American Cleft Palate-Craniofacial Association
75th Anniversary

Original Article

The Cleft Palate-Craniofacial Journal
1-5

DOI: 10.1177/1055665618754632
journals.sagepub.com/home/cpc
SAGE

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

Qun Lou, MD[1,2], Hongping Zhu, MD, PhD[1], Yi Luo, MD, PhD[1], Zhibo Zhou, MD, PhD[1], Lian Ma, MD, PhD[1], Xiaoran Ma, PhD[3], and Yuan Fu, MD[1]

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 palatopalsty 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

[1] Cleft Lip and Palate Center, Department of Oral and Maxillofacial Surgery, Peking University School of Stomatology, Zhongguancun, Beijing, China
[2] Shanghai Jiaotong University School of Medicine, Shanghai, China
[3] Department of Speech and Hearing, The University of Hong Kong, Pok Fu Lam, Hong Kong

Corresponding Authors:
Hongping Zhu, MD, PhD, Cleft Lip and Palate Center, Department of Oral and Maxillofacial Surgery, Peking University School of Stomatology, No. 22 South Main Street, Zhongguancun Beijing 100081, China; and Yi Luo, MD, PhD, PhD, Cleft Lip and Palate Center, Department of Oral and Maxillofacial Surgery, Peking University School of Stomatology, No. 22 South Main Street, Zhongguancun Beijing 100081, China.
Emails: zhuhongping@cndent.com; 13901308044@163.com

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 2014). According to medical history records, 28 of the participants suffered from otitis media and were treated with antibiotics without surgery, but there were no records of previous otolaryngology consultations or information about the specific antibiotics. Approvals from the Human Research Ethics Committee of the University of Hong Kong and the Ethics Committee of Peking University Health Science Center were received before starting the study (IRB reference no. EA140811). Written informed consent was obtained from all study participants or their parents if the participants were younger than 18.

The inclusion criteria were as follows:

1. Nonsyndromic cleft palate patients.
2. All participants could cooperate with the audiologic examinations and were without mental retardation.
3. Types of included clefts: 20 cases of incomplete cleft palates and 106 cases of complete cleft palates (3 cases were accompanied by unilateral incomplete cleft lips, and the remaining cases were simple cleft palates in the former group; the subjects in the latter group were clinically diagnosed with unilateral or bilateral complete cleft lip and palate).
4. All participants underwent palatoplasty surgery at least 24 months prior to the study.
5. None of the participants had undergone other relevant ear surgeries, for example, artificial eustachian tube insertion and tympanostomy tube insertion.

The participants were divided into the following 4 groups based on their age at the time of 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).

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.

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 25dB HL. Hearing loss was classified into the following 5 grades:

1. Mild hearing loss: 26-40 dB HL;
2. Moderate hearing loss: 41-55 dB HL
3. Moderate severe hearing loss: 56-70 dB HL;
4. Severe hearing loss: 71-90 dB HL;
5. Profound hearing loss: $\geq$91 dB HL.

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.

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 χ^2 test; $\chi^2 = 19.051$, $P < .05$.
Prevalence of middle ear dysfunction in each group.

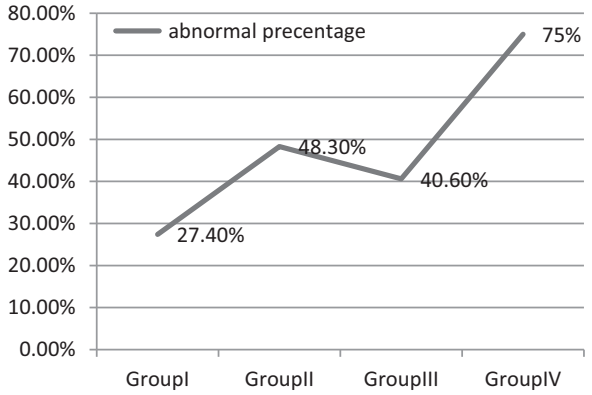
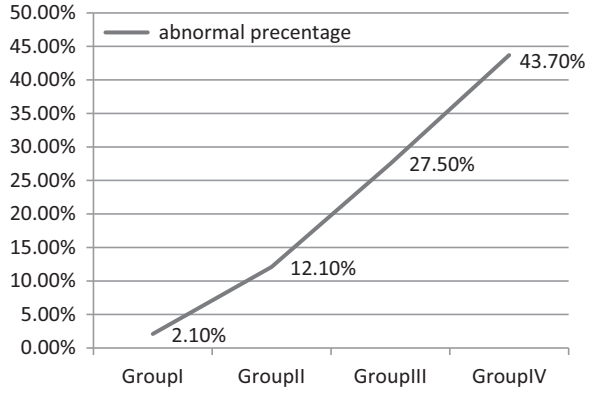


Table 2. Hearing Level Comparisons Between Groups (n = 252).

