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3D Technique-Based Nonsurgical Correction of Deformational Congenital Auricular Deformities

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Keywords

Congenital auricular deformities · Nonsurgical correction · 3D scanning · 3D modeling · 3D designing · 3D printing · Correction bracket

Abstract

Introduction: Congenital auricular deformity (CAD) is a common postpartum deformity, and nonsurgical correction of CAD has been recognized as a safe and effective approach. Three-dimensional (3D) technique has been used in surgical reconstruction of unilateral microtia; however, 3D technique used in nonsurgical correction for deformational CAD has not been reported. ***Methods:*** In this study, 12 CAD patients aged from 0.6 to 7 months with 16 deformational CAD were treated with 3D technique-based personalized nonsurgical correction (3D-NSC). Patients' CAD was photographed pre- and post-correction, and clinical outcome was evaluated as poor, fair, good, and excellent by comparing pre- and post-correction pictures. Different kinds of tests were used to analyze the data. ***Results:*** All patients got an improved auricle shape (10 excellent, 2 good, and 4 fair). Multivariate regression analysis showed that CAD type was significantly associated with correction outcome, sex and age were significantly associated with correction outcome for the 11 constructed types of CAD, and age was significantly associated with the correction outcome when we focused on the male constructed auricles. ***Conclusion:*** 3D-NSC provided a significant nonsurgical clinical treatment for CAD patients, with younger patients getting better clinical outcomes with shorter correction time.

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Introduction

Congenital auricular deformity (CAD) is a common postpartum deformity. A study shows that CAD morbidity within 7 days of birth is 57.46% in southern China,

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with 25.91% of which being unable to self-heal in 30 postnatal days [1]. Induction of CAD could be due to multiple factors like mother's delivery situation, mother's hepatitis history, abnormal pregnancy, abnormal labor, and so on. According to Porter and Tan's research [2], CAD can be classified as malformational and deformational anomalies, which resulted from embryologic maldevelopment and in utero or ex utero deformational forces, respectively.

To date, nonsurgical methods to correct the deformational CAD, like splinting or other methods, are recognized as a safe and effective approach [3–7], and earlier nonsurgical correction can benefit patients better than later [3, 7–9]. However, due to some technique difficulties, such as daily maintenance of correction devices in position and complications, nonsurgical methods like Earwell infant auricle correction system are hampered in utilization [6, 10].

Symmetry and similarity of the left and right auricles play an important role in getting better correction outcome for CAD. Chen et al. [11] reported that his team used three-dimensional (3D) technique in surgical reconstruction of unilateral microtia. By using the 3D technique, a mirror-image framework in high precision of normal auricle implant was produced, thus providing a better symmetry and aesthetic plastic effect. However, 3D technique-based nonsurgical correction (3D-NSC) for the deformational CAD is still not reported.

In this study, we introduced a 3D-NSC method for deformational CAD. Twelve patients with different deformational CAD types were nonsurgically corrected under the help of 3D scanning, modeling, and printing technique. Clinical outcomes, advantage, and disadvantage of the 3D-NSC method was deeply studied.

Materials and Methods

Study Subjects

From September 2015 to June 2018, CAD patients nonsurgically treated with 3D-printed correction brackets (3D-pCB) at Huaihe Hospital of Henan University were enrolled as study subjects. Inclusion criteria included (1) age <12 months, (2) deformational CAD, (3) no other disease, (4) agreement of protectors of patients, and (5) followed-up to the end of treatment. Exclusion

Table 1. Patients with congenital auricular deformities enrolled in study of clinical effects of 3D-printed correction brackets, Kaifeng, China, 2020

