The Effects of Age at Cleft Palate Repair on Middle Ear Function and Hearing Level

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Abstract
Objective: To investigate the age effects of cleft palate repair on middle ear function and hearing level in patients who underwent cleft palate repair at different ages by audiologic examination.

Methods: Medical histories were gathered in detail, and audiologic tests (ie, tympanometry and pure tone hearing threshold) were conducted in 126 patients after palatoplasty. The patients were divided into the following 4 groups according to their ages when they underwent cleft palate repair: group I (0-3 years, 73 patients), group II (4-7 years, 29 patients), group III (8-11 years, 16 patients), and group IV (12 years and older, 8 patients). The data regarding tympanograms, hearing levels, and the average hearing thresholds of each group were analyzed using chi-square tests.

Results: The prevalence of middle ear dysfunction and hearing loss in the patients who underwent palatoplasty before 3 years old (27.4% and 2.0% respectively) was significantly lower than that in patients who underwent palatoplasty at 12 years or older (75.0% and 43.7%, respectively). Linear-by-linear association revealed that the prevalences of middle ear dysfunction and hearing loss among the 4 groups were significantly different ($P < .05$).

Conclusions: The prevalence of middle ear dysfunction and hearing loss tended to increase with advancing age at the time of cleft palate repair. From an audiologist’s perspective, palatoplasty at an early age is very beneficial in helping children with cleft palates acquire better middle ear function and hearing level.

Keywords
cleft palate, cleft palate repair age, middle ear function, hearing

Introduction
Patients born with a cleft palate are at a high risk of developing otitis media with effusion (OME) and conductive hearing loss during infancy and early childhood (Jack, 1975; Yules, 1970), and middle ear inflammation is present in almost all infants younger than 2 years with unrepaired cleft palates (Jack, 1975). The primary factor that causes middle ear effusion is eustachian tube dysfunction (Broen et al., 1996; Skuladottir et al., 2015). However, controversy still exists regarding whether early cleft palate repair can improve the listening level of patients with cleft palate. The middle ear function and hearing level of patients with cleft palates can be improved after palatoplasty because of functional reconstruction of the palatal muscles and eustachian tubes (Yules, 1970; Carroll et al., 2013). More than 70% of patients exhibit normal hearing after cleft palate repair, and the earlier cleft palate surgery is performed, the less the children’s language and hearing development are affected (Polzer et al., 2006; Too-chung, 1983). In contrast, some studies have demonstrated that simple cleft palate repair cannot directly improve the eustachian tube function and restore hearing because middle ear function is...
related to a variety of factors (Kuo et al., 2013; Tiwari et al., 2013). Early myringotomy with grommet insertion has been proposed for those cleft palate patients with middle ear effusion (He et al., 2001).

As mentioned above, controversy remains regarding the benefits of palatoplasty for middle ear function and hearing level. The objective of this study was to investigate the differences in postoperative middle ear function and hearing level between groups that underwent cleft palate repair at different ages.

**Materials and Methods**

**Participants**

One hundred twenty-six patients (81 male, 45 female) with cleft palates from 6 to 31 years old (mean age of 13 years 5 months) were recruited from all cleft palate patients who had been treated in the Cleft Lip and Palate Center of Peking University School and Hospital of Stomatology from July 2011 to September 2012. All of the participants underwent palatoplasty surgeries that were performed by 2 experienced surgeons in our center using a single technique termed the modified Langenbeck’s technique. In the operations, we performed regular Kriens intravelar veloplasty (we began performing Sommerald radical IVV procedures in 2013). Early myringotomy with grommet insertion has been proposed for those cleft palate patients with middle ear effusion (He et al., 2001).

The entire procedure was conducted in a quiet research room, and the background noise was no more than 35 dB. All peripheral hearing assessments were performed by a well-trained PhD student from the department of speech and hearing at Hong Kong University.

**Measures**

**Tympanogram.** According to the Jerger (1980) taxonomy, tympanograms can be categorized into 3 types—A, B, and C. Type A tympanograms, are characterized by a clear peak maximum at or near 0 daPa with the negative pressure in the middle ear not equal or exceeding –100 daPa. Type A represents a normal tympanogram and indicates normal middle ear function. Type B and Type C are abnormal tympanograms and indicate middle ear dysfunction.

