


ORIGINAL RESEARCH

Relationship between cleft palate width and otitis media

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Abstract

Objectives: To investigate the relationship between cleft width and otitis media (OM) and to determine whether a wide cleft palate (CP) is a risk factor of the incidence, type, amount of middle ear effusion, and prolonged morbidity in OM.**Study Design:** Retrospective cohort study.**Methods:** Children with CP who underwent palatoplasty between 2014 and 2018 were analyzed. Cleft width was measured at palatoplasty. The incidence of otitis media with effusion (OME) and acute otitis media (AOM), the type and amount of middle ear effusion, and OME duration and age at resolution were assessed in relation to cleft width.**Results:** One hundred eighteen children were included. The CP types were Veau I in 16, II in 35, III in 48, and IV in 19 patients. The incidence of OME and AOM before palatoplasty was 83.1% and 49.2%, respectively. Cleft width did not differ significantly between patients with or without OME but was significantly greater in those with, than in those without, AOM ($p < .001$), in those with mucoid, than in those with serous, effusion ($p = .012$), and in those with complete, than in those with partial, effusion ($p = .01$). Regardless of cleft width or type, OME persisted for a median duration of 50 months.**Conclusions:** Cleft width was significantly associated with the incidence of AOM and the type and amount of middle ear effusion before palatoplasty. However, it was not significantly related to the incidence, age at resolution, or duration of OME. Regardless of cleft width or type, OM in children with CP requires long-term follow-up.**Level of Evidence:** 2b.

KEYWORDS

children, cleft palate, middle ear ventilation, otitis media, otitis media with effusion

1 | INTRODUCTION

Children with cleft palate (CP) are more likely to experience otitis media with effusion (OME), which is often intractable and persistent because of eustachian tube and palatopharynx dysfunction

stemming from structural abnormalities. These patients present abnormalities in the attachment of the tensor veli palatini and levator veli palatini muscles, causing maladjustment in the opening function of the eustachian tube. Persistent OME is associated with mild to moderate hearing loss and may lead to language

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development issues. In such cases, OME often requires treatment with ventilation tube insertion (VTI).

CP plays an important role in OME formation, but the clinical significance of cleft severity in predicting otologic outcomes in otitis-prone children is controversial.^{1,2} We herein hypothesized that increased CP size is associated with an increased likelihood of the development, greater severity, and prolongation of otitis media (OM). If true, the wider the CP, the earlier and longer should be the VTI. The present study aimed, therefore, to investigate the relationship of cleft width with OM and to identify whether a wide cleft is a risk factor for the incidence, type, amount of middle ear effusion, and prolonged morbidity in OM.

2 | MATERIALS AND METHODS

2.1 | Materials

The present, retrospective, cohort study of children with CP who underwent palatoplasty at Tokyo Metropolitan Children's Medical Center was conducted from January 1, 2014, to May 31, 2018. The patient data were collected from electronic medical records. The inclusion criteria were CP with one-stage palatoplasty at age <2 years in the Department of Plastic and Reconstructive Surgery and treatment for OM in the Department of Otolaryngology from age 0 years every 3–6 months for at least 2 years. Patients with syndromic malformations were also included if they met the inclusion criteria. The exclusion criteria were an external auditory canal that was too narrow for OME evaluation, microtia with external auditory canal obstruction, and VTI performed at another hospital. All the palatoplasties were performed by an experienced surgeon.

The present study was approved by the research ethics committee of Tokyo Metropolitan Children's Medical Center (#2019b–200). This study was supported by a grant from the Clinical Research Fund of the Tokyo Metropolitan Government.

2.2 | Methods

2.2.1 | Cleft palate width and surgical techniques

Cleft width was measured in millimeters from the end of the alveolar process of the maxilla by a single plastic surgeon during palatoplasty using Castroviejo Straight Tip caliper (Inami, S-200) (see Figure 1) and was categorized using the Veau classification as I (soft palate cleft), II (soft and hard palate), III (unilateral cleft lip and palate), or IV (bilateral cleft lip and palate). A cleft width with Veau I classification was defined as 0 mm because a cleft of the soft palate is posterior to the end of the alveolar arch.

The modified two-flap technique was used in almost all cases, but the modified Furlow technique was used only for palatoplasty of cleft soft palates <3 mm.

