The Efficacy of Unilateral Bone-Anchored Hearing Devices in Chinese Mandarin-Speaking Patients With Bilateral Aural Atresia

Yue Fan, MD; Ying Zhang, MD; Pu Wang, MD; Zhen Wang, MD; Xiaoli Zhu, MD; Hua Yang, MD; Xiaowei Chen, MD

IMPORTANCE The bone-anchored hearing device (BAHD) was not introduced in China until 2010. To our knowledge, this is the first study to assess the efficacy of Chinese Mandarin-speaking patients with bilateral aural atresia.

OBJECTIVE To evaluate the speech recognition of Chinese Mandarin-speaking patients with BAHDs as well as patients’ satisfaction using 2 questionnaires.

DESIGN, SETTING, AND PARTICIPANTS A retrospective case review of 16 patients with bilateral aural atresia conducted at a tertiary referral center.

INTERVENTION A BAHD was implanted during auricle reconstruction surgery or after the auricle was rebuilt. A surgical method to combine the BAHD implantation with the second stage of ear reconstruction was introduced.

MAIN OUTCOMES AND MEASURES Speech audiometry test and mean pure-tone threshold results were compared among patients with unaided hearing and those with BAHDs. Scores from the BAHD user questionnaire and Glasgow Children’s Benefit Inventory (GCBI) were used to measure patients’ satisfaction and subjective health benefit.

RESULTS The mean (SD) speech discrimination scores measured in a sound field with a presentation level of 45 dB HL (hearing level) were 6.7% (7.4%) unaided and 86.5% (4.4%) with a BAHD. Scores with a presentation level of 65 dB HL were 56.5% (7.4%) unaided and 90.1% (3.4%) with a BAHD. The speech reception threshold was 60.6 (7.5) dB HL unaided and 24.7 (5.0) dB HL with a BAHD. The mean (SD) pure-tone threshold of the patients was 61.6 (7.8) dB HL unaided and 23.8 (5.9) dB HL with a BAHD. The BAHD application questionnaire demonstrated excellent patient satisfaction. The mean (SD) benefit score of GCBI was 45.6 (14.4).

CONCLUSIONS AND RELEVANCE For aural atresia, the BAHD has been one of the most reliable methods of auditory rehabilitation. It can improve the patient’s word recognition performance and quality of life. The technique of BAHD implantation combined with auricular reconstruction in a 2-stages-in-1 surgery and the modified incision of patients with reconstructed auricle proved to be safe and effective.

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The incidence of congenital aural atresia has been estimated to be between 1 in 8000 to 10,000 births, and approximately 30% of the patients have bilateral aural atresia. Patients with congenital aural atresia often experience conductive hearing loss with an air-bone gap of 50 to 60 dB due to bony or soft-tissue occlusion. The options to improve their hearing include aural canal and hearing reconstruction (atresiaplasty) and the use of a conventional bone-conducted hearing aid. Benefits of these interventions vary across patients and are difficult to predict for individual patients. In addition, there is a high rate of complications associated with these procedures. The use of a conventional bone-conducted hearing aid is constrained by several physical factors, such as headaches and/or skin irritations at the contact site caused by steady pressure on the mastoid cortex.

A bone-anchored hearing device (BAHD) consists of 2 major parts, a titanium implant and an external sound processor. The processor is attached to the titanium implant by a skin-penetrating abutment. According to a study on the vibratory patterns of bone-conducted sound, sound vibrations from 1 BAHD are transmitted via the skull bone to not only the ipsilateral cochlea. Therefore, a unilateral BAHD should theoretically provide benefits for patients with bilateral atresia.

Bilateral aural atresia is often combined with microtia. In addition to hearing rehabilitation, patients also require auricle reconstructive surgery to improve appearance. For those patients, determining the position of the BAHD implantation is crucial. The position of the screw should prevent the sound processor from getting in the way of the auricular reconstruction. If the sound processor touches the ear rim, it can potentially impair the blood supply to the skin flaps. And this, in turn, may lead to necrosis in the reconstructed ear, producing acoustic feedback as a result. If the BAHD was implanted prior to auricle reconstruction, it is relatively difficult for surgeons to determine the position of the screw, whereas a perfect implantation position could be guaranteed if the BAHD implantation and the auricle reconstruction were performed in a combined operation. For the first time to our knowledge, we combined BAHD implantation with the second stage of auricle construction, the BAHD was implanted at the end of the surgery when the auricle had settled. The primary aim of this study was to describe this new surgical procedure of BAHD implantation.