Patient No.	Auricle No.	Gender	Age, month	Location	Types	Classification	Correction, weeks	Follow-up, months	Outcome
1	1	Male	7	Left	Constricted	Class III	15	24	Fair
	2	Male	7	Right	Constricted	Class III	15	24	Fair
2	3	Female	6	Left	Stahl		1	36	Excellent
3	4	Female	2	Right	Constricted	Class III	3	24	Good
4	5	Female	0.6	Right	Lop		1	24	Excellent
5	6	Male	1	Left	Constricted	Class II	11	24	Good
	7	Male	1	Right	Constricted	Class II	11	24	Excellent
6	8	Female	1	Left	Lop		1	24	Excellent
7	9	Female	3	Right	Constricted	Class III	4	24	Fair
8	10	Female	4	Right	Constricted	Class III	28	12	Fair
9	11	Male	3	Left	Stahl		6	36	Excellent
10	12	Female	3	Left	Lop		1	7	Excellent
11	13	Male	1	Left	Constricted	Class II	4	6	Excellent
	14	Male	1	Right	Constricted	Class I	4	6	Excellent
12	15	Male	1	Left	Constricted	Class I	1	1	Excellent
	16	Male	1	Right	Constricted	Class II	1	1	Excellent

criteria included (1) age ≥12 months, (2) malformational CAD, (3) having other disease, (4) disagreement of protectors of patients, and (5) failed to follow-up before completion of the treatment. Finally, 12 patients with 16 deformational CAD were enrolled as study subjects (Table 1). The deformational CAD types included constricted auricles, Stahl's auricles, and lop auricles in the present study. Constricted auricles were classified from class I to III as described [12].

The study protocol conformed to ethical guidelines and was approved by the institutional ethics committee of Huaihe Hospital of Henan University.

Methods and Clinical Evaluation

Preparation of 3D-pCB. (1) 3D scanning and modeling: for patients with one-sided CAD auricle, the normal side of auricle was used as correction template and scanned with Einscan-Pro+ scanner (HINING 3D Technology Co., Ltd., Hangzhou, Zhejiang, PR China) under manufacturer's instruction; for patients with two-sided CAD auricles, the temporarily taped corrected auricles on both sides were scanned (normal or corrected auricle modeling was realized with the help of software Geomigic). (2) Designing correction bracket: correction bracket was designed personalized by using software 3-matic based on each CAD auricle. Briefly, normal auricle model worked as reference for the bracket design, then the digital bracket was overlapped with digital normal auricle and was regulated to fit normal auricle best (Fig. 1a). (3) Printing 3D correction bracket: the finally fixed digital correction bracket was printed with 3D printer (Lite 600HD, UnionTech Science and Technology Co., Ltd., Shanghai, PR China) by using photosensitive resin material (UTR9000, Dongguan Aide Polymer Material Technology Co., Ltd., Dongguan, Guangdong, PR China; Fig. 1b).

Equipment of 3D-pCB. 3D-pCB was equipped to the CAD auricle and fixed by desensitized tape. The situation was checked every week, and new personalized brackets were designed and used if it was necessary (Fig. 2).

Evaluation of the Clinical Effect of 3D-pCB. Correction outcome was evaluated by photographic grading as described by Daniali et al. [12]. Briefly, patient's CAD was photographed pre- and post-correction, and clinical outcome resulted from comparing pre- and post-correction pictures, which were independently and blindly evaluated by 2 plastic surgeons; a third plastic surgeon would be introduced blindly when the 2 surgeons disagreed with each other. In evaluation, main weight factors are symmetry and similarity between corrected CAD auricle and the normal auricle. Clinical outcome was graded as poor, fair, good, and excellent, representing no improvement, improved without normal auricle shape, nearly normal auricle shape, and normal auricle shape, re-

