Objective: To determine whether the type of palate repair affects the frequency of subsequent ventilation tube placement.

Design: Combined retrospective and prospective cohort with more than 2 years clinical follow-up after palatoplasty.

Setting: Tertiary care children’s hospital and clinic.

Patients: A total of 170 patients with cleft palate (with or without cleft lip) underwent palatoplasty between 1995 and 2003. Sixty-nine patients with less than 2 years of follow-up visits and 1 patient who did not require ear tubes were excluded from this analysis.

Interventions: Either traditional 2-flap palatoplasty (group A) or double-opposing Z-plasty (group B) was performed. The type of palatoplasty performed was based on the reconstructive surgeon’s clinical decision. Ventilation tubes were placed for otitis media, conductive hearing loss, or eustachian tube dysfunction. Patients received routine follow-up care every 6 months or whenever acute problems arose. Data were analyzed with independent t tests, \( \chi^2 \) tests, and Fisher exact tests.

Main Outcome Measures: Number of ear tubes placed after palatoplasty in each group.

Results: Group A had a mean (SE) of 2.9 (0.2) sets of tubes placed, while group B had a mean (SE) of 1.8 (0.2) sets of tubes. Group A had significantly more sets of ventilation tubes placed (\( P < .001 \)) than group B. Subgroup analysis based on type of cleft was performed.

Conclusion: Children with cleft palate who underwent double-opposing Z-plasty had fewer sets of ear tubes placed postoperatively than patients who had traditional repair.


Otitis media with effusion occurs in almost all patients with cleft palate.\(^1,5\) In these patients, middle ear disease persists longer and leads to an increased incidence of conductive hearing loss, language delays, and cholesteatoma over that of their peers.\(^3,7\) To alleviate consequences of chronic ear disease, placement of ventilation tubes (VTs) has remained the mainstay of management.\(^2,5,6\) However, VT placement does not appear to alter long-term hearing outcomes.\(^3,4\)

These patients continue to demonstrate considerably more hearing loss and language delays than the rest of the population despite routine or symptomatic VT placement.\(^3,6,8\) Otitis media with effusion is caused by eustachian tube (ET) dysfunction,\(^8\) of which the cause is multifactorial in patients with cleft palate. It is associated with intrinsic ET abnormalities, including abnormal positioning, immaturity of cartilage development, increased collapsibility of the ET,\(^9,10\) skull base morphologic factors including a reduced sphenopalatine angle,\(^11\) and defective palatal muscle function. Abnormal insertion and function of the tensor veli palatini muscle and/or the levator veli palatini muscle are suggested to cause impaired dilation of the ET and physical obstruction at the dilation of the ET with contraction.\(^1,4,6,7,9,12-19\)

Palatoplasty is documented to decrease the frequency of middle ear disease and to improve hearing and ET function compared with untreated cleft palate.\(^3,6,12,13\) Braganza et al\(^10\) found that soft palate closure resolved otitis media otherwise refractory to medical management. Casselbrant et al\(^11\) also demonstrated, with a surgically created cleft palate in monkeys, that ET function improved with cleft palate repair, suggesting a direct relationship between muscle positioning and ET function. Specifically, studies suggest that functional integrity of the tensor and/or levator veli palatini muscles...
Evaluating the impact of palatoplasty method and timing on middle ear function.

METHODS

A retrospective medical record review of 101 patients with cleft palate (with or without associated cleft lip) was performed. Approval from the human subjects review committee was obtained for this study prior to data collection. Children were enrolled in the Craniofacial Disorders Clinic at Oregon Health & Science University (OHSU), Portland, and had their palatoplasty performed at Doernbecher’s Children’s Hospital, a tertiary pediatric care center within OHSU. Palatoplasties were performed by 4 different reconstructive surgeons (otolaryngologists or plastic surgeons) on the craniofacial disorders team. Palatoplasties were completed between February 1995 and December 2003, with clinical data collected through February 2006. The type of palatoplasty performed and timing of VT placement was based on the reconstructive surgeon’s clinical decision. Patients received routine follow-up care every 6 months or whenever acute problems arose.

Ventilation tubes were placed according to clinical protocol, including patients with a failed newborn hearing screen, recurrent acute otitis media, chronic otitis media with effusion, and conductive hearing loss. Two different classes of VTs were used: grommet-style tubes and long-stay T tubes. The majority of patients received their first set of VT at their initial palatoplasty, which for almost all patients were grommet-style tubes. Within our patient population, it was believed that routine T-tube placement would likely lead to a higher risk of perforation. In this study, T tubes were primarily placed for those patients who demonstrated prolonged, chronic ET dysfunction, and the length of follow-up in these patients was longer than the overall average. Because T tubes were placed with a similar frequency between groups (28% for 2-flap palatoplasty and 30% for Furlow palatoplasty), it was believed that this group of patients could be included in our outcomes analysis.