To date, BAHD has been used in patients with atresia for over 30 years, and more than 100,000 patients have been fitted with BAHDs worldwide. However, the BAHD was not introduced in China until 2010. Unlike Western languages, Chinese Mandarin is a tonal language where 1 toneme is phonetically distinguished from other tonemes only by the tone of the vowel, and each toneme is a lexically distinct variant of the same phoneme. Therefore, tonal differentiation is an important factor affecting speech perception for Mandarin-speaking listeners. Many studies have reported good outcomes for the BAHD for people who speak tonontal languages in many countries. However, to our knowledge, very few studies have investigated how well BAHD users perceive tonal languages. The second aim of this study was to evaluate the speech perception of unilateral BAHD using Zhanghua Mandarin Speech Test Materials (MSTM) and 2 questionnaires in the first 16 Chinese Mandarin-speaking users with bilateral aural atresia at our hospital.

Methods

Patients

This single-center retrospective study was conducted at the Peking Union Medical College Hospital (PUMCH) in Beijing, China. Ethical approval for this study was obtained from the institutional review board of PUMCH.

Sixteen patients ranging in age between 6 and 28 years (mean, 9 years) with bilateral conductive hearing loss due to bilateral atresia participated in this study. There were 13 male and 3 female patients. Fifteen patients had nonsyndromic atresia without other craniofacial malformations and 1 patient had Treacher Collins syndrome. Patients with unilateral atresia, who were younger than 5 years, had an accompanying malformation of the inner ear (sensorineural hearing loss), or had concomitant diagnosed conditions such as cerebral palsy or an intellectual disability were excluded from this study.

These 16 patients received a unilateral BAHD (Baha Insero or BP100 [Cochlear Corp]) at the hospital between June 2010 and December 2012. They used the BAHD soft band for 3 to 12 months (mean, 6.2 months) prior to the BAHD implantation surgery. Patient demographics and clinical data are given in the Table.

Surgical Techniques of Implantation

Of the 16 patients, 8 underwent their unilateral BAHD implantation after the auricle construction completed, while 7 patients had the BAHD implantation combined with the auricle reconstructive surgery. Among these patients, 3 children younger than 7 years required 2 stages for implantation. In the first stage of this 2-stage surgical procedure, a soft-tissue skin expander was implanted in the mastoid region to get enough skin. In the second stage, an autogenous rib cartilage framework was carved to reconstruct the auricle. The fixture was inserted into the mastoid bone at the end of the aural reconstruction, and the abutment was attached to the fixture when making the secondary revision of the auricle reconstructions 4 to 6 months later. If a patient with bilateral microtia had a BAHD implanted by the time of ear reconstruction surgery, the BAHD implantation should be performed at the same time as the second stage of ear reconstruction. Another point worth noting is that there should be at least 5.5 cm from the position of the screw posterosuperiorly to the assumptive ear canal site. The patient with Treacher Collins syndrome with grade II microtia did not wish to have plastic surgery. She only had the unilateral BAHD implantation. The sound processor was fitted 3 months after surgery.

Follow-up was arranged every 4 to 6 months once the BAHD site had healed. The degree of soft-tissue reactions was classified according to the classification by Holgers et al (grades 0, no irritation; 1, slight redness; 2, red and moist tissue; 3, granulation tissue; and 4, infection leading to removal of abutment).
Speech perception tests were conducted in a sound field using the Zhanghua MSTM. The monosyllabic test and the disyllabic test both consist of 10 lists, each with 50 Chinese characters or spondaic words. A monosyllabic test list was used to measure unaided speech discrimination scores (SDSs). Speech stimuli were presented at both 45 dB HL (hearing level) and 65 dB HL. A disyllabic test was used to measure speech reception threshold (50% speech perception in a quiet environment [SRT 50%]). All test materials were presented 1 time (without repeat). Sound field pure-tone audiometry (PTA) was conducted for all patients at 500, 1000, 2000, and 4000 Hz in both an unaided and BAHD-aided condition.

All patients received preoperative temporal bone high-resolution computed tomography to evaluate temporal bone thickness and middle ear structure. Patients were graded using the Jahrsdoerfer grading scale. According to Jahrsdoerfer criteria, 10 patients who scored less than 6 points with both ears were considered to be poor candidates for hearing reconstruction. Therefore, atresiaplasty was not performed.