**Pure tone hearing threshold.** To be considered to have normal hearing, the subjects’ pure tone audiometric air-conduction threshold levels were required to be 25 dB HL or less at the average of 4 frequencies (0.5, 1, 2, and 4 kHz) in both ears. These frequencies are considered to reflect the main speech frequencies in real life according to the documents published by WHO in 1991 (Han and Xu, 2004). Hearing loss has occurred once the pure tone hearing threshold is over 25 dB HL. Hearing loss was classified into the following 5 grades:

1. Mild hearing loss: 26–40 dB HL;
3. Moderate severe hearing loss: 56–70 dB HL;
4. Severe hearing loss: 71–90 dB HL;
5. Profound hearing loss: ≥91 dB HL.

**Procedures**

Each external auditory canal and tympanic membrane was examined by electric otoscopy to ensure that the audiologic examinations could be appropriately performed. A diagnostic otoscope, that is, a SA 204 Diagnostic Audiometer (Entomed, Malmo, Sweden) and a GSI 39 Automatic Tympanometry middle ear analyzer (GSI Corp, Inwood, NY), were utilized to assess peripheral hearing. First, the otoscope was used to visually detect any ear canal and/or tympanic membrane pathologies. The external ear canal had to be unobstructed, and cerumen impaction was removed before testing. Second, the automatic Tympanometry Middle Ear Analyzer (GSI Corp) was used to test both ears of each participant, and the tympanograms of each ear were recorded. Furthermore, the SA 204 Diagnostic Audiometer (Entomed) was applied to test both ears of each participant, and the air-conduction average thresholds at different frequencies (0.5 Hz, 1 kHz, 2 kHz, and 4 kHz) were recorded for each ear.

**Statistical analysis**

Database development and statistical analysis were performed with the Statistical Package for the Social Sciences (SPSS) version 13.0 for Windows. The prevalences of middle ear dysfunction and hearing loss were compared between the 4 groups using chi-square tests.
Results

Middle ear function

Based on the results of the tympanogram test, middle ear dysfunction was found in 40 ears in group I (40/146, 27.4%), 28 ears in group II (28/58, 48.3%), 13 ears in group III (13/32, 40.6%), and 12 ears in group IV (12/16, 75.0%); Table 1).

In our study, the patients who underwent cleft palate repair before the age of 3 years (group I) exhibited the lowest prevalence of middle ear dysfunction, and those who underwent cleft palate repair after age 12 years (group IV) presented with the highest prevalence. Linear-by-linear association revealed that the prevalences of middle ear dysfunction in the 4 groups were significantly different ($\chi^2 = 19.051, P < .05$). This finding implied that the prevalence of middle ear dysfunction tended to increase with advancing age at the time of cleft palate repair.

Hearing Level

In this study, abnormal hearing levels were found in 2.0% (3/146) of group I, 12.1% (7/58) of group II, 37.5% (12/32) of group III, and 43.7% (7/16) of group IV (Table 2). Based on the above data, the group of 0-3-year-olds exhibited the lowest prevalence of abnormal hearing levels, and the group of 12 years and older exhibited the highest prevalence. In other words, as the age of cleft palate repair increased, the incidence of abnormal hearing increased.

Average hearing threshold

The average hearing thresholds were 10.77 ± 6.13 dB in the group I, 16.16 ± 10.39 dB in group II, 22.13 ± 13.31 dB in group III, and 26.64 ± 16.61 dB in group IV. Group I (0-3 years) exhibited the lowest hearing threshold, and group IV (12 years and older) exhibited the highest. These findings implied that the hearing threshold in cleft palate patients tended to increase as the age at the time of cleft palate repair increased (Table 3 and Figure 1).

Discussion

This study demonstrated that the patients who underwent palatoplasty at age 12 years or older presented with the highest prevalences of middle ear dysfunction and conductive hearing loss, whereas the patients who underwent palatoplasty before 3 years old presented with the lowest prevalences. Moreover, linear-by-linear association revealed that the prevalences in the 4 groups were significantly different. These findings implied that the prevalences of middle ear dysfunction and conductive hearing loss tended to increase with advancing age at the time of cleft palate repair.

