ORIGINAL RESEARCH

*Laryngoscope*
**Investigative Otolaryngology**

# Comparison of two conchal formers for nonsurgical correction on Conchal Crus

Qijuan Zou MD [1,2] | Shouqin Zhao MD [1,2] | Danni Wang MD [1,2] | Peiwei Chen MD [1,2] | Lin Yang MM [1,2] | Mengdie Gao MM [1,2] | Yujie Liu MM [1,2] | Chunli Zhao MD [1,2] | Sijia Li MM [1,2] | Jinsong Yang MD [1,2]

[1]Department of Otolaryngology Head and Neck Surgery, Beijing Tongren Hospital, Capital Medical University, Beijing, China

[2]Key Laboratory of Otolaryngology Head and Neck Surgery, Ministry of Education, Capital Medical University, Beijing, China

**Correspondence**
Shouqin Zhao, No. 1 Dongjiaominxiang, Dongcheng District, Beijing 100730, China.
Email: shouqinzhao@163.com

## Abstract

**Objectives:** Conchal Crus is a kind of congenital auricular deformation which is often overlooked. Few studies reported a large number of cases. We compared the efficacy of EarWell and self-made conchal formers on Conchal Crus to summarize our experience of correction and to find out the influencing factors.

**Methods:** Two groups of Conchal Crus babies underwent conchal correction with the EarWell and self-made conchal formers respectively. The combined auricular deformities in these babies were corrected with EarWell Infant Ear Correction System. Conchal Crus deformity was classified as severe and mild. Auricular and conchal morphologic outcomes were graded as excellent, good, and poor.

**Results:** The auricular morphologic results were comparable between the two groups. There was no significant difference in the effective (excellent plus good) rate between the two groups, but the excellent rate for conchal results in the Self-made group was significantly higher than that in the EarWell group. The former incidence of pressure ulcers was significantly lower than the latter. Multinomial regression analysis showed that the more severe conchal deformity was, the less likely the conchal shape tended to be improved.

**Conclusion:** Both conchal formers could correct Conchal Crus effectively. The self-made conchal former could make more excellent conchal fossae and lead to less pressure ulcers at the Conchal Crus. The degree of Conchal Crus deformity was an important influencing factor in the conchal correction outcome.