### Table. Demographics and Clinical Data of Patients

<table>
<thead>
<tr>
<th>Patient No./Sex/Age, y</th>
<th>Degree of Auricular Dysplasias (R/L Ear)*</th>
<th>Syndrome</th>
<th>Surgery Performed Before BAHD Implantation</th>
<th>No. of Stages for BAHD Surgery</th>
<th>Unaided AC Threshold, dB HL</th>
<th>AC Threshold With BAHD, dB HL</th>
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<tr>
<td>1/M/15</td>
<td>III/I</td>
<td>None</td>
<td>R auricle reconstruction + R atresiaplasty</td>
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<td>47.5</td>
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<td>18.75</td>
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<td>None</td>
<td>Two-stage (combining auricle reconstruction)</td>
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<td>L auricle reconstruction</td>
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<td>65</td>
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</tr>
<tr>
<td>6/M/10</td>
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<td>None</td>
<td>Single (combining auricle reconstruction)</td>
<td>62.5</td>
<td>32.5</td>
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<tr>
<td>7/F/18</td>
<td>II/II</td>
<td>Treacher Collins</td>
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<td>Single</td>
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<td>III/III</td>
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<td>60</td>
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<tr>
<td>12/M/7</td>
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<td>None</td>
<td>Two-stage (combining auricle reconstruction)</td>
<td>47.5</td>
<td>18.75</td>
</tr>
<tr>
<td>13/M/11</td>
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<td>R auricle reconstruction + R atresiaplasty</td>
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<td>57.5</td>
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<td>14/M/13</td>
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<td>R auricle reconstruction + R atresiaplasty</td>
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<td>Single</td>
<td>72.5</td>
<td>31.25</td>
</tr>
</tbody>
</table>

Abbreviations: AC, air conduction; BAHD, bone-anchored hearing device; HL, hearing level; L, left; R, right.

*Age at the time of BAHD implantation.

*Degrees of auricular dysplasias were evaluated according to the classification by Weerda.6

### Audiological Evaluation and Imaging Evaluation

Speech perception tests were conducted in a sound field using the Zhanghua MSTM. The monosyllabic test and the disyllabic test both consist of 10 lists, each with 50 Chinese characters or spondaic words. A monosyllabic test list was used to measure unaided speech discrimination scores (SDSs). Speech stimuli were presented at both 45 dB HL (hearing level) and 65 dB HL. A disyllabic test was used to measure speech reception threshold (50% speech perception in a quiet environment [SRT 50%]). All test materials were presented 1 time (without repeat). Sound field pure-tone audiometry (PTA) was conducted for all patients at 500, 1000, 2000, and 4000 Hz in both an unaided and BAHD-aided condition.

All patients received preoperative temporal bone high-resolution computed tomography to evaluate temporal bone thickness and middle ear structure. Patients were graded using the Jahrsdoerfer grading scale. According to Jahrsdoerfer criteria, 10 patients who scored less than 6 points with both ears were considered to be poor candidates for hearing reconstruction. Therefore, atresiaplasty was not performed.

### Statistical Analysis

All data were analyzed using SPSS (version 17.0; IBM Corp). Continuous variables are presented as mean (SD). Paired t tests with Bonferroni corrections were used to determine the differences with and without a unilateral BAHD. \( P < .01 \) was considered statistically significant.

### Questionnaires

Two questionnaires were administered via either a face-to-face or a telephone interview. One was the “Daily Use of BAHD” questionnaire, which assesses daily use. It was adapted from the Nobel Biocare (Zurich, Switzerland) questionnaire and translated into Chinese by 2 of the authors (Y.F. and Y.Z.). The revised questionnaire consisted of 17 questions, including the amount of daily use, sound localization ability, and presence or absence of complications. Twelve patients younger than 18 years were also assessed with the Glasgow Children’s Benefit Inventory (GCBI) questionnaire, which were translated into Chinese by the same authors.

### Results

#### Surgical Results

For 7 patients, the surgery for BAHD implantation and the auricle reconstruction were done in one combined operation. Eight patients who already had reconstructed auricles completed their BAHD implantation with the conventional surgical method.
No major complications such as traumatic extrusion or skin necrosis were reported. Two cases of grade 2 soft-tissue reactions that were manifested by mild skin inflammation and effusion around the abutment were encountered, and full recovery was achieved with the administration of anerdian and ethanol. The 2 patients healed without further operation.