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)	27.5% (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



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 ($\chi^2 = 19.05$, $P < .05$). 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 $\pm$ 6.13 dB in the group I, 16.16 $\pm$ 10.39 dB in group II, 22.13 $\pm$ 13.31 dB in group III, and 26.64 $\pm$ 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).

Table 3. Average Hearing Thresholds Compared Between Groups.

Groups	Average Hearing Threshold (n $\pm$ s)
0-3 y old	10.77 $\pm$ 6.13 (dB)
4-7 y old	10.77 $\pm$ 6.13 (dB)
8-11 y old	22.13 $\pm$ 13.31 (dB)
12 y and older	26.64 $\pm$ 16.61 (dB)

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 antecedent studies have indicated that otitis media with effusion

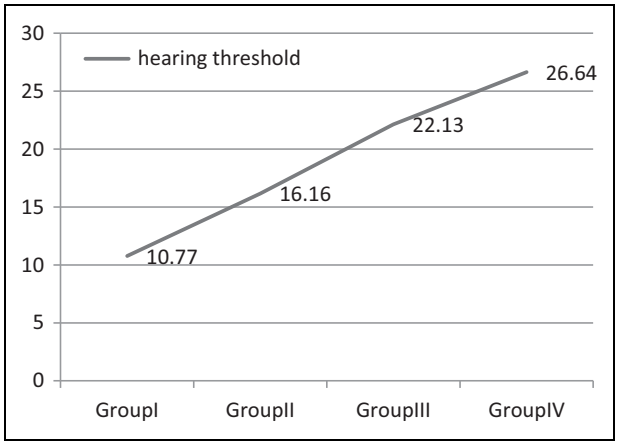


Figure 1. Run chart of the average hearing threshold.

and tympanic membrane dysplasia is often caused by eustachian tube dysfunction (Bluestone and Doyle, 1988). Compared with the normal structure, the eustachian tubes of cleft palate patients are bent in the caudal direction, which creates an obstacle to ventilation function (Broder et al., 1998). Furthermore, the palatopharyngeal muscles of individuals with cleft palates exhibit abnormal adhesion, which prevents normal contraction. In numerous cases of palatal muscle dysfunctions, the tensor veli palatini has been proven to play an important role in opening the eustachian tube (Barsoumian et al., 1998). As a result of tensor veli palatini dysplasia, the muscle cannot complete its physiological function and effectively open the eustachian tube, which eventually causes otitis media with effusion, and even hearing impairment (Huang et al., 1997). Additionally, adenoid hyperplasia is another primary causal factor of otitis media with effusion. Cleft palate patients are at a higher risk of upper respiratory tract infection, which leads to an in increased risk of suffering from adenoid hyperplasia.

Long-term chronic otitis media with effusion can cause permanent hearing impairment (Flynn and Lohmander, 2014). Recently, clinicians and scholars have focused on the treatment of otitis media with effusion and the prevention hearing impairment. The idea of utilizing palatoplasty to improve middle ear function has emerged because the anatomical morphology of the palatal muscles may be reconstructed after palatoplasty (Smith and Losee, 2014). Palatoplasties such as levator muscle reconstruction can separate the oral cavity from the nasal cavity and contribute to eustachian tube opening (Schönmeyr and Sadhu, 2014). More importantly, the tensor veli palatini muscle and the levator veli palatini muscle are anatomically reduced after palatoplasty. With the correction of the abnormal adhesion of the palatal muscles, the eustachian tube function can be improved (Flores et al., 2010).

Studies have demonstrated that a simple cleft palate repair surgery alone is helpful in restoring hearing in patients with cleft palate (Yules, 1970). Certainly, these patients should undergo palatoplasty as early as possible. A retrospective study of 22 patients with cleft lips and palates performed by Polzer et al. (2006) demonstrated the improvement in hearing level after palatoplasty. The Kriens intravelar veloplasty technique was applied in their study cases. The results revealed that this type of palatoplasty can elicit significant benefits in language and hearing recovery. A study by Too-chung (1983) demonstrated that closing the palatal crack of a cleft palate at the age of 4 months after birth can aid the reduction of middle ear disease and other complications. Smith et al. (1994) noted that the improvements in eustachian tube function that result from palatoplasty do not occur immediately. The hearing level returns to normal at an average of 6 years after the operation, and the longest noted delay was 17 years. An animal study conducted by Rader et al. (2008) demonstrated that the palate muscle fiber may exhibit adaptive alterations after palatoplasty, that is, type II muscle fibers transformed into type I after surgery and gradually form a normal distribution of muscle fiber types, which benefits speech and hearing restorations.

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

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

ORCID iD

Qun Lou, MD http://orcid.org/0000-0002-1080-3005

References

Barsoumian R, Kuehn DP, Moon JB, Canady JW. An anatomic study of the tensor veli palatini and dilatator tubae muscles in relation to eustachian tube and velar function. *Cleft Palate Craniofac J*. 1998; 35:101-110.

