Published in final edited form as:

Int J Pediatr Otorhinolaryngol. 2012 March ; 76(3): 388–391. doi:10.1016/j.ijporl.2011.12.017.

Pre- and Post-Palatoplasty Eustachian Tube Function in Infants with Cleft Palate

Cuneyt M. Alper, MD¹, Joseph E. Losee, MD², Ellen M. Mandel, MD¹, James T. Seroky, MA¹, J. Douglas Swarts, PhD¹, and William J. Doyle, PhD¹

¹Department of Otolaryngology, Children's Hospital of Pittsburgh of UPMC and the University of Pittsburgh School of Medicine

²Department of Plastic Surgery, Children's Hospital of Pittsburgh of UPMC and the University of Pittsburgh School of Medicine

Abstract

Objective—One past study conducted in 1986 reported Eustachian tube dilation with swallowing during the forced response test (FRT) in a very high percentage (>80%) of cleft palate patients both before and after palatoplasty. The present study was designed to determine the reproducibility of those results.

Methods—The FRT was used to evaluate Eustachian tube function in a cohort of cleft palate children before and after palatoplasty. Pre-palatoplasty FRT data were available for 25 ears and post-palatoplasty data were available for 31 ears; 14 ears had paired pre-post palatoplasty test data. The results for the FRT tests were compared between the pre- and post-palatoplasty groups for the cross-sectional data and for the paired subset of ears.

Results—The 3 passive function measures of the FRT, the opening pressure, closing pressure and passive resistance were not different before and after palatoplasty for either data set. Similarly, 2 of the 3 active function measures, active resistance and dilatory efficiency, were not different pre- and post-palatoplasty, but the percent of ears evidencing tubal dilation for the cross-sectional data was 39% and 62% (P=NS) and for the paired subset was 33% and 83% (P=.04) at the pre- and post palatoplasty tests.

Conclusion—Palatoplasty had no effect on most measures of the FRT, but may have had a positive effect on the ability to dilate the Eustachian tube during swallowing. The high frequency of ears with tubal dilation before palatoplasty reported in the 1986 study was not reproduced but that frequency after palatoplasty was similar.

Keywords

Palatoplasty; Eustachian tube function; Otitis Media

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Correspondence To: Cuneyt M. Alper, M.D., Children's Hospital of Pittsburgh of UPMC, One Children's Hospital Drive, 4401 Penn Avenue, Pittsburgh, PA 15224, Phone: 412 692-7003, FAX: 412 692-6074, cuneyt.alper@chp.edu.

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INTRODUCTION

Orofacial clefts including cleft palate with or without cleft lip (CL/P) are common congenital abnormalities with a prevalence of approximately 1.6/1000 live births [1]. One of the complications of the CL/P condition is chronic otitis media with effusion (cOME) which is nearly universal in infant CL/P patients [2] and can persist throughout childhood [3, 4] and into adolescence [5, 6]. A number of studies have evaluated the effect of different palatoplasty methods on post-operative measures of cOME duration, but the results have been conflicting, even when evaluating the same surgical procedure [3, 6–13].

Soon after the recognition of the relationship between CL/P and cOME, Bluestone and colleagues presented test results that supported a causal relationship between poor Eustachian tube (ET) function and cOME in both unrepaired and repaired CL/P patients [14, 15]. Since that time, a number of studies have focused on ET function in CL/P patients at various ages after palatal repair using a wide variety of assessment methods [16–21]. However, with few exceptions [14, 22], most studies did not compare tubal function before and after repair of the palate.

In that regard, Bluestone and colleagues compared the results of a simple test of the active opening ability of the ET as measured by equilibration of applied positive and negative middle ear pressures during swallowing (the Inflation-Deflation test) before and after palatoplasty in CL/P infants [14]. They reported that a greater frequency of ears could reduce applied positive pressure (but not applied negative pressure) by swallowing in the group tested after palate repair when compared to the group tested before palatal repair. In contrast, Doyle and colleagues used that test and the Forced Response Test (FRT) to study the effect of palate repair on ET function in CL/P patients [22]. Interestingly, while few ears could reduce applied positive or negative pressures by swallowing either before or after palate repair, the results of the FRT documented a relatively high frequency of ears (>80%) that could further dilate a pre-dilated ET during a swallow at both time points. This result was unexpected given that an earlier study on CP/L children and adolescents with repaired palates and tympanostomy tubes inserted for cOME reported that only 27% of the ears could further dilate a pre-dilated ET during the FRT [16].