**Audiological Improvement**

The mean (SD) unaided SDS evaluated by the monosyllabic test (presentation level, 45 dB HL) was 6.7% (7.4%). With the unilateral BAHD, the mean (SD) score was 86.5% (4.4%). This gain of 80.3% (6.6%) was statistically significant ($t = 47.4; P < .001$). When the presentation level was 65 dB HL, the mean (SD) scores were 56.5% (7.4%) unaided and 90.1% (3.4%) with a unilateral BAHD, giving an improvement of 33.6% (7.4%) ($t = 18.2; P < .001$) (Figure 1). The mean (SD) SRT 50% values with and without a BAHD were 24.7 (5.0) dB HL and 60.6 (7.5) dB HL, respectively. The mean (SD) difference in SRT 50% was 36.0 (7.4) dB, which was statistically significant ($t = 19.5; P < .001$).

For patients with unaided hearing, the mean (SD) preoperative sound field threshold was 61.6 (7.8) dB HL. The mean (SD) postoperative sound field threshold was significantly better for those with BAHDs ($t = 32.9; P < .001$). This gave a mean (SD) hearing improvement of 37.7 (4.6) dB. Mean hearing thresholds with and without a BAHD for each patient are shown in Figure 2.

**Questionnaires**

Sixteen patients answered the daily use questionnaire, and 12 pediatric patients took the GCBI. Patients who were younger than 10 years completed the questionnaires with their parents’ help.

**“Daily Use of BAHD” Questionnaire**

Fourteen patients (88%) wore their BAHD for more than 8 hours per day, and 2 patients (13%) wore their BAHD between 4 and 8 hours per day. A mean satisfaction score of 7.5 indicated an improvement in quality of life. All patients found that it was easy for them to place the sound processor or adjust the volume by themselves. The mean aesthetic score of wearing a BAHD soft band was 5.8. The score increased to 8.4 with a BAHD. Sound localization improved significantly for all the patients, with a mean score of 8.5. However, 5 patients found it difficult to localize the source of sound in a noisy background. Fifteen patients reported a significant improvement (mean score of 7.4) when listening to music, radio, or television. It should be noted that these observations are based on answers to questions posed to the patients in the questionnaires. No sound localization test was included in this study.

**Glasgow Children’s Benefit Inventory**

The GCBI was composed of 24 questions with 5 possible answers for each; a score ranged from −2 (a maximum change for the worse) to +2 (a maximum change for the better). The total score was divided by the number of questions and then multiplied by 50, thus yielding a final score ranging between −100 (maximum change for the worst harm) and +100 (maximum change for the best benefit). The final score was positive with all patients, with a mean (SD) value of 45.6 (14.4).

**Discussion**

**BAHD Instead of Atresioplasty for Bilateral Atresia**

For Chinese patients with congenital aural atresia, atresioplasty had been the most common method for improving their hearing up until 2010. It is one of the more challenging surgical procedures in otology owing to abnormal anatomies. The Jahrsdoerfer grading system has been used to select candidates for atresioplasty. Patients with a Jahrsdoerfer score
higher than 6 are recommended to have the surgery. For patients not suitable for atresiaplasty or with nonoptimal atresiaplasty, a BAHD could be a good intervention option. In this study, 6 patients who had a unilateral atresiaplasties experi-
enced canal stenosis within 3 months after the surgery. They were unwilling to undergo revision surgery for aural canal re-
construction but accepted BAHD implantation. The other 10 pa-
tients who scored less than 6 points for both ears did not have atresiaplasties. The overall mean (SD) improvement of hear-
ing was 38.3 (8.1) dB in these 16 patients.

**Modified BAHD Surgery to Prevent Complications**

In this study, 7 implantations were performed in combina-
tion with the second stage of auricle construction. The BAHD im-
plantation was performed at the end of the surgery when the a-
uricle had settled. This eliminated the necessity to make an 
aditional incision for the BAHD implantation. For some pe-
diatric patients, a 2-stage implantation may be a good choice 
because the thinner and less dense skull bone requires a pe-
riod of 4 to 6 months for osseointegration of the fixture to oc-
cur. In this study, 3 patients younger than 7 years underwent 
the 2-stage implantation. In the second stage of BAHD im-
plantation, the abutment was attached and revisions of the au-
uricle reconstructions were also made at the same time.

Because a foreign body has been placed in the bone and 
through the skin, local skin reactions are possible. In the litera-
ture, the rates go from 5% to 7.5% for skin infections. In this study, 
there were 2 cases of mild skin infection, judged as grade 2 ac-
cording to the classification by Holgers et al.7 Sufficient reduc-
tion of subcutaneous tissue may help prevent complications, such 
as cutaneous overgrowth. Approximately 4 × 6 cm of the sub-
cutaneous tissue around the planned implantation site was fully 
resected in every patient. Obviously, an emphasis on hygiene also 
contributed to the good surgical result. No traumatic losses of fix-
ture and failure of osseointegration have occurred for any patient.

