## Does Palatoplasty Technique Affect The Need For Ventilation Ear Tube Insertion? Mahmoud Sobhy Allam<sup>\*1</sup>, Mamdouh M. Aboulhassan<sup>2</sup>,

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## ABSTRACT

**Background:** Debate continues about the recovery of eustachian tube (ET) function after CP repair. It has been strongly recommended that children with cleft palates should receive aggressive treatment of middle ear dysfunction to prevent hearing loss and speech delays.

**Objective:** To investigate the need for VT insertion in cleft palate patients repaired by modified Furlow palatoplasty versus two flaps palatoplasty.

**Patients and methods:** The study included 72 cleft palate patients who were divided into 2 groups. Group1 (42) patients were repaired by modified Furlow Z-plasty operation. Group 2 (30) patients subjected to two flaps palatoplasty. Eustachian tube function was evaluated preoperatively and postoperatively at 1, 3, 6, 12 months.

**Results:** Palatoplasty directly improved ET dysfunction. Modified Furlow showed early improvement at 3 months postoperatively (p value 0.004) but has no superiority after one year over two flaps palatoplasty. 34.7% of cases spared from VT insertion and its complication.

**Conclusion:** palatoplasty significantly improves ET function. Conservative management of middle ear effusion is recommended for CP patients instead of prophylactic tube insertion.

Keywords: Cleft palate, Eustachian tube, Modified Furlow Palatoplasty, Two flaps palatoplasty.

## INTRODUCTION

One of the most common craniofacial birth abnormalities in the world is cleft palate (CP). From infancy to maturity, the complicated treatment path for CP involves interdisciplinary surgical and nonsurgical therapy <sup>[1,2]</sup>.

Significant eating, hearing, speech, and psychological deficits are linked to CP. Predicting the long-term developmental trajectory of the afflicted individual and maximizing treatment choices are made possible by an understanding of the underlying drivers of these disorders <sup>[3]</sup>.

Normal maxillary development, normal speech, normal eustachian tube (ET) function, and good aesthetic outcomes are the ultimate goals of CP restoration, with the family's and individual's psychological and social well-being being the primary focus<sup>[1-4]</sup>. When compared to the general population, the ET in CP patients exhibits anatomical, morphological, and histological abnormalities<sup>[5]</sup>.

Due to middle ear illness, which is nearly ubiquitous, children with CP have been shown to have it more frequently <sup>[6]</sup>.

**Bluestone and Klein** <sup>[7]</sup> have reported the occurrence of otitis media with effusion (OME) in these youngsters as well as functional impairment of the ET's opening mechanism. without the use of a ventilation tube (VT) or palatoplasty. Children with cleft lip have a

more noticeable and widespread hearing loss than agematched controls <sup>[8,9]</sup>.

The VT implantation in CP patients is still up for debate. According to **Fria** *et al.* <sup>[10]</sup>, kids with functional tubes and early VT had higher hearing thresholds.

When required, **Gerson** *et al.* advised having VTs inserted during palate restoration. Although it is not generally acknowledged, early and regular VT installation to reduce hearing impairments has been a feature of CP care in several countries. The anatomy and hearing of the middle ear may be adversely affected by the insertion and reinsertion of VTs <sup>[11]</sup>.

This study was conducted to investigate the need for VT insertion in CP patients repaired by modified Furlow palatoplasty versus two flaps palatoplasty.

## PATIENTS AND METHODS

#### Study design and setting

Two arms prospective clinical study included 72 CP patients who presented to Maxillofacial Surgery Unit, General Surgery Department, Faculty of Medicine, Sohag University and Department of Plastic Surgery, Cairo University, between January 2020 until September 2023.

**Inclusion criteria:** Patients in the research ranged in age from one to seven years. Their hemoglobin level

was greater than 10 g/dL, and their weight was greater than ten pounds (4.5 Kg).

**Exclusion criteria:** Syndromic individuals and medically impaired patients opposing the procedure, and recurring instances were omitted.