**Level of evidence:** 4

**KEYWORDS**
auricle, Conchal Crus, correction, deformity

## 1 | INTRODUCTION

The Conchal Crus is a kind of congenital auricular deformation, which is mainly manifested as a convex crus crossing the midportion[1] (Figure 1A). It is in fact the extension of the helical root in the conchal fossa and was referred to as prolonged crus helicis by Matsuo et al.[2] Some crus can even extend onto the vertical wall of the concha.
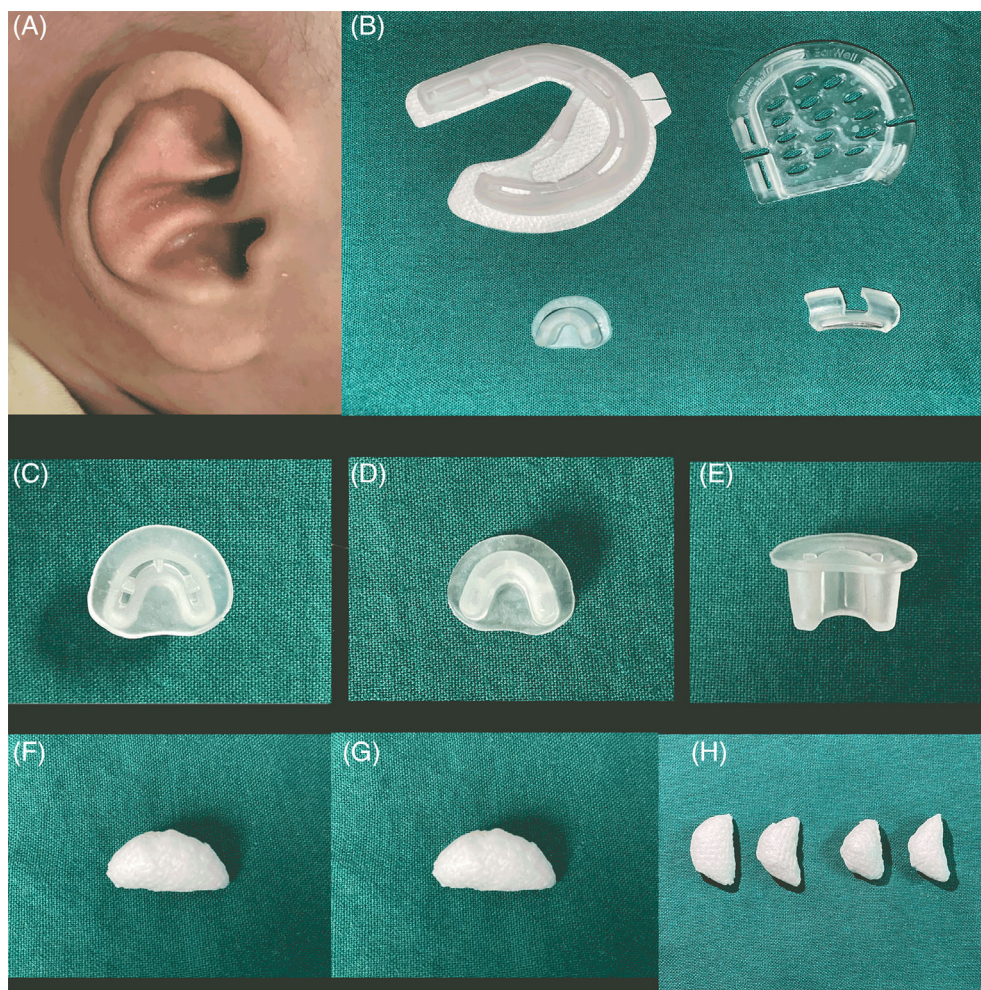
FIGURE 1    Upper row: (A) Conchal Crus deformity. (B) The EarWell Infant Ear Correction System. Middle row: The EarWell conchal former. (C) The outside appearance. (D) The inside appearance. (E) The lateral appearance. Lower row: The self-made conchal former. (F) The surface. (G) The lateral appearance of the curved side. (H) Conchal formers of different sizes shaped according to different babies.

Matsuo et al. reported in 1984 their experience in making a conchal fossa by a round Temporary-stopping (dental material, a kind of gutta-percha). Tan et al.[3] corrected conchal deformities with coiled-up splint or shaped silicone mold. The EarWell Infant Ear Correction System (Figure 1B), which is commonly used at present, includes a conchal former (Figure 1C–E) to correct the Conchal Crus. But, Lennon and Chinnadurai[4] recommended custom-made molds rather than prefabricated molding systems for conchal correction.

Due to the different sizes and shapes of conchal fossae of newborns and infants with Conchal Crus, the prefabricated conchal former could not match the conchal fossa well sometimes and might bring about some problems during the correction. For example, ulcers were more likely to develop at the Conchal Crus under the EarWell conchal former in the following cases: (a) The prolonged conchal crus was connected to the vertical wall of conchal fossa, and its end was as high as the antihelix. (b) The U-shaped bottom of the EarWell conchal former extended beyond the conchal fossa. (c) The EarWell conchal former was too high for the anterior shell to attach to the posterior cradle. Therefore, we used a kind of self-made conchal former (Figure 1F–H) instead of the EarWell conchal former to correct Conchal Crus after we realized these problems. In this study, a series of newborns and infants with Conchal Crus were

followed up to compare the effects of EarWell and self-made conchal formers for nonsurgical correction on this particular kind of congenital auricular deformation.

## 2 | MATERIALS AND METHODS

### 2.1 | Patients

A total of 54 cases (76 ears) with Conchal Crus underwent conchal correction in the outpatient clinic of Beijing Tongren Hospital from July 2020 to April 2022. There were 32 males and 22 females with a median age of 16.0 days (range: 2–117 days). The median duration of correction was 26.0 days (range: 7–86 days).

