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# Hearing improvement with softband and implanted bone-anchored hearing devices and modified implantation surgery in patients with bilateral microtia-atresia



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## ABSTRACT

**Objective:** To evaluate auditory development and hearing improvement in patients with bilateral microtia-atresia using softband and implanted bone-anchored hearing devices and to modify the implantation surgery. **Methods:** The subjects were divided into two groups: the softband group (40 infants, 3 months to 2 years old, Ponto softband) and the implanted group (6 patients, 6–28 years old, Ponto). The Infant-Toddler Meaning Auditory Integration Scale was used conducted to evaluate auditory development at baseline and after 3, 6, 12, and 24 months, and visual reinforcement audiometry was used to assess the auditory threshold in the softband group. In the implanted group, bone-anchored hearing devices were implanted combined with the auricular reconstruction surgery, and high-resolution CT was used to assess the deformity preoperatively. Auditory threshold and speech discrimination scores of the patients with implants were measured under the unaided, softband, and implanted conditions.

**Results:** Total Infant-Toddler Meaning Auditory Integration Scale scores in the softband group improved significantly and approached normal levels. The average visual reinforcement audiometry values under the unaided and softband conditions were  $76.75 \pm 6.05$  dB HL and  $32.25 \pm 6.20$  dB HL ( $P < 0.01$ ), respectively. In the implanted group, the auditory thresholds under the unaided, softband, and implanted conditions were  $59.17 \pm 3.76$  dB HL,  $32.5 \pm 2.74$  dB HL, and  $17.5 \pm 5.24$  dB HL ( $P < 0.01$ ), respectively. The respective speech discrimination scores were  $23.33 \pm 14.72\%$ ,  $77.17 \pm 6.46\%$ , and  $96.50 \pm 2.66\%$  ( $P < 0.01$ ).

**Conclusions:** Using softband bone-anchored hearing devices is effective for auditory development and hearing improvement in infants with bilateral microtia-atresia. Wearing softband bone-anchored hearing devices before auricle reconstruction and combining bone-anchored hearing device implantation with auricular reconstruction surgery may be the optimal clinical choice for these patients, and results in more significant hearing improvement and minimal surgical and anesthetic injury.

## 1. Introduction

Congenital microtia-atresia results from developmental defects of the auricle and is generally associated with malformations of the external auditory canal and the middle ear. The incidence of congenital microtia-atresia is estimated to be between 0.81 in 10,000 and 3.06 in 20,000 live births in China [1]. Approximately 10% of patients with congenital microtia-atresia have the condition in both ears. Patients with congenital microtia-atresia often experience conductive hearing loss with an air-bone gap of 50–60 dB due to bony or soft-tissue occlusion [2].

The first two years of life are critical in language acquisition. During

this period, hearing ability is crucial in learning spoken language. There is growing evidence that the absence of sound and language access leads to cognitive delay, mental health difficulties, a higher possibility of traumatic accidents, and limited literacy [3]. Early intervention for children with hearing impairment is thus essential. Patients with microtia-atresia have lower self-esteem and social dysfunction [4], and require hearing rehabilitation and auricular reconstruction surgery to improve their appearance.

Until now, the use of bone-anchored hearing devices has been one of the most reliable methods for auditory rehabilitation [5,6]. Softband bone-anchored hearing devices fix the processor around the head via a soft band. Sound is thus transmitted directly by the skull bone to the

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inner ear. Implanted bone-anchored hearing devices transmit sound using a titanium implant, which couples the vibration transducer to the skull bone via a skin-penetrating abutment [7]. Operation timing and the position of implanted bone-anchored hearing devices are crucial.

Our group has previously studied hearing improvement following the use of softband and implanted bone-anchored hearing devices in patients with bilateral microtia-atresia [8]. We have also recommended the early use of softband bone-anchored hearing devices in infants with bilateral microtia-atresia [9]. The growth curve describing auditory development in infants with bilateral microtia-atresia using softband bone-anchored hearing devices is yet unknown. Choosing the operation time and implantation position are also major challenges for surgeons. Here we aimed to evaluate the auditory development of Mandarin-speaking children with bilateral microtia-atresia using the Ponto softband by following up 40 infants over two years. We also aimed to modify the implantation surgery by combining it with auricle reconstruction.

## 2. Methods

### 2.1. Subjects

This single center retrospective study included 46 patients with bilateral microtia-atresia who were enrolled at Peking Union Medical College Hospital in Beijing, China, from January 1, 2014, to April 30, 2016. The study subjects comprised 40 infants (aged 3 months to 2 years) and 6 patients with implants (aged 6–28 years). Ethical approval for this study was obtained from the Institutional Review Board of Peking Union Medical College Hospital. Parents of all patients in the study provided written informed consent for the use of soft-band and implanted bone-anchored hearing devices and the tests.