**Preoperative assessment:** All cases were subjected to full history taking and general examination. Also, Local examination was performed to assess the type of CP. **Preoperative** ear examination was done using the otoscope and tympanometry. Routine laboratory investigations (CBC, Bleeding profile) were performed for all cases. Echocardiography was done if indicated.

#### METHODOLOGY

#### Patients were separated into two groups:

**Group 1:** 42 patients were repaired using modified Furlow palatoplasty (Standard technique with buccinator myomucosal flap modification)<sup>[12]</sup>.

**Group 2:** 30 patients were treated by tow flap technique (Standard procedure) <sup>[13]</sup>.

**Pressure Tympanogram** was done one-month postoperatively routinely, if it was normal, it would not be repeated. If tympanometry was abnormal, medical treatment was prescribed for the patient and the test was repeated after 3 months.

Tympanometry was then done on all of the children using a portable tympanometer (Welch-Allyn Diagnostics Inc., USA). Tympanograms were classified as type A (+99 to -99 mm H<sub>2</sub>O), type C (>100 mm H<sub>2</sub>O), or type B (flat curve with no discernible peak) (Figure 1). Children with otoscopic indications of OME and abnormal tympanograms (type B or C) were considered positive screenings and scheduled for a follow-up session within three months after the first screening.



**Ventilation tubes** were not routinely placed before palatoplasty, but only postoperatively in indicated cases, which were persistent type B and type C, persistent otitis media for more than three months despite the medical treatment, and recurrent otitis media more than five times per year.**Follow up: all cases were asked for regular visits for** postoperative follow-up at one weak, three weeks, one month, three months, six months, and one year.

#### Data collection:

Among the data gathered were demographics, type of palatal cleft, palatoplasty technique, preoperative and postoperative ear examination, and time and frequency of VT insertion.

#### **Ethical approval:**

The Declaration of Helsinki's guiding principles were followed in the performance of this investigation, which was authorized by the Sohag Faculty of Medicine's Institutional Review Board and Ethics Committee. The patients' parents or legal guardians completed an informed consent form.

#### Statistical analyses:

Each patient's data were entered into a file, processed with SPSS version 20.0, and then loaded into an Excel

spreadsheet. Frequencies and relative percentages were used to display the qualitative data. To determine the difference between two or more sets of qualitative variables,  $X^2$ - test was used. Age was presented as mean and range. P value of 0.05 was seen as noteworthy.

## RESULTS

This study included seventy-two patients with CP. Regarding the overall patient population, there was thirty-five (48.6%) males, thirty-seven (51.4%) females, their age ranged from nine months to eighty-four months (7y), and with mean age of  $39.49 \pm 19.286$  months. The patients were divided into two groups: group (1) and group (2). In group (1) there were 21 males (50%) and 21 females (50%) ranging between nine and eighty-four months with a mean age of 32.29 months, while in group (2), there were fourteen males (46.7%), sixteen females (53.3%). Their age ranged from nine and eighty-four months with a mean age of 49.57 months.

Preoperative examination revealed type of cleft classified according to Veau classification <sup>[15]</sup>.

## **Preoperative ear evaluation:**

Preoperatively, most of the patients in the studied groups had effusion (Table 1).

Type of tympanometry	(Tympanometry type B and C)		(Tympanometry type A)
Otoscopic examination	Effusion	Otitis Media	Normal
Group 1	37(88.1%)	2(4.8%)	3(7.1%)
Group 2	24(80%)	3(10%)	3(10%)

Modified Furlow palatoplasty was performed in group 1 patients (42 cases), while two flap technique was performed in group 2 patients (30 cases).

Postoperative ear evaluations were done at 1 month, 3 months, 6 months and one year. Results showed no significant difference between groups.