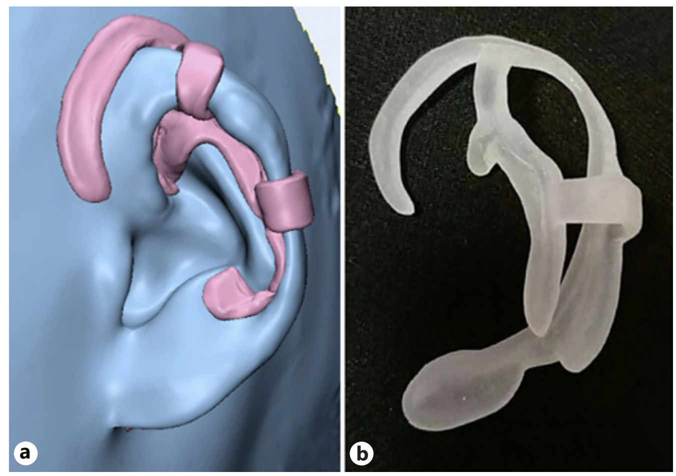

Fig. 1. 3D designing and printing of correction bracket. **a** 3D digital bracket was overlapped and regulated to fit normal auricle model best. **b** 3D correction bracket printed using photosensitive resin.

Fig. 2. A constructed auricle of class III corrected with 3D-pCB for 2 months. **a** Before correction. **b** Auricle equipped with 3D-pCB. **c** After correction for 2 months (outcome = fair).

Table 2. Congenital auricular deformity types, age, correction time, and correction outcomes

Types	Auricles	Age[1], months	Correction time[1], weeks	Outcomes			
				excellent	good	fair	poor
Stahl's auricle	2	4.5 (3–6)	3.5 (1–6)	2	0	0	0
Lop auricle	3	1 (0.6–3)	1 (1–2)	3	0	0	0
Constructed auricle							
Class I	2	1 (1–1)	2.5 (1–4)	2	0	0	0
Class II	4	1 (1–1)	7.5 (1–11)	3	1	0	0
Class III	5	4 (2–4)	15 (1–28)	0	1	4	0
Total	11	1 (1–7)	4 (1–28)	5	2	4	0
Total	16	1.5 (0.6–7)	4 (1–28)	10	2	4	0

[1] Median (min–max).

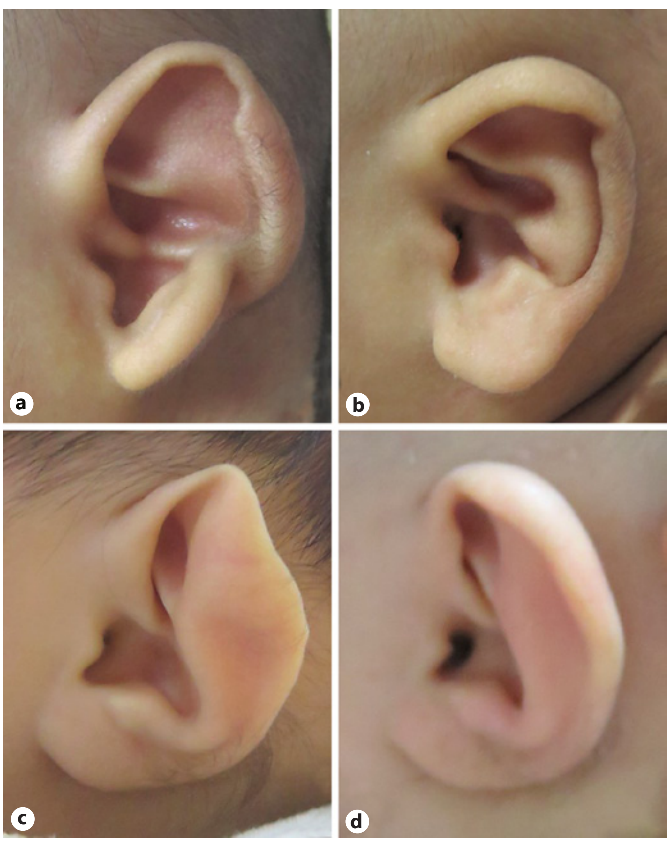

Fig. 3. Examples of clinical correction outcome. Upper row: class II constricted auricle before (**a**) and after (**b**) correction (outcome = excellent). Lower row: Stahl's auricle before (**c**) and after (**d**) correction (outcome = excellent).

spectively. Excellent, good, or fair was treated as clinically responding, and poor as no response.