#### 2.1.1. Softband group

The softband group consisted of 40 infants with bilateral microtia-atresia comprising 23 boys and 17 girls ranging in age from 3 months to 2 years (average age,  $8.45 \pm 5.67$  months; median age, 7 months), wearing Ponto softband (Ponto pro, made by Oticon). All 40 patients were classified as grade III according to the Marx classification of the severity of deformity and bilateral aural atresia [10]. The average bone conduction threshold of the deformed ear, as assessed using the auditory brainstem response, was  $18.13 \pm 4.84$  dB nHL (range, 0–25 dB nHL) and the average air conduction threshold was  $76.38 \pm 4.53$  dB nHL (range, 70–85 dB nHL).

#### 2.1.2. Implanted group

Six patients aged 6–28 years (average age,  $15.17 \pm 10.00$  years) received Ponto (Ponto, made by Oticon) implantation surgery between May 2015 and December 2016 after using the Ponto softband (Ponto pro, made by Oticon) for 3–12 months (mean, 6 months). All 6 patients, who were male, were classified as grade III according to the Marx classification of the severity of deformity and bilateral aural atresia [10]. The average bone conduction threshold of the deformed ear, as assessed using pure tone audiometry, was  $17.50 \pm 2.74$  dB HL (range, 0–20 dB HL), and the average air conduction threshold was  $76.67 \pm 5.16$  dB HL (range, 70–85 dB HL) for tones between 250 and 8000 Hz. One patient had undergone auricle reconstruction surgery in 1992 in another hospital. This patient underwent bilateral bone-anchored hearing device implantation.

### 2.2. Main outcome measures

#### 2.2.1. Softband group

Auditory and speech development of infants were mainly assessed using the translated Chinese version of the Infant-Toddler Meaningful Auditory Integration Scale. The Infant-Toddler Meaningful Auditory Integration Scale is a structured parent interview questionnaire that

includes 10 items grouped into 3 domains: vocalization behavior (items 1 and 2), alerting to sounds (items 3–6), and deriving meaning from sound (items 7–10). Each question has five different response alternatives: 0 = never, 1 = rarely, 2 = occasionally, 3 = frequently, and 4 = always [11]. The Infant-Toddler Meaningful Auditory Integration Scale was used to evaluate auditory development at baseline (0 months), and 6, 12, and 24 months after wearing the Ponto softband. Visual reinforcement audiometry was used to assess the auditory threshold after wearing the Ponto softband for 6 months under unaided and aided conditions.

#### 2.2.2. Implanted group

##### 2.2.2.1. Imaging evaluation and modified implantation surgery.

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

In the first stage of auricular reconstruction surgery, a soft-tissue skin expander was implanted in the mastoid region to enable us to obtain a sufficient amount of skin. In the second stage, an autogenous rib cartilage framework was carved to reconstruct the auricle. The third stage comprised the second revision of the auricular reconstruction. Ponto implantation was performed during the auricular reconstructive surgery, especially the second stage. In patients who had undergone the second stage of surgery, we were able to combine Ponto implantation with the third stage. In patients who required 2-stage implantation, the titanium implant was inserted into the mastoid bone at the end of the soft-tissue skin expander or the auricle reconstruction surgeries. The abutment was attached to the titanium screw during the next stage of auricle reconstructions, which was performed 4–6 months later.

##### 2.2.2.2. Audiological evaluation.

Sound field pure-tone audiometry was conducted for all patients at 250, 500, 1,000, 2,000, 4,000, and 8000 Hz under unaided, softband-aided, and implantation-aided conditions. The speech perception tests were conducted in a sound field using the Mandarin speech test system [12]. A bisyllabic test list was used to obtain speech discrimination scores under the unaided, softband, and Ponto-implanted conditions. All test materials were presented twice. The average score was used in the final analysis.

### 2.3. Statistical analysis

All data were analyzed using SPSS (version 19.0, IBM Corp.). Continuous variables are presented as mean  $\pm$  SD. Infant-Toddler Meaningful Auditory Integration Scale scores were compared to normal scores for this scale [11]. Repeated measures ANOVAs with Greenhouse-Geisser corrections were used to assess differences between the standard and softband-aided Infant-Toddler Meaningful Auditory Integration Scale scores. Paired t tests were used to assess the differences between patients with and without Ponto softbands in the softband group. ANOVAs were used to assess differences among the unaided, softband-aided, and implant-aided conditions in the implanted group. P values < 0.01 were considered statistically significant.

## 3. Results

### 3.1. Auditory development in infants using Ponto softbands

The Infant-Toddler Meaningful Auditory Integration Scale scores of the 40 children in the softband group were assessed at baseline (0 month), and 3, 6, 12, and 24 months after baseline. The mean follow-up time was  $21.9 \pm 4.6$  months. 17.5% of the patients were lost to follow-up. The patients wore the devices for an average of  $6.57 \pm 1.22$  h per

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