Since 1986, no study has examined the frequency of tubal dilation during the FRT in CL/P patients before and after palatoplasty [22] and, consequently, the reproducibility of those provocative results has not been evaluated. The present study was designed to either replicate or refute the results of that study.

METHODS

The study was approved by the University of Pittsburgh Institutional Review Board (IRB). The parent(s) of non-syndromic infants with CL/P were approached during an early visit to the Cleft Palate Craniofacial Clinic at the Children's Hospital of Pittsburgh of UPMC concerning enrolling their infant with CL/P into this longitudinal study. The study design, parental obligations and study procedures were explained to those parents expressing interest and; if in agreement, written informed consent was obtained.

The FRT requires the presence of a patent tympanostomy tube (or a non-intact tympanic membrane) with no evidence of otorrhea or acute otitis media. Infants seen at the Cleft Palate Craniofacial Clinic of the Children's Hospital of Pittsburgh of UPMC have bilateral tympanostomy tubes placed prior to palatoplasty. On presentation for testing, otoscopy was done by a study physician to document the lack of otorrhea and the status of the tympanostomy tube. Tympanometry was also done to document the patency of the tympanostomy tube. For FRT testing, the child was seated in the parent's lap and gently

restrained. A hermetically sealed plastic probe was introduced into the ear canal. The probe was coupled to a flow sensor, pressure transducer and, via a 3-way valve, to a variable-speed, constant flow pump as described by Cantekin and colleagues [23]. For testing, the constant flow pump was set to deliver ≈ 23 ml/min of air-flow to the middle ear. Preliminary studies showed that lesser flow rates did not maintain an open tubal lumen and that higher flow rates caused discomfort. The application of air-flow to the middle ear increased its pressure to a point where the ET passively opened (Opening pressure-PO). Continued delivery of air-flow usually resulted in a semi-stable system pressure (PS) with the flow rate through the ET being equal to that delivered by the pump (QO). The child was induced to swallow at this time by drinking liquid from a cup or bottle which causes activity of the two paratubal muscles, the tensor veli palatini and levator veli palatini muscles. The activity of these muscles can be associated with either further dilation of the pre-dilated ET lumen, no change or constriction of the pre-dilated ET lumen. These events are measured by recording the pre-swallow system pressure (PA) and maximum air-flow (QA) during the swallow. The pump is then turned off allowing the ET to passively close (PC). The FRT variables analyzed are those representing the passive characteristics of the ET (PO, PC and passive ET resistance $[RS=PS/QO]$), and those representing the active, muscle-assisted function of the ET (ET constriction/dilation, active ET resistance $[RA=PA/QA]$ and ET dilatory efficiency $[DE=RS/RA]$). Note that DE values less than 1 are associated with ET constriction during swallowing while those greater than 1 are associated with tubal dilations. An early convention used in some previous papers was to not include DE values less than 1 in calculating summary statistics for that variable and, for purposes of comparisons, we indicate this as DE'.

Where possible, this test protocol was performed bilaterally and before and after palatoplasty. However, approximately 50% of the pre-palatoplasty and 40% of the post-palatoplasty tests were not done because the child could not tolerate the procedures, the child began to cry during the procedure (which results in un-interpretable test results), the child moved and broke the seal between the test system and ear-canal or the tympanostomy tube was occluded or displaced, or otorrhea/acute OM was observed.

The results are summarized as the average and standard deviations of PO, PC, RS, RA, DE, DE' and the percent of tests evidencing an increase in airflow for the pre-dilated ET lumen (ET dilation) for the pre and post-palatoplasty tests. The results for the continuous variables for all completed tests during the pre-palatoplasty session were compared with those for the post-palatoplasty session using a two-tailed Student's t test evaluated at $p .05$. In a secondary analysis, the results for all ears with paired pre-post palatoplasty tests were compared using a paired Students t test evaluated at $p .05$. The frequency data for ET dilation during swallowing for the pre- and post-palatoplasty data were compared using a Fisher's Exact test evaluated at $p .05$.

RESULTS

Data on at least 1 ear at 1 test time were available for 27 subjects (17 males, 10 females; 22 White, 2 Black, 1 Asian and 2 bi-racial). The average ages at the time of the pre-palatoplasty test, palatoplasty and post-palatoplasty test were 260 ± 91 , 404 ± 67 and 580 ± 144 days and the average times between the pre-palatoplasty test and palatoplasty and the post-palatoplasty test and palatoplasty were -143 ± 56 and 176 ± 143 days, respectively. The distribution of Veau types in the population was 1, 3, 15 and 8 for Veau types 1, 2, 3 and 4, corresponding to a cleft of the palate limited to the soft palate (Veau 1); soft and hard palate (Veau 2), cleft palate with unilateral cleft lip (Veau 3) and cleft palate with bilateral cleft lip (Veau 4). Four surgeons performed the palatoplasties using a Double Opposing Z plasty in all cases.