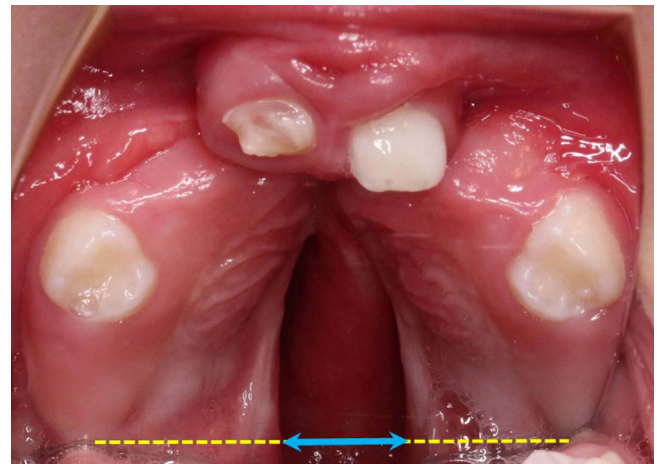


FIGURE 1 Measurement of cleft width at the end of the alveolar process of the maxilla using a caliper during palatoplasty

2.2.2 | Factors indicating ventilation tube insertion (VTI), type and amount of middle ear effusion, and duration of otitis media

Three experienced pediatric otolaryngologists diagnosed OME by otomicroscopy or otoendoscopy and performed all VTI. The indications for VTI were (1) middle ear effusion lasting 3 months; (2) bilateral hearing loss >40 dB; (3) delayed language development; or (4) abnormal tympanic membrane findings according to guidelines.³

The incidence of OME and acute otitis media (AOM) with a tympanic bulge before palatoplasty was assessed. Patients with AOM with a tympanic bulge were defined as having at least one episode of AOM with a bulge during the regular, three to six monthly visits.

The type and amount of middle ear effusion were assessed at the first VTI before or concurrently with palatoplasty. The type of effusion was classified as serous or mucoid. Effusion not filling the middle ear cavity was classified as “partial”, and effusion or inflammatory tissue, filling the middle ear cavity was classified as “complete”. The types of ventilation tubes used were the Shepard grommet (inner diameter: 1.14 mm; Medtronic Xomed, Inc., Jacksonville, FL, USA), the Bobbin-type (KOKEN B type; inner diameter: 1.2 mm; KOKEN, Tokyo, Japan), and the Goode T-Tubes™ (Medtronic Xomed, Inc.; inner diameter: 1.14 mm). The Goode T-Tubes™ were used only when the middle ear cavity was very narrow and other tubes would not fit. Any long-acting VT was removed within 3 years.

OME resolution was defined as no OME recurrence for at least 6 months. The patient age at OME resolution was defined as the age at which no further recurrence was observed. OME duration was defined as the period from the initial diagnosis to resolution. For the patients with VTI, dwell time was included in the OME duration. OME resolution in these patients was defined as no OME recurrence >6 months after VT extrusion or removal and tympanic membrane closure. Ongoing cases were defined as those with persistent OME, an indwelling VT, or duration <6 months after improvement. Perforation was defined as a perforation persisting >6 months after VT

extrusion or removal. To determine the effect of the initial type of VT used, that is, a short-acting or long-acting tube, on OME duration and age at OME resolution, we examined how these latter items differed by the type of VT initially used.

2.3 | Study design and primary outcomes

Cleft width and type were independent variables, and OME incidence, duration, age at resolution, type and amount of middle ear effusion, AOM incidence, VTI number, and VT dwell period were dependent variables.

2.4 | Statistical analysis

The test results were statistically analyzed using SPSS ver.28 (Chicago, IL, USA). $p < .05$ was considered to indicate statistical significance. The difference in cleft width by the incidence of OM and the type and amount of middle ear effusion was evaluated using the Mann-Whitney U-test. To evaluate cleft width among the CP types, the Kruskal-Wallis test and Steel-Dwass post hoc test for multiple comparisons were performed as nonparametric tests. To investigate the relationship between the incidence of OM according to the CP type, the Mantel-Haenszel test for trends in proportions and logistic regression analysis was used. Age at OME resolution and OME duration for the various CP types were evaluated using Kaplan-Meier curves and the log-rank test. Patients with perforation of the tympanic membrane and those who were lost to follow-up were categorized as censored. Spearman's correlation coefficient was used to assess for any correlation between age at OME resolution, OME duration, and cleft width. Age at OME resolution and OME duration by the type of VT initially used were also evaluated using Kaplan-Meier curves and the log-rank test.