Data Analysis

The Doornik-Hansen test was used to test normality of the distribution of age and correction time. The Kruskal-Wallis equality-of-populations rank test was used to examine differences of age and correction time among excellent, good, and fair groups of correction outcomes. Multivariate regression analysis was used to observe associations of correction outcomes with sex, age, correction time, and types of CAD in the 11 constructed auricles and the 8 male constructed auricles. A p value <0.05 ($p \leq 0.05$) was considered statistically significant. All tests were two-sided. Data were analyzed using Stata 13.0.

Results

Among the 12 patients of 16 deformational CAD auricles, there were 2 Stahl's auricles, 3 lop auricles, and 11 constricted auricles (2 class I, 4 class II, and 5 class III). The youngest patient was 0.6 months (lop auricle), and the eldest was 7 months (constricted auricle). The overall clinical response rate was 100%, and there were 10 excellent, 2 good, and 4 fair correction outcomes, respectively (Table 2; Fig. 3).

The Doornik-Hansen test showed that neither age (chi-squared = 9.522, $p = 0.009$) nor correction time (chi-squared = 9.342, $p = 0.009$) were normally distributed.

The Kruskal-Wallis equality-of-populations rank test showed that both age ($n = 16$, chi-squared = 6.492, df = 2, $p = 0.039$; Fig. 4) and correction time ($n = 16$, chi-squared = 6.783, df = 2, $p = 0.034$; Fig. 5) were differently distributed among fair, good, and excellent correction groups. Correlation analysis did not show a significant relation-

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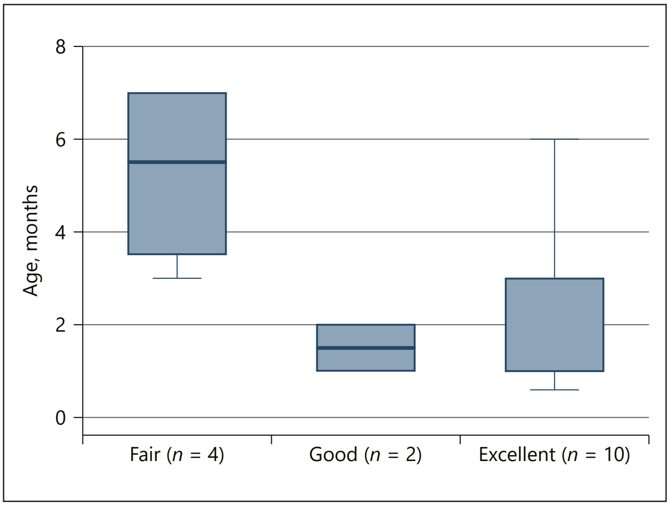

Fig. 4. Distribution of patient age among correction outcomes. Younger patients were significantly distributed in the better correction outcome groups ($n = 16$, chi-squared = 6.492, df = 2, $p = 0.039$). Age of the excellent group was significantly younger than that of the fair group (chi-squared = 6.337, df = 1, $p = 0.012$). Kruskal-Wallis equality-of-populations rank test, two-sided.