Preoperative FRT data are available for 11 left and 14 right ears and post-operative test data are available for 17 left and 14 right ears; 14 ears had paired pre-post palatoplasty test data.

The Table reports the values for all FRT variables measured pre- and post-palatoplasty for the cross-sectional data and for the paired data. The lower sample sizes for the closing pressure represent tests where the subject moved and broke the seal between the ear-canal and test instrument before completion of the testing and those with missing values for the active resistance and dilatory efficiency represent tests during which the subject failed to swallow. For the cross-sectional data, there were no significant differences in the tubal opening pressure, closing pressure, active and passive resistances or the dilatory efficiency (as measured by DE or DE') for the pre- versus post-palatoplasty tests. While 62% of the ears tested further dilated their ET post-palatoplasty, only 39% of the ears further dilated their ET pre-palatoplasty, but the difference was not statistically significant. For the paired data set, a similar lack of an effect of palatoplasty on most FRT measures was observed, but in that subset, 83% of the ears further dilated their ET post-palatoplasty as compared to only 33% pre-palatoplasty and this difference was statistically significant (0.04).

DISCUSSION

Chronic OME is very common in CL/P infants and children [2]. While CL/P children tend to "outgrow" the condition by age 5–6 years [3, 4], in a subset of these children the disease persists into adolescence [5, 6]. Chronic OME in the CL/P population is believed to be caused by poor ET function attributable to abnormalities in the morphology of the ET [24–26] and/or altered relationships between the ET and the paratubal muscles that actively open the ET lumen [27].

A variety of methods to assess ET function in CL/P infants and children have been used through the years including, but not limited to, roentgenographic evaluations [15], the sniffing test [17], the compliance test [18], the inflation-deflation test [14, 28] and the FRT [16, 22]. However, with few exceptions, these tests were done on CL/P children after palate repair and most showed ET dysfunction. In the few studies that evaluated ET function before and after palatoplasty, Bluestone and colleagues used the inflation-deflation test and reported an improved ability to reduce applied positive pressure after palatoplasty [14, 28], while Doyle and colleagues used that test and the FRT and reported no significant effect of palatoplasty on any test measure [22]. This discrepancy is mirrored in studies that evaluated the effect of palatoplasty on the time to cOME resolution where some studies reported no effect while others reported a positive effect of palatoplasty [3, 6–13].

The FRT is designed to measure both the passive and active (i.e. muscle assisted opening) properties of the ET [23]. Of the passive variables, the opening pressure is a measure of the mechanical or organic obstruction of the ET lumen, the closing pressure is a measure of the intra-luminal pressure required to maintain a patent lumen and passive resistance is a measure of periluminal pressures acting on the tubal lumen. The active function variables, dilatory efficiency, active resistance and presence/absence of tubal dilation when airflow is being passed through the ET, provide a measure of the ability of the paratubal muscles to actively open the ET lumen during swallowing. In clinical testing of adults and children with cOME, the passive function variables are usually similar in populations of adults and children with and without a history of cOME, but the active function variables are quite different [29, 30]. Specifically, in patients with a history of cOME or with ventilation tubes inserted for cOME, the ET constricts ($DE < 1$) during a swallow, as compared to the normal population where the ET usually dilates ($DE > 1$) upon swallowing as reflected by an increase in tubal airflow.

In that regard, the average estimated values (from graphs that presented mean values but no measures of variability) for the passive FRT parameters of ET opening pressure, closing pressure and passive resistance for the pre-palatoplasty tests recorded in the earlier 1986 study were 390 daPa, 130 daPa and 11 daPa/ml/min as compared to the post-palatoplasty mean values of 400 daPa, 100 daPa and 10 daPa/ml/min, respectively. In the present study, the average pre-palatoplasty values of the opening pressure, closing pressure and passive resistance were 359 daPa, 138 daPa and 9 daPa/ml/min and the post-palatoplasty mean values for those variables were 351 daPa, 108 daPa and 9 daPa/ml/min, respectively. While for both the pre- and post-palatoplasty tests, the values for the ET opening pressure and passive resistance were higher in the previous study when compared to the present study, the significance of these differences cannot be evaluated because the data in the earlier study were presented as graphs without any measure of variability reported. Nonetheless, all of the mean values for the passive ET function variables measured in the previous study were within 1 standard deviation of the respective values measured in the present study.