Data collected on each patient included cleft type, age at palatoplasty, type of palatoplasty, duration of clinical follow-up, and total number of VT placements. To be included in the study, patients had to have received palatoplasty by one of the surgeons on the craniofacial disorders team and have 24 months or more of complete otologic charting.

Of 170 children, there was adequate detail regarding the palatoplasty method and frequency of VT placement in 101 patients. One patient in group A was also excluded from the outcomes analysis because she was the only patient in this study who never required VTs. Of the 100 patients left in the study population, group A comprised 60 patients and group B comprised 40 patients. There were no significant differences in regard to the number of boys and girls, age at initial palatoplasty, or duration of follow-up between groups A and B. These values were also secondarily compared between the subgroups of each type of palatoplasty.

RESULTS

Of 170 children, there was adequate detail regarding the palatoplasty method and frequency of VT placement in 101 patients. One patient in group A was also excluded from the outcomes analysis because she was the only patient in this study who never required VTs. Of the 100 patients left in the study population, group A comprised 60 patients and group B comprised 40 patients. There were no significant differences in regard to the number of boys and girls, age at initial palatoplasty, or duration of follow-up between groups A and B or among their subgroups (Table 2). Table 3 presents the number of syndromic patients in each group.

The decision to schedule VT placement at the same time as palatoplasty for the majority of patients was based on there being 1 less anesthetic event and the high rates of otorrhea (88%) observed in patients with VTs and open cleft palates. Within each group, the rates of early or “preplasty” VT placement were approximately the same, 28% (17 of 60) in group A and 23% (9 of 40) in group B. In these patients in whom early VTs were placed, 39% in

### Table 1. Palatoplasty Group Demographics

<table>
<thead>
<tr>
<th>Demographic</th>
<th>Palatoplasty Group</th>
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<tbody>
<tr>
<td></td>
<td>2-Flap (Group A)</td>
</tr>
<tr>
<td></td>
<td>Furlow (Group B)</td>
</tr>
<tr>
<td>Patients, No.</td>
<td>61</td>
</tr>
<tr>
<td>Boys, No.</td>
<td>31</td>
</tr>
<tr>
<td>Girls, No.</td>
<td>30</td>
</tr>
<tr>
<td>Age at palatoplasty, mean (range), mo</td>
<td>14 (7-51)</td>
</tr>
<tr>
<td>Follow-up duration, mean (range), mo</td>
<td>56 (24-113)</td>
</tr>
<tr>
<td>Age at last follow-up appointment, mean (range), mo</td>
<td>69 (31-129)</td>
</tr>
</tbody>
</table>

aDouble-opposing Z-plasty.

plays an influential role in ET function and the subsequent development of middle ear disease.1,4,5,7,12,14-19

In the 1980s, double-opposing Z-plasty, or Furlow palatoplasty, was introduced by Leonard Furlow Jr, MD, at the Annual Meeting of the American Association of Plastic Surgeons.20 His technique greatly differed from the standard of traditional 2-flap palatoplasty in the degree of dissection and realignment of the palatal muscles, primarily involving the tensor veli palatini muscle and levator veli palatini muscle. When Furlow introduced his technique, he reported that of patients receiving this palatoplasty, 90% or more were without velopharyngeal insufficiency and 14 of 20 patients demonstrated normal hearing at their last evaluation.20 Numerous studies have substantiated that these patients demonstrate better speech and language outcomes than their counterparts who underwent traditional 2-flap palatoplasty.21-24

Studies comparing the effect of Furlow vs other types of palatoplasty on ET function outcomes are limited in the primary literature. Considering the improvement that double-opposing Z-plasty has on speech outcomes in patients with cleft palate, we attempted to identify the effect of the Furlow palatoplasty on ET function and middle ear disease compared with 2-flap palatoplasty. Our hypothesis is that directed repositioning of the 2 muscles thought to be responsible for ET function during Furlow palatoplasty could lead to improved otologic outcomes compared with other techniques. One measure of ET function in patients with cleft palate is frequency of VT placement. This study compares ET function by measuring the frequency of subsequent ear tube placement after each type of palatoplasty.
group A (10 of 17) and 45% in group B (4 of 9) had their VTs replaced at palatoplasty.

