



A Novel Noninvasive Treatment for Microtia Using 3D Printing and Cartilage Conduction Technology to Improve Both Aesthetics and Function

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1. Aim

Microtia occurs in approximately 1 in 10,000 people, with 90% of cases being unilateral. Because many cases are associated with atresia, both aesthetic and functional aspects of treatment are required. Auricular reconstruction is a common treatment for the aesthetic aspect, however, there are many cases that are not satisfied with the outcome despite the need for staged surgeries (Fig.1). Regarding the functional aspect, the success rate of hearing improvement surgery is about 40% [1] and sometimes postoperative ear discharge also occurs. Thus, we believe existing treatments for microtia remain problematic. Therefore, we devised the APiCHA (auricular prosthesis incorporating with a cartilage conduction hearing aid), a high-quality auricular prosthesis based on 3D-printing technology, with a cave that can use combination with the CCHA (cartilage conduction hearing aid) (Fig.2). We conducted a prospective clinical study of APiCHA as a noninvasive treatment for microtia and reported the usefulness and safety of the APiCHA.

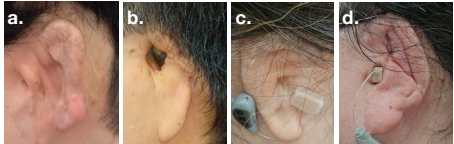


Fig.1 Four representative cases after reconstruction surgery
a. Left ear, b. c. Left ear with canal plasty. These patients need to use hearing aid, d. Right ear. All patients were not satisfied with appearance.

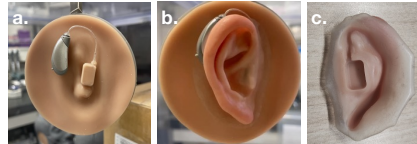


Fig.2 Application of APiCHA in Lab
a. Microtia model with CCHA, b. Microtia model with CCHA and APiCHA, c. Back side of APiCHA. It has a cave of transducer of CCHA.

2. Materials and Methods

Participants

- Nine patients with 11 ears with microtia who were treated with APiCHA from September 2021 to April 2024.
- The median age of the patients was 6 years (5-47 years). 8 patients (9 ears) were children, and 1 patient (2 ears) was an adult.
- None of the children had a history of surgery.
- One adult patient had undergone bilateral auricular reconstruction and canaloplasty in childhood and was not satisfied with both his appearance and hearing.
- The mean hearing threshold (average of 500, 1000, 2000, 4000 Hz) ± SD of the affected ear was 68.1 ± 13.5 dB HL.

Methods

- APiCHA was created by taking a mold of both ears and using 3D image editing technology to invert the data from the healthy ear to the affected ear, creating a groove for the CCHA (Fig.3).
- The effectiveness of the APiCHA was evaluated by aided hearing thresholds and quality of life (QOL) questionnaires* before and after use.
* We used GBI (Glasgow benefit inventory) and SF-36 (Short form 36) for adult, and CGBI (Glasgow children's benefit inventory) for children.
- Subjects were asked to use APiCHA daily and write a diary for 6 months to assess usage and whether there were any side effects, such as dermatitis.

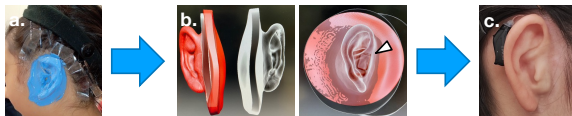
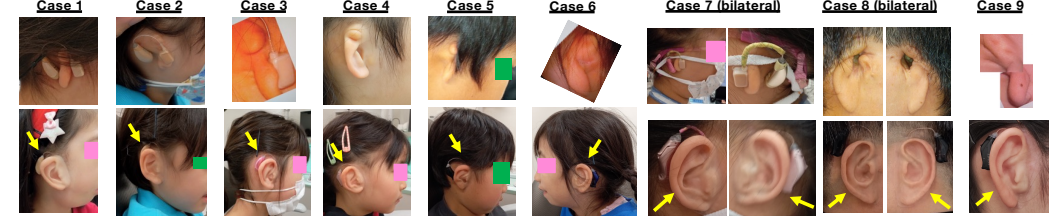


Fig.3 Production process of APiCHA
a. Taking a mold of both ears to obtain those 3D data, b. Create an APiCHA on the affected ear by inverting the data from the healthy ear with a space to store the transducer (arrowhead), c. Creating APiCHA by using a silicon 3D printer and colored it.

3. Results

Appearance of all 11 ears



- One of 11 ears (one patient) did not come after 3 months, but 10 ears were continued to use APiCHA and finished the study.

Hearing outcome

- The mean average hearing thresholds* ± SD for CCHA alone and with APiCHA were 36.8 ± 5.7 and 36.3 ± 4.9 dB HL, respectively, and there was no significant difference (p = 0.89, Fig.4).

* Average of the thresholds at 500, 1000, 2000, and 4000 Hz

QOL outcome and diary analysis

- Quality of life results showed a slightly lower trend with APiCHA, although not significantly different (Table).
- There was no case of adverse effects, however, increased feedback noise was observed in 2 ears, accidental removal in 3 ears, and difficulty in wearing due to aspirations in 5 ears.

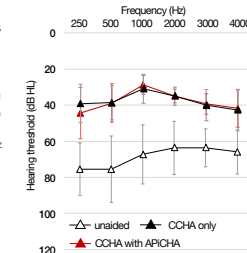


Fig.4 Hearing thresholds of each conditions. Error bars mean SD.

Table. QOL outcome with and without APiCHA

	Score of QOL questionnaire		
	CCHA only	CCHA with APiCHA	
	after 3 month	after 6 month	
Case 1	8.3	14.6	2.1
Case 2	56.25	25	NA
Case 3	2.1	16.7	29.2
Case 4	50	27.1	35.4
Case 5	18.8	-2.1	4.2
Case 6	10.4	16.7	18.8
Case 7	45.8	NA	NA
Case 8	GBI: 65 SF-36: 17.4	GBI: 65 SF-36: 18.4	GBI: 63 SF-36: 16.4
Case 9	18.8	NA	NA
Ave* (SD)	25.3 (21.1)	16.3 (10.3)	17.9 (14.8)

* Averaged only for pediatric cases.

4. Conclusion

- This is the first report on the use of APiCHA as a noninvasive treatment for microtia. APiCHA can improve aesthetics and hearing function through high-quality auricular prosthesis with no functional deterioration compared to CCHA alone.
- We confirmed the safety of APiCHA. However, there are still issues regarding the fixation and solution for perspiration. As a result, the improvement in QOL was limited.
- We are trying several solutions to these issues and will grow the treatment to be more useful for patients with microtia.

5. Références

[1] Nishiyama T., Hayashi S., Oishi N. A novel auricular prosthesis which incorporates a cartilage conduction hearing aid based on 3D data processing technique: a preclinical evaluation. *European archives of otorhino-laryngology* 2022, 279, 3741-3744.