3 | RESULTS

3.1 | Baseline characteristics and course of otitis media

In total, 158 patients who underwent palatoplasty between January 1, 2014, and May 31, 2018 were extracted from the medical records. Among these, 36 failed to meet the inclusion criteria, including 13 who underwent palatoplasty at 2 years of age or older; 21 with a follow-up period for OME at our hospital <2 years due to relocation or other reasons; and two with palatoplasty using the two-stage method. Two more patients with a very narrow external auditory canal and two with VTI at another hospital were also excluded. Finally, 118 patients with CP comprising 63 (53.4%) males and 55 (46.6%) females were included.

The CP types observed were 16 cases of soft palate (Veau I), 35 cases of hard and soft palate (Veau II), 48 cases of unilateral cleft

lip and palate (Veau III), and 19 cases of bilateral cleft lip and palate (Veau IV). Syndromic malformation was observed in 14 patients comprising seven with Pierre Robin Sequence, one with CHARGE syndrome, one with Goldenhar syndrome, one with Sotos syndrome, and four with multiple congenital anomalies.

The mean age at palatoplasty was 15.1 months (SD: 2.8), the mean age at the first otolaryngological examination was 5.7 months (SD: 2.4), and the mean OME follow-up period was 59.1 months (SD: 18.3).

Table 1 shows the incidence of OME and AOM with a tympanic bulge before palatoplasty, the number of VTI, the total VT indwelling period, and OME status at the endpoint. Before palatoplasty, OME occurred in 196 ears (83.1%) in 100 patients, and AOM occurred in 116 ears (49.2%) in 67 patients. During the study, VTI was performed in 194 ears, and the timing of the initial VTI was before palatoplasty in six ears, concurrent with palatoplasty in 183 ears, and after palatoplasty in five ears. In two ears, only myringostomy was performed.

The OME status at the end of the study was resolution in 186 ears (78.8%), indwelling VT in 25 ears (10.6%), ongoing OME in 18 ears (7.6%), and perforated tympanic membrane in seven ears (3.0%).

TABLE 1 Incidence of OME and AOM, number and indwelling period of ventilation tube (VT), and OME status at endpoint

Total number of ears = 236	Number of ears (%)
<i>OME incidence before palatoplasty</i>	
Present	196 (83.1)
Absent	40 (16.9)
<i>Incidence of AOM with tympanic bulge before palatoplasty</i>	
Present	116 (49.2)
Absent	118 (50.0)
<i>Number of VT insertions (VTI)</i>	
0	42 (17.8)
1	125 (53.0)
2	56 (23.7)
3	9 (3.8)
>4	4 (1.7)
<i>Total VT indwelling period</i>	
None	42 (17.8)
<1 year	23 (9.7)
<2 years	39 (16.5)
<3 years	75 (31.8)
<4 years	41 (17.4)
>4 years	16 (6.7)
<i>OME status at endpoint</i>	
Resolution	186 (78.8)
VT in place	25 (10.6)
Ongoing OME	18 (7.6)
Perforation	7 (3.0)

Abbreviations: AOM, acute otitis media; OME, otitis media with effusion; VT, ventilation tube.

The median dwell period of the initial VT was 8 months (IQR: 4–12) for the short-acting type and 26 months (IQR: 22–30) for the long-acting type. However, the median age at OME resolution at the endpoint of the study was 52.0 months (95% CI: 34.5–69.5) for the short-acting type and 54.0 months (95% CI: 49.2–58.8) for the long-acting type, with no significant difference in terms of the VT type initially used ($p = .357$). And the median OME duration was 43.0 months (95% CI: 21.0–65.0) for the short-acting type and 48.0 months (95% CI: 42.1–53.8) for the long-acting type, with no significant difference in terms of the VT type initially used ($p = .375$). The patients with the short-acting type had more recurrences after the initial VT extrusion compared with those with the long-acting type, and eventually age at OME resolution and OME duration did not differ significantly by the initial VT type.

3.2 | Cleft palate width and OM incidence and effusion

The median cleft width was 8 mm, the interquartile range was 5–10 mm, and the maximum width was 15 mm. Figure 2 compares cleft width by the incidence of OME and of AOM with a tympanic bulge before palatoplasty. Cleft width did not differ in terms of OME incidence ($p = .343$) but differed in terms of the AOM incidence, with the AOM group having a wider cleft ($p < .001$).