**Speech Recognition of Chinese Mandarin-Speaking Patients**

**Comparable to English-Speaking Patients**

Mandarin Chinese is a lexical tone language that has 4 tones 
distinguished by syllable-level variations in the level and/or con-
tour of the fundamental frequency (F0), including tone 1 (high 
level), tone 2 (high rising), tone 3 (falling rising), and tone 4 (high 
falling).14 A subtle difference in tone, produced by varying the 
frequency pattern during a single vowel, may completely 
change the meaning of a Mandarin word. The difference be-
tween English and Chinese raises a question about whether the 
speech understanding for Chinese Mandarin-speaking pa-
tients using a BAHD are comparable to those of patients who 
are native speakers of English. To our knowledge, this is the first 
study to assess the speech perception of patients with a BAHD who 
are native speaker of Mandarin Chinese.

To evaluate patients’ performance for different listening 
situations, we measured SDS at 2 presentation levels. Our re-
results showed that SDS measured at a presentation level of 65 
dB HL was 90.1% (3.4%), which is almost as good as those mea-
sured from normal hearing. For patients with BAHDs in this 
study, the mean (SD) SRT 50% was 24.7 (5.0) dB HL. Previous 
studies reported that the average recognition for speech in a

**Increased General Benefit and Good Quality of Life**

**With BAHD**

The subjective evaluation provided another perspective of the 
advantages of the BAHD in the treatment of patients with bilat-
eral atresia. According to the results of the “Daily Use of BAHD” 
questionnaire, the overall satisfaction score was 7.5 in our study. 
It was lower than the score reported by Fuchsmann et al,3 which 
was 8.7 on average. This difference may in part be because Chi-
inese patients are likely to be more conservative when self-rating. 
An important outcome in the efficacy evaluation of the BAHD 
is the duration of daily use of the device.3 Fourteen patients (88%) 
wore their BAHDs for more than 8 hours per day, close to what 
is reported in the literature, with a mean time of use higher than 
8 hours per day for 75% of the patients.15

All the patients reported that the fitted BAHD remarkably 
Improved their communication both in a quiet and a noisy en-
vironment. Five patients (31%) reported difficulties, es-
specially with sound localization and speech understanding in a 
noisy background. This may be due to the disadvantage of uni-
lateral hearing, even though the BAHD theoretically could 
stimulate both cochleae. Nevertheless, several studies in adults 
and children fitted with bilateral BAHDs showed improve-
ment in binaural hearing tasks.16-18

The GCBI described by Kubba et al19 in 2004 is a subjec-
tive child-orientated postintervention questionnaire de-
veloped to evaluate outcomes of pediatric otorhinolaryngologic 
surgery and therapy. In terms of quality of life, assessment 
using the GCBI showed a high satisfaction of BAHD with all the 
patients in our study. The mean (SD) score was 45.6 (14.4), 
which is consistent with other reports.10,19

The shortcoming of the questionnaires was that they were 
not normed and validated Chinese versions, so the reliability 
of the results may be poorer than the original. We aim to es-

**Conclusions**

We found that patients with bilateral atresia are suitable for 
BAHD implantation. The surgical method of combining 
BAHD implantation with the second stage of ear reconstruction 
helps in the screw positioning and can spare an additional 
aesthetic administration for the patients. The auditory and subjective evaluations of unilateral BAHD use are encouraging. Our findings are consistent with the published outcomes from other countries and languages. We believe that an intervention with BAHD can be an option for patients with atresia in China.
ARTICLE INFORMATION
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Author Contributions: Dr Chen had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Study concept and design: Fan, Chen.
Acquisition of data: Fan, Zhang, Z. Wang, Yang, Chen.
Analysis and interpretation of data: Fan, Zhang, P. Wang, Zhu, Chen.
Drafting of the manuscript: Fan, Zhang, P. Wang, Z. Wang, Yang, Chen.
Critical revision of the manuscript for important intellectual content: Fan, P. Wang, Z. Wang, Zhu, Yang, Chen.
Administrative, technical, and material support: Chen.
Study supervision: Chen.

Conflict of Interest Disclosures: None reported.
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Additional Contributions: Dengge Ma at the Beijing Second Language Institute and K. J. Lee at the Southern New England Ear, Nose, Throat & Facial Plastic Surgery Group assisted in providing an English language review.

Additional Information: Dr Chen completed the BAHD implantations in this study as a head surgeon. Drs Fan, Zhang, P. Wang, Z. Wang, Zhu, and Hua participated in some of the surgical procedures as assistants.

REFERENCES