#### Table (2): Postoperative Ear evaluation

Time of ear evaluation	Variable	Group 1	Group 2	P Value	
One-month postoperatively	Effusion	36(85.7%)	20(66.6%)	0.101	
	Otitis Media	1(2.4%)	4(13.3%)		
	Normal	5(11.9%)	6(20%)		
3 months postoperatively	Effusion	30(71.4%)	17(56.7%)	0.004	
	Otitis Media	2(4.8%)	10(33.3%)		
	Normal	10(23.8%)	3(10%)		
6 months postoperatively	Effusion	31(73.8%)	15(50%)	0.012	
	Otitis Media	0	5(16.7%)	_	
	Normal	11(26.2%)	10(33.3%)		
One-year postoperatively	Effusion	25(59.5%)	20(66.7%)	0.142	
	Otitis Media	0	2(6.7%)		
	Normal	17(40.5%)	8(26.7%)		

**Regarding frequency and time of VT insertion:** twenty-five cases (34.7%) were spared from ear VT insertion, but in one case (1.4%) ear VT was inserted at three months postoperatively, while tube insertion was done in three cases (4.2%) at six months postoperatively and were inserted in forty-three cases (59.7%) at one-year postoperatively.

There was no significant relation between time and frequency of VT insertion and type of the operation (Table 3).

Variable	Crearen 1	Carora 2	D
operation.			
Table (3): Postope	rative VT ins	sertion in relat	ion to the

Variable	Group 1	Group 2	Р
			value
No tube	17(40.5%)	8(26.7)	0.355
insertion			
Insertion of tube	0	1(3.3%)	
at 3 m			
Insertion of tube	1(2.4%)	2 (6.7%)	
at 6 m			
Insertion of tube	24(57.1%)	19(63.3%)	
at 12 m			

## DISCUSSION

Because of its complicated etiology, potential for lifelong morbidity, and the significant multidisciplinary commitment needed for treatments, CP is a significant public health concern <sup>[3]</sup>. If middle ear illness is not surgically treated during infancy, there is a chance that a persistent middle ear infection and irreversible hearing loss may occur <sup>[7]</sup>. The method used in palatoplasty is a crucial component that may have an impact on how well speech and middle ear function will be after cleft palate surgery. Regretfully, disagreements on this still dominate <sup>[15,16]</sup>.

Also, there is controversy regarding timing of VT insertion in these patients. Some authors advocate that prophylactic insertion is associated with better hearing outcomes. Others recommend VT insertion when indicated after palatoplasty <sup>[11]</sup>.

In this study, we found increasing number of spontaneous improvements of ET dysfunction under conservative management, which is more significant at short follow up regardless the used palatoplasty technique. However, with no significant different at long term (one-year postoperatively) between the two groups. On the contrary, **Lou** *et al.* <sup>[17]</sup> noticed that the improvement was progressive, and hearing returned to normal at age of 6 year. We can attribute this discrepancy to the shorter follow up period in our cases which was less than 6 years.

We think that spontaneous improvement of ET function after palatoplasty can be explained by the fact that realignment of palatal musculature helps middle ear drainage resulting in fewer tubes insertion. Some audiological studies indicated that a basic CP repair operation alone can help restore hearing in persons with CP<sup>[18,19]</sup>.

**Koudoumnakis** *et al.* <sup>[20]</sup> showed that patients' hearing thresholds improve and their incidence of OM decreases with frequent tube insertion; however, a more cautious approach is advised by other studies because to the increased risk of tympanosclerosis and conductive hearing loss with repeated tube insertion. **Smith** *et al.* <sup>[21]</sup> noted that the improvement of ET function that results from palatoplasty do not occur immediately.

In our study, we avoided prophylactic VT insertion but it was performed only postoperatively in indicated cases, which were persistent type B and type C, persistent otitis media more than three months despite the medical treatment, and recurrent otitis media more than five times per year. We think that palatal repair improves ET function regardless the palatoplasty technique. This is consistent with many authors <sup>[18,22-24]</sup> who noticed that all type of palatoplasty improve the ET function and ear condition.