Nineteen of the 60 patients in group A (31%) and 12 of the 40 patients in group B (30%) received T tubes during their clinical follow-up examination. T tubes extruded at a mean of 2.3 years or were removed by 4 years, and they were mainly used in patients with the longest follow-up period. Patients in the traditional 2-flap palatoplasty group (group A) had a mean of 76 months (range, 38-113 months) of clinical follow-up, and the Furlow palatoplasty group (group B) had a mean clinical follow-up of 75 months (range, 33-106 months).

Independent t tests were used to compare the mean number of VT placements in respect to palatoplasty type. Group A had significantly more VT sets placed (mean [SE], 2.9 [0.2]) than group B (mean [SE], 1.8 [0.2]) (P < .001) (Table 4). To further examine this relationship, we constructed a 2 χ2 table and contracted the data for VT frequency into the following 2 groups: patients receiving 1 to 2 VT placements vs those receiving 3 or more VT placements. A larger table containing the full range of the number of VT placements for patients receiving 1 to 7 sets would have divided the patients groups into numbers too small to provide a meaningful analysis. We found that there was a significant difference between the 2 treatment groups (P < .001). The patients treated by Furlow palatoplasty required far fewer VT sets, with only 7 of 40 patients (18%) needing more than 2 sets of VTs, whereas 32 of 60 patients (53%) of the traditional palatoplasty patients required 3 or more VT sets.

Subgroup analysis was completed using a Fisher exact test to measure the difference between number of VT placements within each cleft type (cleft lip and palate and isolated cleft palate) (Table 6). This analysis did not reveal a significant difference between cleft subtypes; however, the data appeared to demonstrate a trend toward fewer VT treatments in the Furlow palatoplasty patients (P = .08). Of the 30 Furlow patients (group B) with isolated cleft palate, 25 (83%) required 1 to 2 VT sets during the study period, whereas 7 of the 15 patients (47%) with isolated cleft palate who underwent traditional 2-flap palatoplasty required 3 or more VT sets.

Both groups had comparable frequency of complications, with 28% (17 of 60) in group A and 30% (12 of 40) in group B. Complications included perforations, adhesive otitis, and cholesteatoma. Two patients, both in group A, developed cholesteatomas, which had not recurred after canal wall down tympanomastoidectomy by their last follow-up appointment. No patients had any major perioperative or postoperative complications from their palatoplasty (eg, listulas, airway obstruction, bleeding).

Table 2. Palatoplasty Subgroup Demographics

<table>
<thead>
<tr>
<th>Demographic</th>
<th>2-Flap (Group A)</th>
<th>Furlow (Group B)</th>
<th>2-Flap (Group A)</th>
<th>Furlow (Group B)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients, No.</td>
<td>15</td>
<td>30</td>
<td>46</td>
<td>10</td>
</tr>
<tr>
<td>Boys, No.</td>
<td>10</td>
<td>24</td>
<td>21</td>
<td>2</td>
</tr>
<tr>
<td>Age at palatoplasty, mean (range), mo</td>
<td>14 (9-17)</td>
<td>13 (9-19)</td>
<td>15 (7-51)</td>
<td>12 (10-17)</td>
</tr>
<tr>
<td>Follow-up duration, mean (range), mo</td>
<td>77 (29-113)</td>
<td>70 (30-106)</td>
<td>72 (24-105)</td>
<td>58 (28-82)</td>
</tr>
<tr>
<td>Age at last follow-up appointment, mean (range), mo</td>
<td>63 (44-129)</td>
<td>58 (41-125)</td>
<td>58 (31-129)</td>
<td>46 (43-93)</td>
</tr>
</tbody>
</table>

Abbreviations: CLP, cleft lip and palate; ICP, isolated cleft palate.

Table 3. Patients With Syndromic Cleft Palate

<table>
<thead>
<tr>
<th>Syndrome</th>
<th>2-Flap (Group A), No./Total No. (%)</th>
<th>Furlowb (Group B), No./Total No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Robin sequence</td>
<td>2/61 (3)</td>
<td>3/40 (8)</td>
</tr>
<tr>
<td>Stickler syndrome</td>
<td>2/61 (3)</td>
<td>2/40 (5)</td>
</tr>
<tr>
<td>Other syndromesa 8/61 (13)</td>
<td>3/40 (8)</td>
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</table>

Available literature suggests that Furlow palatoplasty yields better speech outcomes and velopharyngeal closure than other types of 2-flap palatoplasty. Yet, studies are largely absent that assess how double-opposing Z-plasty affects middle ear outcomes and ET function compared with other techniques. Only 1 study was found to directly compare techniques in respect to ET function. Güneren et al7 compared ET function in patients undergoing traditional 2-flap palatoplasty vs Furlow palatoplasty and found no significant differences between groups in the incidence of secretory otitis media after palatoplasty. However, patients underwent their initial palatoplasty at the mean age of 3.2 years, which is considerably later than our mean age of 14 months. The study by Güneren et al7 also used different parameters to assess ET function, placing VT tubes based on tympanometry measurements.