### 2.2 | Correction

The EarWell conchal formers were used for correction from July 2020 to May 2021. The self-made conchal formers were used from June 2021 to April 2022. As shown in Figure 2A, the EarWell conchal former is designed to fit in the conchal fossa. It is soft and compressible,
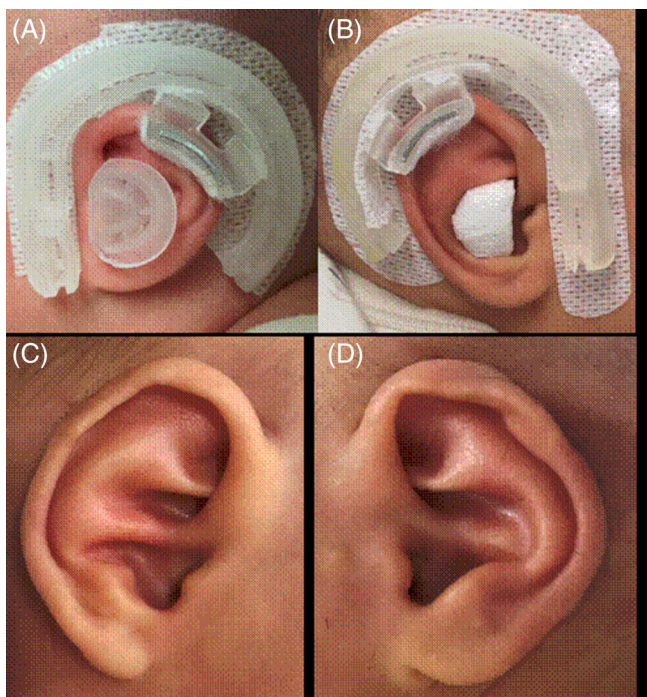
**FIGURE 2** Upper row: Conchal correction. (A) Correct Conchal Crus with the EarWell conchal former. (B) Correct Conchal Crus with the self-made conchal former. Lower row: Classification of Conchal Crus deformity. (C) A severe Conchal Crus. (D) A mild Conchal Crus.

with a U-shaped bottom. To correct the Conchal Crus, the EarWell conchal former should be rest against the vertical wall of the conchal fossa with the opening of the U-shaped bottom towards the external auditory canal (Figure 2A). The height of the conchal former could be varied by the addition of cotton to its surface.[1]

The self-made conchal formers are made of 38–40 layers of hypoallergenic double-faced adhesive tapes which are pasted together. The creating process is as follows: Fold the tapes up to make a lump. Rotate the lump of tapes as pasting more tapes to it. Pinch it constantly to produce a curved side and a flat side. More details of how to make such a conchal former are shown in Supporting Information S1. The curved side of the self-made conchal former fits the vertical wall of the conchal fossa. Its flat side is close to the external auditory canal but does not obstruct it (Figure 2B). It could easily be trimmed with a pair of scissors and be reshaped to fit the patient's conchal fossa during the treatment. As Figure 2B shown, the self-made conchal former was placed in the conchal fossa to give an anterior force at the conchal crus. It could be fixed by hypoallergenic tapes.

Measurements of self-made conchal formers are as follows. The length of the flat side varies between 1.8 and 2.0 cm. The width of the conchal former, that is the distance between the most prominent point on the curved side and the flat side, varies between 1.1 and 1.3 cm. The height varies between 1.0 and 1.1 cm. The width and the length of the flat side are totally decided by the size of conchal fossa. But, the height depends both on the depth of conchal fossa and on

the height of anterior shell of the EarWell Infant Ear Correction System. A conchal former with optimal height should just reach the anterior shell to ensure a proper force at the conchal crus. If it is too high, it will cause too much force at the conchal crus and can easily lead to skin complications. If it is too low, the shell cannot exert a force at the conchal former.

Other deformities mixed with the Conchal Crus were corrected with components of the EarWell Infant Ear Correction System, including posterior cradle, anterior shell, and retractors. Mothers were told to press the conchal formers gently when feeding their babies to exert an additional force at the conchal crus. Parents were taught how to observe and take care of the auricular skin during the correction. No matter which conchal former was used, the instructions for parents were the same.

## 2.3 | Follow-up

All babies who underwent ear correction returned to the clinic after the first week of treatment. If the device was stable and the auricular skin was in good condition, the follow-up interval could be extended up to 2 weeks. Photos of corrected ears were taken before the treatment and at each follow-up visit. Correction continued until 2 weeks after the normalization of the ear anatomy was achieved.