Figure 3 compares cleft width in terms of the type and amount of middle ear effusion at the initial VTI before, and concurrently with palatoplasty. A significant difference in cleft width was found in terms of the type ($p = .012$) and amount ($p = .01$) of effusion in the middle ear. Patients with mucoid, complete effusion had a significantly wider cleft.

3.3 | Cleft palate type and OME incidence and duration

Table 2 shows the cleft width and incidence of OM by CP type. The median cleft width was 6 mm (IQR: 5–8 mm) for Veau II, 9 mm (IQR: 8–10 mm) for Veau III, and 11 mm (IQR: 10–12 mm) for Veau IV. Cleft width was significantly wider in the order of Veau categories I, II, III, and IV ($p < .001$). There was no significant trend toward increased OME incidence by Veau classification ($p = .202$). However, there was a significant trend toward an increased incidence of AOM with a tympanic bulge by Veau classification ($p = .004$). When Veau I and Veau III were compared, Veau III had a significantly higher incidence of OME (OR: 4.394; 95% confidence interval [CI]: 1.593–12.122) and AOM (OR: 2.914; 95% CI: 1.263–6.725) than Veau I. Veau II and Veau IV did not have a significantly different incidence of OME (OR: 2.197; 95% CI: 0.831–5.808, OR: 1.465; 95% CI: 0.509–4.216) or AOM (OR: 1.128; 95% CI: 0.47–2.709, OR: 2.358; 95% CI: 0.894–6.222) compared with Veau I.

Table 2 also shows the median values for age at OME resolution and OME duration for each CP type. Figure 4 shows the cumulative

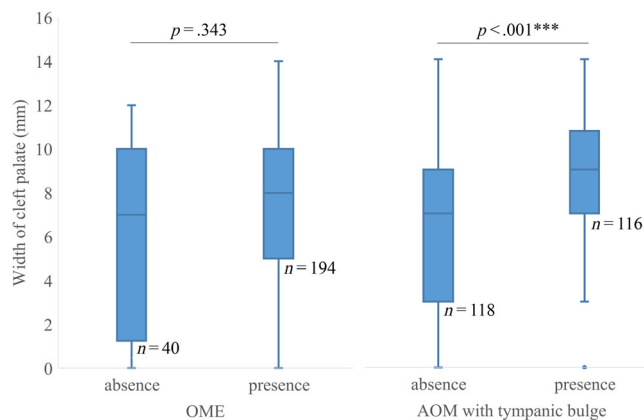


FIGURE 2 Comparison of cleft width by the incidence of OME and AOM with a tympanic bulge before palatoplasty. Cleft width did not differ significantly in terms of the OME incidence but differed significantly in terms of the incidence of AOM with tympanic bulge. Patients with AOM had a wider cleft palate. (OME = otitis media with effusion; AOM = acute otitis media). *** $p < .001$

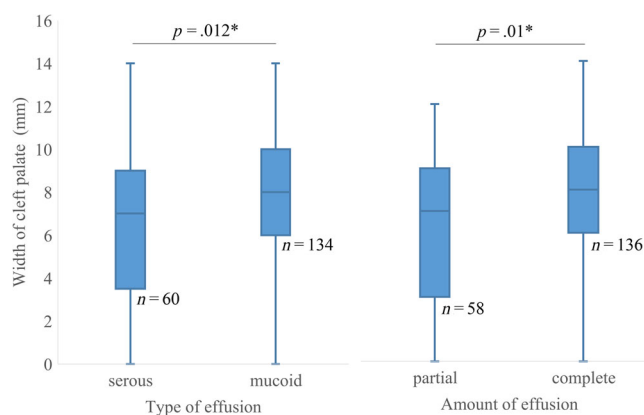


FIGURE 3 Comparison of cleft width by the type and amount of middle ear effusion at the initial VT insertion before, or concurrently with, palatoplasty. Cleft width differed significantly in terms of the type and amount of middle ear effusion. Patients with mucoid, complete effusion had a significantly wider cleft palate. (VT = ventilation tube). * $p < .05$

OME resolution rate for each CP type. The median age at OME resolution was 50.0 months (95% CI: 47.5–52.5), and the median OME duration was 44.0 months (95% CI: 40.4–47.6), with no significant difference among the CP types ($p = .744$; 0.681).