Our study compares the otologic outcomes of patients undergoing 2-flap vs Furlow palatoplasty using the number of VT placements as a measure of ET function. Although there were no significant differences between palatoplasty groups with respect to age at palatoplasty and duration of clinical follow-up, using both indepen-
dent t tests and χ² analysis, we found that traditional palato-
plasty patients received significantly more VT place-
ments than Furlow patients (Table 4 and Table 5). This
may suggest a faster return of ET function in Furlow pa-
tients, however, a randomized controlled study with a
larger number of patients would likely be needed to verify
these conclusions. Results could be further evaluated in
future studies with longer durations of clinical fol-
low-up that also incorporate audiologic data analysis to
evaluate overall middle ear outcomes.

Selection of palatoplasty type may have introduced
some bias into the study, since cleft type is often a de-
terminate for the type of palatoplasty a patient receives
and Furlow palatoplasty is known to be more difficult
in wider clefts. In this retrospective study the decision
regarding the type of palatoplasty was left to the 4 sur-
geons, that is, there is no information from the medical
record review that would indicate why which type of pala-
plasty was chosen. There is no information how wide
a cleft palate was, for example. Consequently, we wanted
to assess if the type of cleft affected VT frequency inde-
pendent of palatoplasty type. A subgroup analysis of pa-
tients with cleft lip and palate and those with isolated cleft
palate compared with the number of VT placements did
not reveal significant differences. Results suggested a trend
toward Furlow patients requiring fewer VT placements
in both the cleft lip and palate and isolated cleft palate
subgroups. This could indicate that patients in the Fur-
low group regained better ET function during the study
period regardless of cleft type; however, the small num-
ber of patients within each subgroup makes it difficult
to make any inference from the data.

Palatoplasty is observed to decrease the frequency of
middle ear disease and improve hearing compared with
untreated cleft palate. Still, the beneficial ef-
fects of palatoplasty on middle ear function are not ob-
served until later in life. Smith et al found that ET
function and resolution of middle ear function did not
occur until a mean of 6 years after palatoplasty. Our
patients were followed for a mean of just under 5 years
after their initial palatoplasty. The decreased frequency
of VT placement found between the 2 groups in the pres-
ent study occurred over a shorter duration than that
observed by Smith et al. This may indicate that ET dys-
function may resolve more quickly after double-
opposing Z-plasty.
Limitations of the present study include retrospective data collection and nonrandom assignment to treatment groups. Surgeon bias may also confound the results reported. Two different classes of VTs were used—long-stay T tubes and grommet-style tubes. In this patient population, it was believed that routine T tube placement may lead to a higher risk of perforation. Many of the patients live far from our center in a rural state, where routine follow-up can be challenging. T tubes placed in this study were primarily for those patients who demonstrated prolonged, chronic ET dysfunction. The length of follow-up in these patients was longer than the overall average. Because T tubes were used in the same frequency between groups, it was believed that we could include data from these patients in our outcomes analysis. Finally, retrieval of final middle ear outcome data was sporadic owing to the diverse geography from which our patient population was drawn. No relationships were found on explicit examination of both audiological and tympanometric data. The data within each subset were too small to make a meaningful statistical analysis. Our database continues to expand in terms of the number of patients and length of follow-up. Future studies will hopefully elucidate final middle ear outcome measures.

In conclusion, in patients with cleft palate, the type of initial palatoplasty performed may affect the resolution of ET dysfunction as measured by frequency of ear tube placement. Our findings suggest that double-opposing Z-plasty may lead to fewer VT placements during the first few years after palatoplasty. The type of cleft palate does not appear to affect these outcomes if double-opposing Z-plasty palatoplasty is performed.

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Author Contributions: Dr Milczuk had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Milczuk. Acquisition of data: Smith, Gubbels, MacArthur, and Milczuk. Analysis and interpretation of data: Smith, Gubbels, MacArthur, and Milczuk. Drafting of the manuscript: Smith, MacArthur, and Milczuk. Critical revision of the manuscript for important intellectual content: Gubbels, MacArthur, and Milczuk. Administrative, technical, and material support: Smith, MacArthur, and Milczuk. Study supervision: Gubbels, MacArthur, and Milczuk.

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REFERENCES