## 2.4 | Main outcome measures

Based on the distance between the end of prolonged crus and the antihelix, the Conchal Crus deformity was classified as follows: (a) Severe: The protruding conchal crus extended onto the antihelix (Figure 2C). (b) Mild: The protruding conchal crus extended beyond more than half of conchal fossa, but it wasn't connected to the antihelix (Figure 2D).

Final conchal morphology result was classified into three grades: (a) Excellent: The protruding prolonged conchal crus disappeared. The conchal fossa was normal or nearly normal (Figure 3A,B). (b) Good: The prolonged conchal crus was less protruding, but the conchal fossa was still abnormal (Figure 3C,D). (c) Poor: The prolonged conchal crus was not improved or slightly improved. The conchal fossa was obviously abnormal.

Final auricular morphology result was also classified into three grades: (a) Excellent: The auricular shape was normal or nearly normal; (b) Good: The auricular shape was significantly improved, but it was still not normal; (c) Poor: The auricular shape was not improved or slightly improved.

Pretreatment and posttreatment ear photos were reviewed at the end of treatment. Final auricular morphologic results were graded by the doctor and parents independently. Final conchal morphologic results were graded by two blinded doctors. If the two people who interpreted the results had different conclusions, the worse result was selected for analysis.
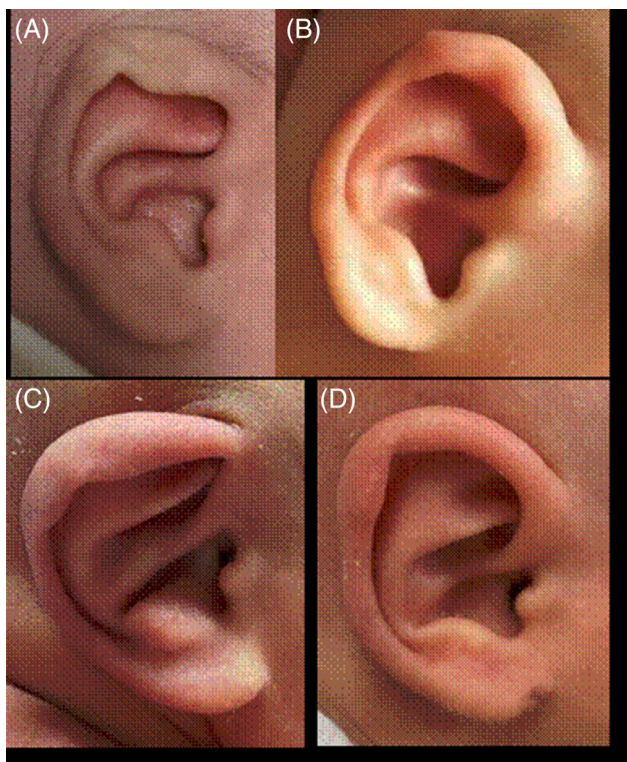
**FIGURE 3** Upper row: Conchal Crus combined with lop ear. (A) Before correction. (B) Normal conchal fossa after correction. Lower row: Conchal Crus combined with lop ear and cryptotia. (C) Before correction. (D) Improved conchal fossa after correction.

## 2.5 | Ethics

This study was approved by the Ethic Committee of Beijing Tongren Hospital and was conducted in accordance with the Declaration of Helsinki. Written informed consents were obtained from all parents of patients before the treatment. When analyzing the data, personal information was replaced by index number.

## 2.6 | Statistical analysis

Values of skewed distribution were represented by medians (range) and were compared using Mann–Whitney $U$ test. Percentages were used to describe incidence rates and were compared using Fisher's exact test. Factors which might influence conchal morphologic results were analyzed using multinomial regression analysis. Statistical significance was defined as a two-sided $p$-value < .05. All statistical analyses were performed using the IBM SPSS Statistics (version 22.0).

