the importance of education and identification of ear anomalies early on. An interesting new finding in this study was the significant sex-based difference in bilaterality of ear anomalies. Why the male population shows a bilateral anomaly more often is not known, but it could have a genetic basis which has not yet been discovered.

This study tried to specifically focus on breastfeeding and requires more thorough evaluation in future studies. The amount of breast milk received differed per infant,

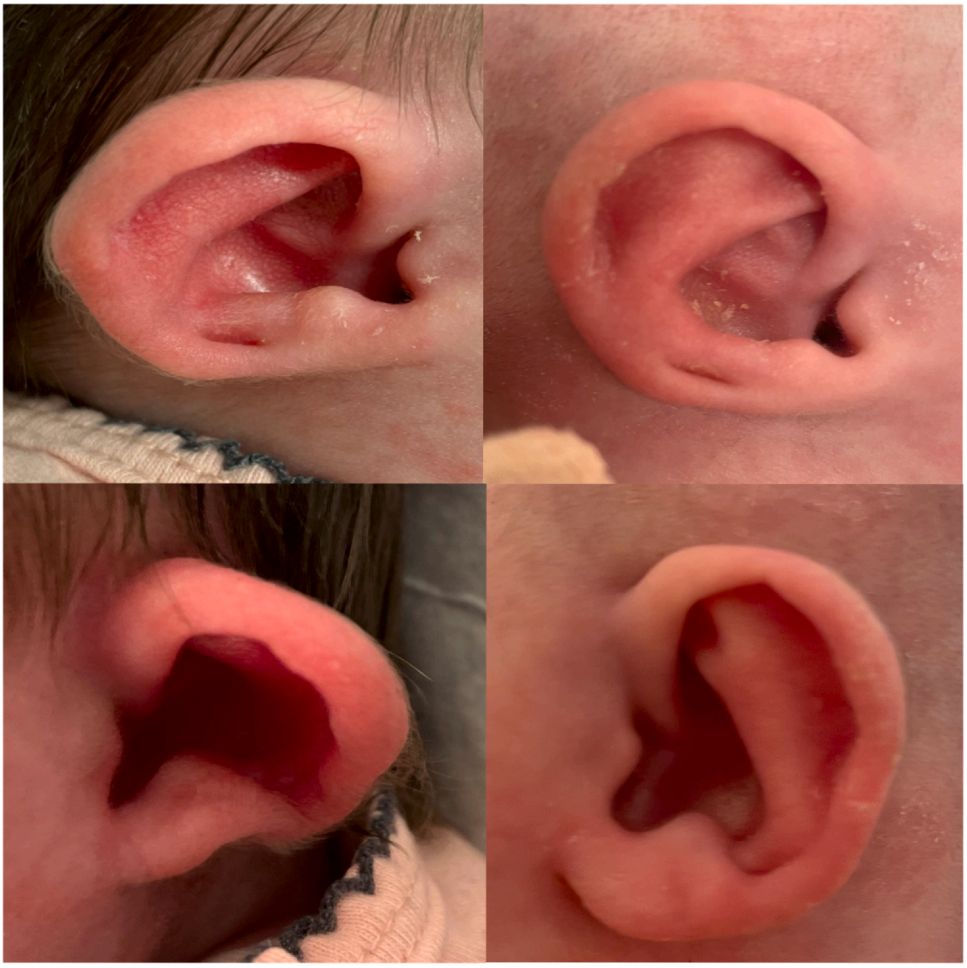

Figure 9 Pictures of results after treatment with prolonged stabilization of an infant with a severe anomaly.