Additionally, the incidence and prevalence of VT insertion across various palatal closure procedures were studied by **Antonelli** *et al.* <sup>[25]</sup>. They said that the Furlow and von Langenbeck palatoplasties did not vary in the requirement for a tympanostomy. According to **Felton** *et al.* <sup>[26]</sup>, there were comparable results on the insertion of VT between the Sommerlad approach and the Furlow palatoplasty.

**Koudoumnakis** *et al.* <sup>[20]</sup> demonstrated that repair with the 2 flap technique resulted in spontaneous resolution of OME in 45% of patients without the use of VT. **Gerson** *et al.* recommended that VT be implanted as necessary for palate repair <sup>[11]</sup>.

On contrary to our results, **Wyszynski** *et al.* <sup>[24]</sup> noted the advantages of the Sommerlad procedure over VWK palatoplasty. Comparing the von Langenbeck and VWK palatoplasties to the Furlow and 2-flap palatoplasties, **Carroll** *et al.* <sup>[6]</sup> found that the former were linked to a greater incidence of VT placement. Furthermore, examining the distinction between the Furlow palatoplasty and the 2-flap palatoplasty, **Smith** *et al.* <sup>[21]</sup> came to the conclusion that children required less VT following the Furlow Palatoplasty than following the 2-flap palatoplasty. **Téblick and associates** <sup>[3]</sup> found that children had fewer OME episodes requiring VT as a result of the Furlow palatoplasty, which produced superior results on ET function.

In agreement with **Sischo** *et al.* <sup>[22]</sup>, **Lithovius** *et al.* <sup>[23]</sup> **and Felton** *et al.* <sup>[26]</sup>, our study did not show a significant relation between the type of palatoplasty operation and the number or time of VT insertion.

## CONCLUSION

Repair of CP results in direct improvement of ET dysfunction. Modified Furlow shows early improvement of ET dysfunction and middle ear condition but has no superiority after one year over two flaps palatoplasty. The modified Furlow and tow flaps palatoplasty procedures show significant effect as regard to decreasing of severity of hearing loss and ET dysfunction. That is allowing of conservative management of middle ear instead of prophylactic tube insertion.

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### REFERENCES

- 1. Goh B, Tang C, Hashim N *et al.* (2019): Hearing status and behavioural patterns among school aged children with cleft lip and/or palate. International Journal of Pediatric Otorhinolaryngology, 118: 1-5.
- 2. Cheong J, Soo S, Manuel A (2016): Factors contributing to hearing impairment in patients with cleft lip/palate in Malaysia: A prospective study of 346 ears. International Journal of Pediatric Otorhinolaryngology, 88: 94-97.
- Téblick S, Ruymaekers M, Van de Casteele E et al. (2019): Effect of cleft palate closure technique on speech and middle ear outcome: a systematic review. Journal of Oral and Maxillofacial Surgery, 77(2): 405. doi: 10.1016/j.joms.2018.09.027.
- 4. Luthra S, Singh S, Nagarkar A *et al.* (2009): The role of audiological diagnostics in children with cleft lip & palate (CLP). International Journal of Pediatric Otorhinolaryngology, 73(10): 1365-1367.
- 5. Kappen I, Schreinemakers J, Oomen K *et al.* (2017): Hearing sensitivity in adults with a unilateral cleft lip and palate after two-stage palatoplasty. International Journal of Pediatric Otorhinolaryngology, 94: 76-81.
- 6. Carroll D, Padgitt N, Liu M *et al.* (2013): The effect of cleft palate repair technique on hearing outcomes in children. International Journal of Pediatric Otorhinolaryngology, **77**(9): 1518-1522.
- 7. Bluestone C, Klein J (2001): Otitis Media in Infants and Children. 3<sup>rd</sup> ed. Saunders; Philadelphia; pp. 58–77.
- 8. Sheahan P, Miller I, Sheahan J *et al.* (2003): Incidence and outcome of middle ear disease in cleft lip and/or cleft palate. International Journal of Pediatric Otorhinolaryngology, 67(7): 785-793.
- **9.** Szabo C, Langevin K, Schoem S *et al.* (2010): Treatment of persistent middle ear effusion in cleft palate patients. International Journal of Pediatric Otorhinolaryngology, 74(8): 874-877.
- **10.** Fria T, Paradise J, Sabo D *et al.* (1987): Conductive hearing loss in infants and young children with cleft palate. The Journal of Pediatrics, 111(1): 84-87.
- **11.** Gerson C, Kernahan D, Rosenstein S (1990): Otologic disease in the cleft palate patient. Cleft lip and palate: a system of management. Baltimore: Williams & Wilkins, pp. 163-166.
- **12.** Khodir M, Soliman M, Aboulhassan M (2022): Evaluation of furlow z-plasty technique with addition of