## 3 | RESULTS

Of the 76 Conchal Crus ears in the study, 24 cases (35 ears) were corrected with the EarWell conchal former (EarWell group) and 30 cases (41 ears) were corrected with the self-made conchal former

(Self-made group). Conchal Crus presents as an isolated deformity in 7 ears (7/76, 9.2%). It presents with mixed deformities in the remaining 69 ears (69/76, 90.8%). According to the classification mentioned above, Conchal Crus deformity was severe in 47 ears (47/76, 61.8%) and mild in 29 ears (29/76, 38.2%). Patients' characteristics of two groups are shown in Table 1.

As there were 7 isolated Conchal Crus ears with normal auricles in the study, 69 ears underwent auricular correction. Excellent auricular morphologic results were observed in 55 of the 69 ears (55/69, 79.7%) and good results in 14 ears (17/76, 20.3%). Each ear was improved in the auricular shape. Define both excellent and good results as effective results, the effective rate for auricular correction was 100.0%. There were 35 ears (35/76, 46.1%) with excellent conchal morphologic results, 37 ears (37/76, 48.7%) with good results, and 4 ears (4/76, 5.3%) with poor results. The effective rate for Conchal Crus correction was 94.7%. Fisher's Exact test showed that there was a significant difference between auricular results and conchal results in excellent, good, and poor rates ($p$ = .000), but no difference in effective rate ($p$ = .122, $a$ = 0.05). More details of correction results are shown in Table 2.

Multinomial logistic regression analysis (Table 3) showed that the degree of Conchal Crus deformity had an impact on the correction results. The more severe the deformity was, the less likely conchal shape tended to be improved. Besides, Table 3 provided the same conclusion as Table 2: Conchal Crus patients in the Self-made group were more likely to have excellent results than those in the EarWell group.

During the treatment, a total of 26 ears (26/76, 34.2%) experienced skin complications (Table 4) which were caused by either conchal or auricular correction. The skin ulcers (Figure 4D,E) were all found at the conchal crus under the EarWell conchal former. All of them occurred within the first 2 weeks of correction and were cured with antibiotic ointment in a week. However, all the patients suffered skin ulcers from the conchal former gave up conchal correction but continued auricular molding. Adhesive dermatitis and eczema (Figure 4E) usually resolved after 2–3 days of treatment interruption and did not affect auricular and conchal correction.

## 4 | DISCUSSION

### 4.1 | Incidence of Conchal Crus

Conchal Crus could either be an isolated deformity or accompany with other auricular deformities. The proportions of isolated Conchal Crus in congenital auricular deformities reported in literatures were quite different. Byrd et al.[1] reported 3.01% and Doft et al.[5] reported 0.5%. In Zhao et al.'s[6] study, the data was as high as 30.68% (181/590). In Byrd's[1] study, even though cases in the mixed deformities were also included, the proportion was only 13.00%. But in Daniali et al.'s[7] series, 26.4% (80/303) of the treated deformities were Conchal Crus. The difference among these studies might be related to race, method for counting, criteria for diagnosis, and so forth. There were only

**TABLE 1** Patient demographics and ear characteristics

| Category | EarWell (n) | Self-made (n) | |
|---|---|---|---|
| Cases | 24 | 30 | |
| Ears | 35 | 41 | |
| Male | 15 | 17 | |
| Female | 9 | 13 | |
| Left ear | 18 | 18 | |
| Right ear | 17 | 23 | |
| Isolated Conchal Crus | 2 | 5 | |
| Mixed deformities | | | |
|   Helical rim deformities | 16 | 26 | |
|   Constricted ear | 4 | 7 | |
|   Lop ear | 6 | 8 | |
|   Stahl's ear | 6 | 7 | |
|   Cryptotia | 3 | 4 | |
|   Antihelical deformities | 1 | 1 | |
| Classification of Conchal Crus | | | |
|   Severe | 21 | 26 | $p = .639, \alpha = .05$; Fisher's exact test |
|   Mild | 14 | 15 | |
| Age at application, days | | | |
|   Median (range) | 17.0 (5.0–101.0) | 16.0(2.0–117.0) | $p = .851, \alpha = .05$; Mann–Whitney $U$ test |
| Duration of correction, days | | | |
|   Median (range) | 26.0 (7.0–84.0) | 32.0 (7.0–86.0) | $p = 0.136, \alpha = 0.05$; Mann–Whitney $U$ test |