There was also no correlation between cleft width and the age at OME resolution ($p = .724$; Spearman's correlation coefficient: 0.023) or between cleft width and OME duration ($p = .835$; Spearman's correlation coefficient: 0.014).

4 | DISCUSSION

Orofacial clefts, including cleft lip and CP, are the most common congenital abnormalities of the head and neck. The prevalence of cleft lip

TABLE 2 Cleft width, OME and AOM incidence, age at OME resolution, and OME duration by Veau classification

Cleft palate type	No. of children (%)	No. of ears	Cleft width (median [IQR], mm)	OME incidence (% [no. of ears])	Odds ratio (95% CI)	AOM incidence (% [no. of ears])	Odds ratio (95% CI)	Age at OME resolution (median [95% CI], months)	OME duration (median [95% CI], months)
Veau I	16 (13.8)	32	0	68.8 (22/32)	Ref	34.4 (11/32)	Ref	48.0 (30.0–66.0)	40.0 (24.8–55.2)
Veau II	35 (29.7)	70	6.0 (5.0–8.0)	82.9 (58/70)	2.197 (0.831–5.808)	37.1 (26/70)	1.128 (0.47–2.709)	47.0 (41.0–53.0)	40.0 (33.0–47.0)
Veau III	48 (40.7)	96	9.0 (8.0–10.0)	90.6 (87/96)	4.394 (1.593–12.122)	60.4 (58/96)	2.914 (1.263–6.725)	53.0 (50.1–55.9)	47.0 (42.2–51.8)
Veau IV	19 (16.4)	38	11.0 (10.0–12.0)	76.3 (29/38)	1.465 (0.509–4.216)	55.3 (21/38)	2.358 (0.894–6.222)	49.0 (43.0–55.0)	37.0 (29.8–44.2)
Total	118	236	8.0 (5.0–10.0)	83.1 (196/236)		49.2 (116/236)		50.0 (47.5–52.5)	44.0 (40.4–47.6)
p-value			<.001***	.202		.004**	.744		.681

Abbreviations: AOM, acute otitis media; 95% CI, 95% confidence interval; IQR, interquartile range; OME, otitis media with effusion. *** $p < .01$, **** $p < .001$.

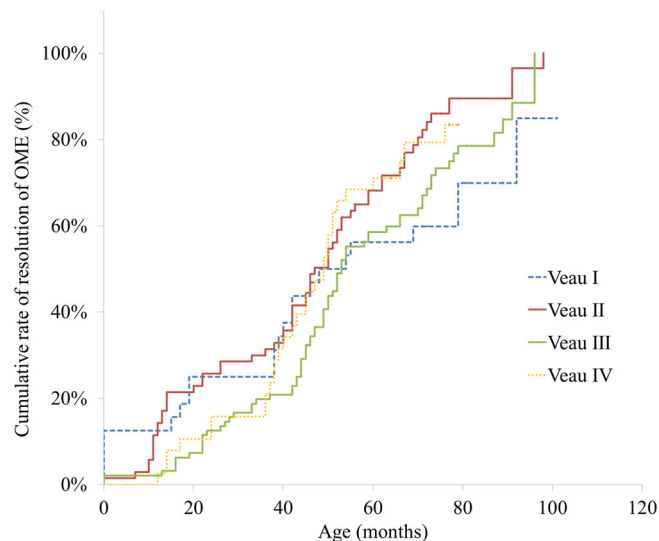


FIGURE 4 Cumulative rate of OME resolution by cleft palate type. There was no significant difference in the cumulative rate of OME resolution by cleft palate type. (OME = otitis media with effusion).

with or without CP is 10.0/10000 live births and varies by race/ethnicity.^{4–6} In Japan, the prevalence of cleft lip with or without CP is 18.1/10000 live births and that of CP is 4.3/10000.⁶ The incidence of OM in children with CP ranges from 55% to 98%.^{7–12}

The present study examined whether a wide CP is a risk factor of the incidence, type, amount of middle ear effusion, and prolonged morbidity. The results demonstrated that the overall OME incidence was 83.1%, that cleft width did not differ significantly by OME incidence, and that there was no significant association between OME incidence and Veau classification on trend analysis although Veau III was associated with a significantly higher incidence of OME than Veau I. However, patients with AOM with a tympanic membrane bulge had a significantly wider cleft ($p < .001$). The AOM incidence also tended to increase with Veau classification ($p = .004$).