Otitis media with effusion is quite prevalent in patients with cleft palates, especially among cleft palate infants. Many anteecedent studies have indicated that otitis media with effusion

| Table 1. Middle Ear Function Comparisons Between Groups (n = 252). |
|---------------|--------------|--------------|----------------|
| Groups        | Type A (ear) | Type B&C (ear) | Total Ears |
| 0-3 y old     | 72.6% (106/146) | 27.4% (40/146) | 146 |
| 4-7 y old     | 51.7% (30/58) | 48.3% (28/58) | 58 |
| 8-11 y old    | 59.4% (19/32) | 40.6% (13/32) | 32 |
| 12 y and older| 25% (4/16) | 75% (12/16) | 16 |
| Total ears    | 63.1% (159/252) | 36.9% (93/252) | 252 |

Trend $\chi^2$ test: $\chi^2 = 19.051, P < .05$.

Prevalence of middle ear dysfunction in each group.

| Table 2. Hearing Level Comparisons Between Groups (n = 252). |
|---------------|--------------|--------------|----------------|
| Groups        | Normal Hearing (ear) | Abnormal Hearing (ear) | Total Ears |
| 0-3 y old     | 97.9% (143/146) | 2.1% (3/146) | 146 |
| 4-7 y old     | 87.9% (51/58) | 12.1% (7/58) | 58 |
| 8-11 y old    | 62.5% (20/32) | 37.5% (12/32) | 32 |
| 12 y and older| 56.3% (9/16) | 43.7% (7/16) | 16 |
| Total ears    | 88.5% (223/252) | 11.5% (29/252) | 252 |

Chi-square test linear-by-linear association, $\chi^2 = 50.39, P < .05$.

Hearing level distribution of each group.

| Table 3. Average Hearing Thresholds Compared Between Groups. |
|---------------|--------------|----------------|
| Groups        | Average Hearing Threshold (n ± s) |
| 0-3 y old     | 10.77 ± 6.13 (dB) |
| 4-7 y old     | 10.77 ± 6.13 (dB) |
| 8-11 y old    | 22.13 ± 13.31 (dB) |
| 12 y and older| 26.64 ± 16.61 (dB) |

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et al. (2006) demonstrated the improvement in hearing level of 22 patients with cleft lips and palates performed by Polzer under the age of 3 years, whereas the threshold was 26.64 dB in the patients who underwent cleft palate repair more than 12 years old; the latter threshold is beyond the normal standard. Thus, we speculate that the timing of palatoplasty affects middle ear function and hearing level.

Among patients, hearing loss begins to stabilize at 6 years old, and the chance of permanent hearing loss in cleft palate patients reaches approximately 50% at this age (Yules, 1970). All of the patients in this study were more than 6 years old, but the prevalences of abnormal middle ear function and conductive hearing loss were somewhat different. Additionally, as the age at repair increases, the hearing thresholds of patients with cleft palates significantly increase. The average hearing threshold was 10.77 dB in the patients who underwent cleft palate repair before the age of 3 years, whereas the threshold was 26.64 dB in the patients who underwent cleft palate repair more than 12 years old; the latter threshold is beyond the normal standard. Thus, we speculate that the timing of palatoplasty affects middle ear function and hearing level.

The incidence of hearing loss in patients with cleft palates has been found to be higher than that of normal individuals, especially in the early childhoods of the patients (Viswanathan et al., 2008). Audiologists have claimed that intermittent hearing loss might influence central auditory function (Moore et al., 2003). Moreover, audiologists have found that patients with cleft palates have poor auditory processing ability, and this processing ability is very important for the learning of language, speech, and other skills (Boscariol et al., 2009).

**Conclusion**

The prevalence of middle ear dysfunction and hearing loss tended to increase with advancing age at the time of cleft palate repair. From an audiologist’s perspective, palatoplasty at early age is very beneficial in terms of aiding the acquisition of better middle ear function and hearing level by children with cleft palates. The early combination of cleft repair surgery and intense and detailed otolaryngology and audiology care and follow-up is important.

**Declaration of Conflicting Interests**

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