**TABLE 2** Auricular and conchal morphologic results

| Outcome | | EarWell n (%) | Self-made n (%) | p |
|---|---|---|---|---|
| Auricular morphology | Excellent | 26 (78.8) | 29 (80.6) | 1.000; Fisher's exact test |
| | Good | 7 (20.0) | 7 (19.4) | |
| | Poor | 0 (0.0) | 0 (0.0) | |
| | Effective (Excellent + Good) | 33 (100.0) | 36 (100.0) | NA |
| Conchal morphology | Excellent | 11 (31.4) | 24 (58.5) | .038[a]; Fisher's exact test |
| | Good | 22 (62.9) | 15 (36.6) | |
| | Poor | 2 (5.7) | 2 (4.9) | |
| | Effective (Excellent + Good) | 33 (94.2) | 39 (95.1) | 1.000; Fisher's exact test |

[a]Statistical difference, $a = 0.05$.

7 isolated Conchal Crus ears in our study due to its low incidence. On the other hand, it had not been recognized as an abnormality by some parents.

## 4.2 | Outcome of conchal correction

Though the excellent rate for conchal results in our study was lower than that for auricular results, its overall effective rate was 94.7%. That corresponded well with Daniali et al.'s[7] study. Possible reasons for more difficulties in conchal correction are as follows: (a) The rigidity of the auricular cartilage is variable. The concha is relatively rigid because of its configuration and proximity to the external auditory canal.[8] van Wijk et al.[9] found that the stiffness of cartilage was an important factor determining the end result. Therefore, the relatively rigid concha is less susceptible to deforming forces comparing with the softer helix, antihelix, scaphoid fossa, and triangular fossa, (b) Too few isolated Conchal Crus were corrected. Parents were more likely to take their babies to see doctors for other auricular deformities rather than Conchal Crus because they paid more attention to the overall auricular morphology. Even if the conchal fossa was still abnormal but the overall auricular shape was already satisfactory, some parents might give up conchal correction.

**TABLE 3**  Multinomial logistic regression analysis for outcome of conchal correction

| | Factors | B | SE | Wald | df | p | Exp (B) | Exp (B) 95% CI Lower | Upper |
|---|---|---|---|---|---|---|---|---|---|
| Good[a] | Duration of correction | 0.022 | 0.016 | 1.899 | 1 | .168 | 1.022 | 0.991 | 1.055 |
| | Age at application | −0.008 | 0.013 | 0.338 | 1 | .561 | 0.992 | 0.966 | 1.019 |
| | EarWell conchal former | 1.763 | 0.618 | 8.152 | 1 | .004[b] | 5.832 | 1.738 | 19.567 |
| | Self-made conchal former | 0 | — | — | 0 | — | — | — | — |
| | Severe Conchal Crus | 2.023 | 0.640 | 9.986 | 1 | .002[b] | 7.561 | 2.156 | 26.516 |
| | Mild Conchal Crus | 0 | — | — | 0 | — | — | — | — |
| Poor[a] | Duration of correction | −0.017 | 0.042 | 0.157 | 1 | .692 | 0.984 | 0.906 | 1.067 |
| | Age at application | 0.007 | 0.022 | 0.099 | 1 | .753 | 1.007 | 0.964 | 1.052 |
| | EarWell conchal former | 0.932 | 1.133 | 0.676 | 1 | 0.411 | 2.539 | 0.275 | 23.410 |
| | Self-made conchal former | 0 | — | — | 0 | — | — | — | — |
| | Severe Conchal Crus | 1.894 | 1.332 | 2.024 | 1 | .155 | 6.648 | 0.489 | 90.388 |
| | Mild Conchal Crus | 0 | — | — | 0 | — | — | — | — |

[a]Compared with "Excellent."
[b]Statistical difference: $a = 0.05$.