buccinator myomucosal flap on palatal lengthening for primary cleft palate repair. Alexandria Dental Journal, 47(1): 143-148.

- **13. Bardach J** (1995): Two-flap palatoplasty: Bardach's technique. Operative Techniques in Plastic and Reconstructive Surgery, 2(4): 211-214.
- 14. Kucur C, Şimşek E, Kuduban O *et al.* (2015): Prevalence of and risk factors for otitis media with effusion in primary school children: case control study in Erzurum, Turkey. Turk J Pediatr., 57(3): 230-35.
- **15.** Veau V, Récamier J (1938): Bec de lièvre. Formes cliniques, Chirurgie. Masson et Cie, Paris. pp. 133-147. https://search.worldcat.org/title/bec-de-lievre-formes-cliniques-chirurgie/oclc/803877246
- **16.** Dong Y, Dong F, Zhang X *et al.* (2012): An effect comparison between Furlow double opposing Z-plasty and two-flap palatoplasty on velopharyngeal closure. Int J Oral Maxillofac Surg., 41(5): 604-11.
- **17.** Lou Q, Zhu H, Luo Y *et al.* (2018): The effects of age at cleft palate repair on middle ear function and hearing level. Cleft Palate Craniofac J., 55(5): 753-757.
- **18.** Yules R (1970): Hearing in cleft palate patients. Arch Otolaryngol., 91(4): 319-23.
- **19.** Kuşcu O, Günaydın R, İcen M *et al.* (2015): The effect of early routine grommet insertion on management of otitis media with effusion in children with cleft palate. Journal of Cranio-Maxillofacial Surgery, 43(10): 2112-2115.
- 20. Koudoumnakis E, Vlastos I, Parpounas K *et al.* (2012): Two-flap palatoplasty: description of the surgical technique and reporting of results at a single center. Ear, Nose & Throat Journal, 91(3): 33-37.
- **21.** Smith L, Gubbels S, MacArthur C *et al.* (2008): The effect of the palatoplasty method on the frequency of ear tube placement. Arch Otolaryngol Head Neck Surg., 134(10): 1085-89.
- 22. Sischo L, Wilson-Genderson M, Broder H (2017): Quality-of-life in children with orofacial clefts and caregiver well-being. Journal of Dental Research, 96(13): 1474-1481.
- **23.** Lithovius R, Lehtonen V, Autio T *et al.* (2015): The association of cleft severity and cleft palate repair technique on hearing outcomes in children in northern Finland. J Craniomaxillofac Surg., 43(9): 1863-67.
- 24. Wyszynski D, Sárközi A, Czeizel A (2006): Oral clefts with associated anomalies: Methodological issues. The Cleft Palate Craniofacial Journal, 43(1): 1-6.
- **25. Antonelli P, Jorge J, Feniman M** *et al.* (2011): Otologic and audiologic outcomes with the Furlow and von Langenbeck with intravelar veloplasty palatoplasties in unilateral cleft lip and palate. The Cleft Palate-Craniofacial Journal, 48(4): 412-418.
- **26.** Felton M, Lee J, Balumuka D *et al.* (2017): Early placement of ventilation tubes in infants with cleft lip and palate: A systematic review. Otolaryngology–Head and Neck Surgery, 158(3): 459-464.