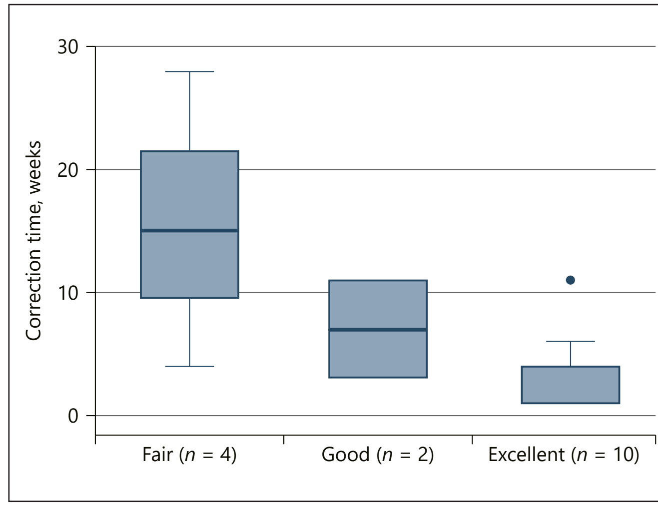

Fig. 5. Correction time of 3D-pCB and correction outcome. Deformational CADs that needed longer correction time were significantly distributed in better correction outcome groups ($n = 16$, chi-squared = 6.783, df = 2, $p = 0.034$). Correction time of the excellent group was significantly shorter than that of the fair group (chi-squared = 6.116, df = 1, $p = 0.013$). Kruskal-Wallis equality-of-populations rank test, two-sided.

ship between age and correction time ($n = 16$, Spearman's rho = 0.395, $p = 0.131$), but among the constructed types of CAD ($n = 11$, Spearman's rho = 0.621, $p = 0.041$).

Multivariate regression analysis of the association of age, correction time, sex, and CAD types showed that CAD type was significantly associated with correction outcome ($n = 16$, coefficient = 0.506, 95% CI 0.030 to 0.982, df = 4, $p = 0.039$). For the 11 constructed types of CAD, sex (coefficient = –0.845, 95% CI –1.462 to –0.227, df = 3, $p = 0.014$) and age (coefficient = –0.284, 95% CI –0.431 to –0.137, df = 3, $p = 0.003$) were significantly associated with correction outcome. When we focused on the male constructed auricles, only age was significantly associated with the correction outcome (coefficient = –0.219, 95% CI –0.393 to 0.045, df = 2, $p = 0.023$).

Discussion

Nonsurgical correction of CAD has been recognized as a safe and effective method now [3–7], and different techniques have been used in clinics. In our study, 12 patients with 16 deformational CAD treated with 3D-NSC totally got improved (excellent, good, and fair) outcomes. Our further analysis demonstrated that the younger to correct the deformational ACD, the better to get the correction outcomes. Together with the potential positive relationship between age and correction time, it is suggested that younger patients should get a better correction outcome with a shorter correction time.

A neonate's cartilage is of better pliability due to higher amount of hyaluronic acid in extra-cellular matrix of cartilage, which is upregulated by higher estrogen received from the mother. With the drop of hyaluronic acid and estrogen after few days of birth, pliability of cartilage will also down-step [13, 14]. This could be the reason for the fact that younger patients had better correction outcomes with shorter correction time. Therefore, awareness about CAD is needed for patient's parents and clinicians, which provides patient opportunities to be corrected at earlier postnatal time to get better clinical outcome.

Our study is the first to use 3D-NSC technique to correct deformational CAD. From our experience, 3D-NSC technique could provide an individualized 3D-pCB, easier daily preservation of auricle shape, and certain clinical outcomes at early postnatal age, and 3D-pCB is easier to be reformed to fit the development of the CAD auricles in case of needing more brackets.

According to our study, stiffness and flexibility both are required to force the deformational CAD auricle to a right position and to fit local cartilage shape. Besides, material softness and surface smoothness are also needed to avoid local skin damage. Flexibility improvement of photosensitive resin used in this study is needed. The only complication during correction was allergy to adhesive tape. After changing to hypoallergenic tape, the complication disappeared.

A shortage of the present study is the small number of subjects, which might diminish statistical powers. Although we have got significant clinical results with small numbers of subjects, we suggest to examine and confirm the present results with more subjects with various CAD types in future studies.

Conclusion

3D-NSC provided a personalized CAD correction selection with certain clinical outcomes. Correction in earlier postnatal age would reach a better clinical outcome with shorter correction time.

Statement of Ethics

The parents or guardians of all patients have given their written informed consent. The study protocol conformed to ethical guidelines of World Medical Association Declaration of Helsinki and was approved by the institutional ethics committee of Huaihe Hospital of Henan University (2015113).