**TABLE 4**  Complications

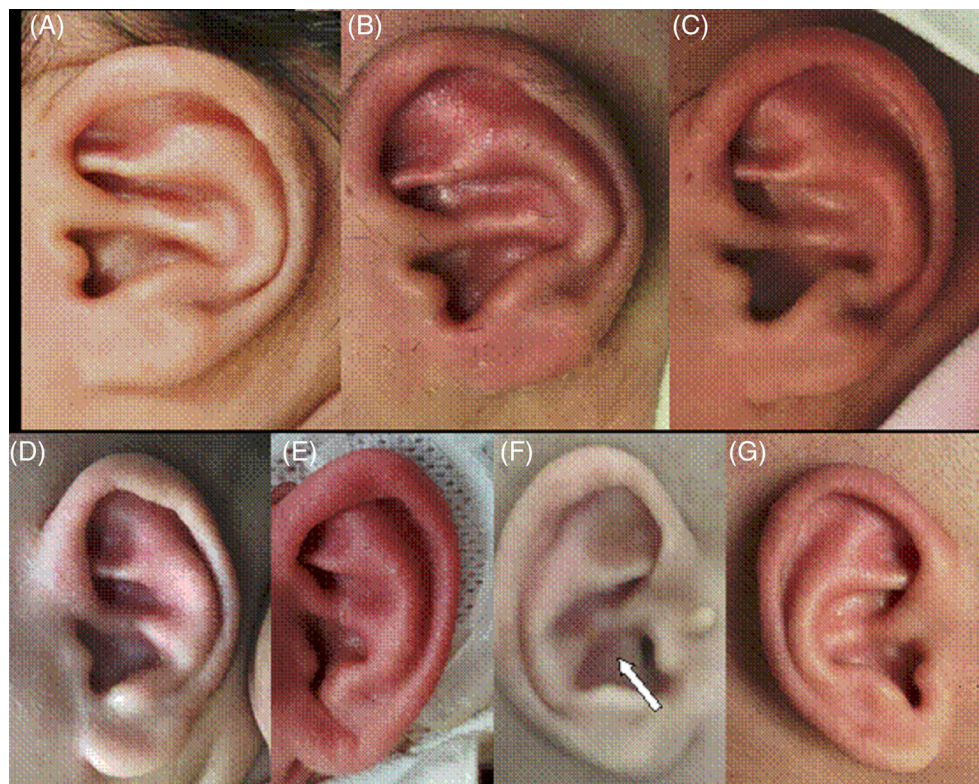| Types of complications | EarWell n (%) | Self-made n (%) | p |
|---|---|---|---|
| Pressure ulcers | 6 (17.1) | 0 (0.0) | .007[a]; Fisher's exact test |
| Adhesive dermatitis | 4 (11.4) | 8 (19.5) | .367; Fisher's exact test |
| Eczema | 2 (5.7) | 6 (14.6) | .275; Fisher's exact test |
| Total no. | 12 (34.3) | 14 (34.2) | 1.000; Fisher's exact test |

[a]Statistical difference: $a = 0.05$.



**FIGURE 4**  Upper row: Conchal Crus combined with deformed superior limb of the antihelix. (A) Before the correction on the fourteenth day after birth. (B) Improved conchal fossa after 12-day correction. (C) Normal conchal fossa after 33-day correction. Lower row: Skin complications and conchal morphologic results. (D) Skin ulcer at the conchal crus by the EarWell conchal former. (E) Exacerbated auricular eczema and pressure ulcer at the conchal crus. (F) A notch (white arrow) at the conchal crus corrected with the EarWell conchal former. (G) The smooth curvature of the conchal crus corrected with the self-made conchal former.

As the degree of Conchal Crus deformity had an impact on the correction results in our study, the more obvious the Conchal Crus deformity was, the earlier and faster the correction should be carried out. Though Chan et al.'s[10] study concluded that successful correction was unrelated to the age at application of the EarWell system, several studies have shown absolutely advantages in early molding in newborns and infants with auricular deformities. Byrd et al.[1] found that only approximately half of the infants had a good response when molding was initiated after 3 weeks from birth. Doft et al.[5] reported initiating molding during the first week of life could reduce the treatment period. In addition, according to Zhao et al.'s[6] observation, the healing rate was only 35.36% for Conchal Crus after 1 month from birth. All of these above supported that early correction of Conchal Crus was reasonable.

However, age at application almost had no effect on conchal morphologic results in our study. That's because only four infants who were treated after 2 months from birth. That brought a selection bias. Though the duration of correction also has no significant effect on conchal morphologic results, there was a minor problem with recorded duration. Some parents gave up conchal correction as soon as they were satisfied with the auricular shape, so the recorded duration of correction was exactly for the auricle but might not be true for the concha.