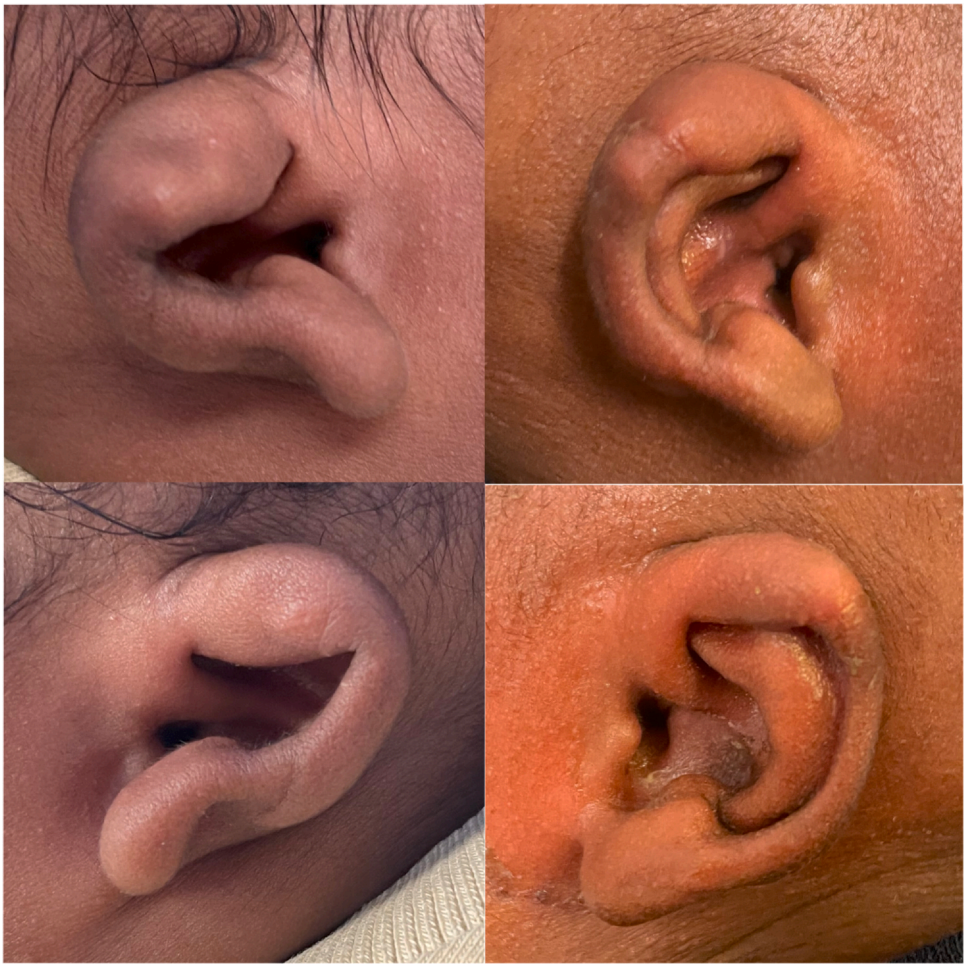

Figure 10 Pictures of results of 2 weeks of treatment of a participant with a severe anomaly.

which would lead to a different amount and impact of the maternal estrogen. In this study, no correlation was found between being breastfed and other outcomes and we would like to suggest a registration of amount of breast milk received in further studies.

An important discussion point in regard of the treatment of ear anomalies is the focus of the outcome. Is parent satisfaction as important as, if not more important than, success rate in terms of severity decline? This research has shown that almost all parents graded their satisfaction rate with a score of 8 or higher. This does not reflect the severity decline. Can this be attributed to lack of knowledge or to properly delivered care and understanding? Because parents instead of children are seeking out treatment, parents' satisfaction cannot be neglected in the treatment process.

A factor that was not included in this study, which the physicians noted may impact the outcome of treatment, is socio-economic status. Although most parents reported that the explanation of treatment was understandable, it was noted that the parents with a relatively lower socio-economic status did not alert the physician in case of detachment of the treatment system. Systems were sometimes also seen to be relatively dirty.

Unfortunately, this study population had little variety in ethnicity, but this only indicates that research is needed in various countries to evaluate the differences in treatment efficacy. Furthermore, some subgroups of the different anomalies were relatively small. Another limitation is that a lot of results are based on subjective judgment, something that is usually difficult when dealing with esthetics. For prominent ears, certain cut-off measurements exist, but for the other anomalies, there is no measurement system to objectively evaluate correction grade.

The benefit of this system, compared to others, is that it is easily applicable with the manufacturer's instructions; other methods often require extensive knowledge on the anatomy of the ear or a certain dexterity. This means that parents could be instructed to readjust the device might detachment occur for any reason. Furthermore, the device maintains a certain standard shape, making it applicable for a multitude of anomalies. A reason to choose this system is its high success rate compared to some other devices, its broad and easy applicability, and the extensive research that has been done on its efficacy[41]. A comparative cohort study between EarWell and these other treatment methods is yet to be performed.

Conclusion

The EarWell Infant Corrective System is an easily understandable, applicable, and effective treatment method for

ear anomalies in infants. Treatment can effectively be initiated up to an age of 12 weeks old. Treatment duration mostly depends on evaluation of correction but usually takes up to 4–10 weeks, including stabilization. Education on and identification of ear anomalies remain of great importance.

Ethical approval and informed consent

This study was approved by the Ethical Committee of Zuyderland MC (METC Z). Written informed consent was obtained from both parents of the participants.

Financial disclosure

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Declaration of Competing Interest

M.M.W. Feijen is an importer of the EarWell Infant Corrective System in the Netherlands. The other authors have nothing to disclose.

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