Does Palatoplasty Technique Affect The Need For Ventilation Ear Tube Insertion?
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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 [1,2].

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 [3].

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 [1,4]. When compared to the general population, the ET in CP patients exhibits anatomical, morphological, and histological abnormalities [5].

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

Bluestone and Klein [7] 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 age-matched controls [8,9].

The VT implantation in CP patients is still up for debate. According to Fria et al. [10], 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 [11].

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) [12].

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

**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.

Typanometry 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 H₂O), type C (>100 mm H₂O), 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.

![Different types of tympanogram](image)

**Figure (1):** Different types of tympanogram[14].
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 week, 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, X²-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 ± 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 [15].

**Preoperative ear evaluation:**
Preoperatively, most of the patients in the studied groups had effusion (Table 1).

<table>
<thead>
<tr>
<th>Table (1): Preoperative ear evaluation of study groups.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type of tympanometry</strong></td>
</tr>
<tr>
<td>Otoscopic examination</td>
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<tr>
<td>Group 1</td>
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<tr>
<td>Group 2</td>
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</tbody>
</table>

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>
<thead>
<tr>
<th>Table (2): Postoperative Ear evaluation</th>
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<tbody>
<tr>
<td><strong>Time of ear evaluation</strong></td>
</tr>
<tr>
<td>One-month postoperatively</td>
</tr>
<tr>
<td>Otitis Media</td>
</tr>
<tr>
<td>Normal</td>
</tr>
<tr>
<td>3 months postoperatively</td>
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<tr>
<td>Otitis Media</td>
</tr>
<tr>
<td>Normal</td>
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<tr>
<td>6 months postoperatively</td>
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<tr>
<td>Otitis Media</td>
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<tr>
<td>Normal</td>
</tr>
<tr>
<td>One-year postoperatively</td>
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<tr>
<td>Otitis Media</td>
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<tr>
<td>Normal</td>
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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).

Table (3): Postoperative VT insertion in relation to the operation.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group 1</th>
<th>Group 2</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No tube insertion</td>
<td>17(40.5%)</td>
<td>8(26.7)</td>
<td>0.355</td>
</tr>
<tr>
<td>Insertion of tube at 3 m</td>
<td>0</td>
<td>1(3.3%)</td>
<td></td>
</tr>
<tr>
<td>Insertion of tube at 6 m</td>
<td>1(2.4%)</td>
<td>2(6.7%)</td>
<td></td>
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<tr>
<td>Insertion of tube at 12 m</td>
<td>24(57.1%)</td>
<td>19(63.3%)</td>
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</table>

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 [3]. 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 [7]. 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 [15,16].

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 [11].

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. [17] 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 [18,19].

Koudoumnakis et al. [20] 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. [21] 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 [18,22-24] 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. [25]. They said that the Furlow and von Langenbeck palatoplasties did not vary in the requirement for a tympanostomy. According to Felton et al. [26], there were comparable results on the insertion of VT between the Sommerlad approach and the Furlow palatoplasty.

Koudoumnakis et al. [20] 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 [11].

On contrary to our results, Wyszynski et al. [24] 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. [6] 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. [21] came to the conclusion that children required less VT following the Furlow Palatoplasty than following the 2-flap palatoplasty. Téblick and associates [3] 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. [22], Lithovius et al. [23] and Felton et al. [26], 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