In addition, cleft width was found to be significantly greater in the presence of mucoid ($p = .012$), complete ($p = .01$) middle ear effusion at the initial VT insertion before or concurrently with palatoplasty. Moreover, age at OME resolution and OME duration was not significantly associated with cleft width or type.

To the best of our knowledge, the present study is the first to describe the relationship between cleft width and AOM incidence, the type and amount of middle ear effusion, OME duration, and age at OME resolution although some previous studies have reported the prevalence of VT.¹³ Schwartz et al.¹³ for example, reported that the cleft type and width had no statistical association with VTI prevalence, in line with the findings of our study.

The present study found that the AOM incidence and the type and amount of middle ear effusion before palatoplasty were associated with cleft width possibly because wide clefts were more likely to be contaminated by food, fluids, and saliva in the eustachian tube triggering an immune/inflammatory response and leading to severe

OM. Severe cases of OM carry the risk of hearing loss leading to delayed language acquisition and thinning and retraction of the tympanic membrane. The results of our study suggested that earlier VTI may be effective in patients with OME with a wide cleft who are often more prone to exacerbation and have a high incidence of severe AOM. Several studies on the timing of VTI have reported that VT insertion before the age of 6 months is beneficial^{12,14} although VTI before palatoplasty increases the risk of prolonged otorrhea.^{15,16}

The present study found no significant association between cleft width or type and age at OME resolution or OME duration; a wide CP was not a risk factor of prolonged OM if palatoplasty and VTI were performed. Regardless of cleft width or type, OME in children with CP persisted for a median duration of 50 months. In such patients, it may be advisable to maintain VT until at least the age 3–4 years. Alper et al.¹⁷ reported that the cumulative percentage of OME resolution in children was 50% at 4 years of age, which was similar to the findings of the present study and suggests that long-term follow-up is required.

Schwarz et al.¹³ explained that in patients with a wide cleft, the surgeon must mobilize tissue more extensively and perform the adaptation under a higher tissue drag. The drag on the eustachian tube may increase in patients with a wider cleft, enabling better middle ear ventilation. Moreover, Alper et al.¹⁸ reported that the results of eustachian tube function tests before and after palatoplasty demonstrated that eustachian tube dilation was more frequent postoperatively than preoperatively. Properly performed, palatoplasty can reduce contamination around the eustachian tube, further improve middle ear ventilation, and increase eustachian tube dilation while VTI enables continued pneumatization of the mastoid¹⁹; thus, a wide CP is not a risk factor of prolonged OME as long as palatoplasty and VTI are provided.

The present study has several strengths. First, only one skilled plastic surgeon performed the palatoplasties at our hospital, and the surgical technique was therefore uniform. Second, most of the patients were examined for the type and amount of effusion under general anesthesia during palatoplasty. More uniform and accurate evaluation was possible when the VT was placed under general anesthesia, which allowed more effusion to be removed than under local anesthesia.

This study also has several limitations. First, the type and amount of middle ear effusion were subjectively, rather than quantitatively, assessed. Second, the VT dwell period was an inaccurate reflection of OME duration. Third, because the cleft width was measured at a single point on the posterior edge of the alveolar arch, the cleft width in Veau I had to be uniformly evaluated as 0 mm, and the differences in cleft width between Veau I cases could not be evaluated. Fourth, the study was retrospective. Fifth, 78.8% of the cases resolved while the remaining 21.8% were still unresolved at the end of the study period and required continued follow-up. Future research is needed to evaluate OME objectively by measuring patients' hearing level and using wideband reflectance to obtain more detailed information on the middle ear.^{20,21} In addition, a prospective study is needed to determine whether early VT insertion can further shorten OME duration.

5 | CONCLUSION

Cleft width was associated with AOM incidence and the type and amount of middle ear effusion before palatoplasty. However, it was not significantly associated with the incidence, age at resolution, or duration of OME. Even patients with a wide cleft did not differ significantly in terms of age at resolution or OME duration from patients with a narrow cleft if appropriate palatoplasty and VT insertion were performed. Regardless of cleft width or type, the median OME duration was 50 months, and OM in children with CP required long-term follow-up.

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CONFLICT OF INTEREST

The authors have no conflicts of interest to disclose.

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