Conflict of Interest Statement

The authors declare that they do not have financial and any other conflict of interest.

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Author Contributions

Yifan Zhu and Yuemin Zhou contributed equally to this work, they acquired the figures and drafted the manuscript; Qiannan Zhao collected the clinical case data and prepared the figures; Yuanyuan Ma was involved in planning the study and revised the article critically; Yuquan Lu and Yuemin Zhou made the conception and design of the study, revised and performed the final approval of the manuscript.

References

1 Zhao H, Ma L, Qi X, Qin J, Yin B, Zhong M, et al. A Morphometric Study of the Newborn Ear and an Analysis of Factors Related to Congenital Auricular Deformities. Plast Reconstr Surg. 2017 Jul;140(1):147–55.

2 Porter CJ, Tan ST. Congenital auricular anomalies: topographic anatomy, embryology, classification, and treatment strategies. Plast Reconstr Surg. 2005 May;115(6):1701–12.

3 Ullmann Y, Blazer S, Ramon Y, Blumenfeld I, Peled IJ. Early nonsurgical correction of congenital auricular deformities. Plast Reconstr Surg. 2002 Mar;109(3):907–13; discussion 914–5.

4 Lindford AJ, Hettiaratchy S, Schonauer F. Postpartum splinting of ear deformities. BMJ. 2007 Feb;334(7589):366–8.

5 Mohammadi AA, Imani MT, Kardeh S, Karami MM, Kherad M. Non-surgical Management of Congenital Auricular Deformities. World J Plast Surg. 2016 May;5(2):139–47.

6 Chang CS, Bartlett SP. A Simplified Nonsurgical Method for the Correction of Neonatal Deformational Auricular Anomalies. Clin Pediatr (Phila). 2017 Feb;56(2):132–9.

7 Chen PW, Li J, Zhao SQ, Yang JS, Dou JM, Wei CY. [The treatment efficiency of a new ear moding device in the infants with congenital ear abnormalities]. Lin Chung Er Bi Yan Hou Tou Jing Wai Ke Za Zhi. 2017 Jun; 31(11):849–53.

8 Yotsuyanagi T. Nonsurgical correction of congenital auricular deformities in children older than early neonates. Plast Reconstr Surg. 2004 Jul;114(1):190–1.

9 Byrd HS, Langevin CJ, Ghidoni LA. Ear molding in newborn infants with auricular deformities. Plast Reconstr Surg. 2010 Oct;126(4): 1191–200.

10 Zhang JL, Li CL, Fu YY, Zhang TY. Newborn ear defomities and their treatment efficiency with Earwell infant ear correction system in China. Int J Pediatr Otorhinolaryngol. 2019 Sep;124:129–33.

11 Chen HY, Ng LS, Chang CS, Lu TC, Chen NH, Chen ZC. Pursuing Mirror Image Reconstruction in Unilateral Microtia: Customizing Auricular Framework by Application of Three-Dimensional Imaging and Three-Dimensional Printing. Plast Reconstr Surg. 2017 Jun;139(6):1433–43.

12 Daniali LN, Rezzadeh K, Shell C, Trovato M, Ha R, Byrd HS. Classification of Newborn Ear Malformations and their Treatment with the EarWell Infant Ear Correction System. Plast Reconstr Surg. 2017 Mar;139(3):681–91.

13 Matsuo K, Hirose T, Tomono T, Iwasawa M, Katohda S, Takahashi N, et al. Nonsurgical correction of congenital auricular deformities in the early neonate: a preliminary report. Plast Reconstr Surg. 1984 Jan;73(1):38–51.

14 van Wijk MP, Breugem CC, Kon M. Non-surgical correction of congenital deformities of the auricle: a systematic review of the literature. J Plast Reconstr Aesthet Surg. 2009 Jun; 62(6):727–36.