Bluestone CD, Doyle WJ. Anatomy and physiology of eustachian tube and middle ear related to otitis media. *J Allergy Clin Immunol*. 1988;81:997-1003.

Boscariol M, André KD, Feniman MR. Cleft palate children: performance in auditory processing tests. *Braz J Otorhinolaryngol*. 2009; 75:213-220.

Broder H, Richman L, Matheson P. Learing disability, school achievement, and grad retention among children with cleft: a two-center study. *Cleft Palate Craniofac J*. 1998;35:127-131.

Broen PA, Moller KT, Carlstrom J, Doyle SS, Devers M, Keenan KM. Comparison of the hearing histories of children with and without cleft palate. *Cleft Palate Craniofac J*. 1996;33:127-133.

Carroll DJ, Padgitt NR, Liu M, Lander TA, Tibesar RJ, Sidman JD. The effect of cleft palate repair technique on hearing outcomes in children. *Int J Pediatr Otorhinolaryngol*. 2013;77:1518-1522.

Flores RL, Jones BL, Bernstein J, Karnell M, Canady J, Cutting CB. Tensor veli palatini preservation, transection, and transection with tensor tenopexy during cleft palate repair and its effects on eustachian tube function. *Plast Reconstr Surg*. 2010;125:282-289.

Flynn T, Lohmander A. A longitudinal study of hearing and middle ear status in individuals with UCLP. *Otol Neurotol*. 2014;35: 989-996.

Han DM, Xu SA. Basic and Clinical Audiology. *Beijing :Scientific and Technical Documents Publishing House*. 2004:283-284.

He Y, Xu H, Zhen Q, Liao X, Xu L, Zhen Y. The influence of palatoplasty and tympanotomy on middle ear function in cleft palate patients. *Hua Xi Kou Qiang Yi Xue Za Zhi*. 2001;19: 243-245.

Huang MH, Lee ST, Rajendran K. A fresh cadaveric study of the paratubal muscles: implications for eustachian tube function in cleft palate. *Plast Reconstr Surg*. 1997;100:833-842.

Jack L. An internationally-oriented review. *Cleft Palate J*. 1975;12: 17-22.

Jerger J, Hayes D, Jordan C. Clinical experience with auditory brainstem response audiometry in pediatric assessm ent. *Ear Hear*. 1980;1:19-25.

Kuo CL, Lien CF, Chu CH, Shiao AS. Otitis media with effusion in children with cleft lip and palate: a narrative review. *Int J Pediatr Otorhinolaryngol*. 2013;77:1403-1409.

Moore DR, Hartley DE, Hogan SC. Effects of otitis media with effusion (OME) on central auditory function. *Int J Pediatr Otorhinolaryngol*. 2003;1:63-67.

Polzer I, Breitsprecher L, Winter K, Biffar R. Videoendoscopic, speech and hearing in cleft palate children after levator-palatopharyngeus surgery according to Kriens. *J Craniomaxillofac Surg*. 2006;34:52-56.

Rader EP, Cederna PS, McClellan WT, Caterson SA, Panter KE, Yu D, Buchman SR, Larkin LM, Faulkner JA, Weinzweig J. Effect of cleft palate repair on the susceptibility to contraction-induced injury of single permeabilized muscle fibers from congenitally-clefted goat palates. *Cleft Palate Craniofac J*. 2008;45:113-120.

Schönmeyr B, Sadhu P. A review of the tensor veli palatine function and its relevance to palatoplasty. *J Plast Surg Hand Surg*. 2014; 48:5-9.

Skuladottir H, Sivertsen A, Assmus J, Remme AR, Dahlen M, Vindenes H. Hearing outcomes in patients with cleft lip/palate. *Cleft Palate Craniofac J*. 2015;52:23-31.

Smith DM, Losee JE. Cleft palate repair. *Clin Plast Surg*. 2014;41: 189-210.

Smith TL, DiRuggiero DC, Jones KR. Recovery of eustachian tube function and hearing outcome in patients with cleft palate. *Otolaryngol Head Neck Surg*. 1994;111:423-429.

Tiwari R, Sharma R, Panda N, Munjal S, Makkar S. Tensor tenopexy: a clinical study to assess its effectiveness in improving eustachian tube function and preventing hearing loss in patients with cleft palate. *J Plast Reconstr Aesthet Surg*. 2013;66:239-245.

Too-chung MA. The assessment of middle ear function and hearing by tympanometry in children before and after early cleft palate repair. *Br J Plast Surg*. 1983;36:295-299.

Viswanathan N, Vidler M, Richard B. Hearing thresholds in newborns with a cleft palate assessed by auditory brain stem response. *Cleft Palate Craniofac J*. 2008;45:187-192.

Yules R. Hearing in cleft palate patients. *Arch Otolaryngol*. 1970;91: 319-323.