## 4.3 | Comparison of two conchal formers

In our study, Conchal Crus babies in the Self-made group had more excellent conchal morphologic results than whom in the EarWell group. Doctors who graded the conchal results found that the EarWell conchal former did improved the morphology of conchal fossa, but usually, there was a notch at the midportion of the conchal crus (Figure 4F) and the end of the crus still extended onto or was close to the antihelix. That made the curvatures of crus in the EarWell group look not as natural as those in the Self-made group (Figure 4G). Coincidentally all the pressure ulcers caused by the EarWell conchal former were observed at the same part of the conchal crus. The EarWell conchal former might possibly give an uneven force at the conchal crus because of its U-shaped bottom.

Our self-made conchal former was made of hypoallergenic tape which has been used in nonsurgical correction of auricular deformities for several years. Though nowadays prefabricated ear molds are well-designed and very convenient to use, we choose tape again for conchal correction because the prefabricated conchal former does not match with the conchal fossa sometimes. Zhao et al.[6] indicated that the size of EarWell might not be suitable for Chinese newborns. An improper conchal former not only could not make an excellent conchal fossa but also lead to skin complications easily.

## 4.4 | Importance of conchal correction

Byrd et al.[1] found many infants who had poor outcomes or failures in molding protruding ears had Conchal Crus. Sometimes, the crus was

only seen when the auricle was pushed back to its normal position. We also observed that the Conchal Crus deformity became more obvious when some constricted ears and cryptotia were pushed backwards. In fact, Daniali et al.[7] pointed out that conchal correction played an important role in correcting constricted ears.

The EarWell posterior cradle has a posterior conformer that is positioned into the antihelix to create the superior limb of triangular fossa. This process pulls the auricle backwards and keeps it in overcorrection, resulting in a decreased conchal-mastoid angle and a posterior force on the conchal fossa. However, the conchal correction needs anterior force. In other words, the direction of shaping force for deformities involved the upper third of ear, such as helical and antihelical deformities, is opposite to that for Conchal Crus. The conchal former can just right antagonism the traction of the upper auricle and keep the conchal shape normal.

Matsuo et al.[2] believed that an important point in the nonsurgical correction of congenital auricular deformities was to make an overcorrection to prevent the corrected auricle to return to the previous state when there was a lack of elasticity. In the early neonatal period, if the direction of shaping force is opposite to that is needed for conchal correction, keeping the pliable auricle in overcorrection without additional anterior force on the conchal fossa might result in a more obvious or even an acquired Conchal Crus. In our clinic, a small number of parents who managed the correction procedure themselves at home, complained of a protruding Conchal Crus despite improved auricular shape.

## 4.5 | Limitations

The grouping was not randomized in this study because we just began to use the self-made conchal former after we realized shortcomings of the prefabricated conchal former. Second, there was no quantitative measure to classify the Conchal Crus deformity, so we used a classification made by ourselves. Third, the same as some other studies on ear correction, the judgment on the treatment results was also subjective and not validated. Due to many parents' neglect of Conchal Crus, final conchal morphologic results were only graded by doctors. Fourth, the recommended time window for correction in literature varied from 3 days to 3 months after birth.[1–3,11,12] In our series the median age of babies at application was 16.0 days and only four babies began correction after 2 months from birth. That might bring a selection bias. Conchal correction results of older children remained unknown. Fifth, the self-made conchal former was not conducive to the promotion. Maybe 3D printing technology will be helpful for producing personalized conchal formers in the future.

## 5 | CONCLUSION

Both EarWell and our self-made conchal formers are effective in correction on Conchal Crus. The self-made conchal former could make

the conchal morphology more excellent and lead to less pressure ulcers at the conchal crus.

## CONFLICT OF INTEREST

The authors declare that there is no conflict of interest that could be perceived as prejudicing the impartiality of the research reported.

## ORCID

*Qijuan Zou* https://orcid.org/0000-0002-3656-9077
*Shouqin Zhao* https://orcid.org/0000-0002-6069-9656

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## SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.