In contrast, it was surprising that in the 1986 study, the ability of CL/P patients to reduce applied positive and negative pressures was quite limited before and after palatoplasty while the frequency of tubal dilation was more than 80% at both assessments [22]. These data contrast with the pre-palatoplasty and post-palatoplasty frequencies of tubal dilation reported in the present study of 39% and 62%, respectively. Moreover, in the earlier study, DE' for those times was 5.2 and 6.9 (no standard deviation or range reported) while DE' at those times measured in the present study was 4.2 and 3.2, respectively. Thus, while the earlier study did not support an effect of palate repair on active ET function, the present study did. This discrepancy is largely attributable to the much higher frequency of tubal dilation prepalatoplasty in the earlier study (88%) compared to the present study (39%). The post-palatoplasty frequency of tubal dilation was 84% in the previous study and 62% in the present study and we do not consider this difference to be meaningful given the relatively small sample sizes.

There is insufficient information to explain the large between-study differences in the pre-palatoplasty frequency of tubal dilations. However, during a swallow, the pressure-flow recordings during the FRT have different patterns ranging from pure dilation through constriction interrupted by dilation or dilation followed by a constriction or constriction followed by dilation to pure constriction. While the same individual (WJD) analyzed these patterns for both studies (twice for the present study), only recently has the interpretation of these complex waveforms been standardized within and between persons performing the analyses. There, assignment of tubal dilation requires an increase in flow (above the steady state) and a simultaneous pressure drop when measured during an approximate steady-state pressure. We suggest that the between-study difference in the frequency of tubal dilation with swallowing is attributable to differences in the methods of interpreting the raw study data and that the earlier study overestimated the frequency of that event. Unfortunately, the printouts from the 1986 study are no longer available and this possibility cannot be tested.

In summary, ET function was tested in ears of CL/P patients before and after palatoplasty using the FRT. Palatoplasty had little to no effect on the 3 passive parameters measured by the FRT or on 2 of the 3 active parameters measured during that test of ET function. However, the frequency of tubal dilation was much greater after palatoplasty than before palatoplasty and this difference was significant for the subset of ears measured before and after palatoplasty. The high frequency of ears with tubal dilation recorded using the FRT before palatoplasty in a similar study conducted in 1986 [22] was not reproduced but that frequency after palatoplasty was similar between the two studies. Major limitations of both the present and earlier study are the small sample sizes available for analyses and the

difficulties of testing young infants and children which may have introduced artifacts into the results.

Acknowledgments

Supported in Part by NIH grant DC005832. The authors would like to thank Kathleen Tekely, RN, for assistance with subject recruiting, and Juliane Banks, Maria Swarts and Jenna El-Wagga for assistance with data abstraction and formatting.

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TABLE

Sample Size (N), Average (Avg) and Standard Deviation (SD) of the Parameters of the Forced Response Test for the Pre vs. Post Palatoplasty Results and the Corresponding 2-tailed Students t value (t-value) and Probability Level (p-level) for the Cross-Sectional Sample of Individual Ears (Top Rows) and for the Paired Data (Bottom Rows)

	Cross-Sectional Data			Pre-Palatoplasty			Post-Palatoplasty			Statistics	
	N	Avg	Std	N	Avg	Std	N	Avg	Std	t-value	p-value
PO *	25	359.2	154.3	31	351.4	116.8				0.22	0.83
PC	22	138.2	69.4	25	107.5	37.9				1.90	0.07
RO	25	8.8	3.8	31	8.6	3.1				0.22	0.83
RA	23	26.5	26.6	29	18.7	27.8				1.04	0.30
DE	23	1.8	2.4	29	2.1	1.9				-0.50	0.62
DE'	9	4.2	2.2	18	3.2	1.6				1.35	0.19
% Dilation	23	39		29	62						0.16 **
Paired Data											
PO	14	295.7	92.6	14	356.9	158.8				1.14	0.27
PC	10	99.6	39.4	10	108.2	36.1				-0.77	0.46
RO	14	7.9	3.1	14	8.6	4.0				-0.50	0.56
RA	12	23.2	18.5	12	7.6	12.1				2.00	0.07
DE	12	1.6	2.4	12	2.7	1.6				-1.38	0.19
DE'	4	4.4	2.6	10	3.2	1.3				1.18	0.26
% Dilation	12	33		12	83						0.04 **

* Pressure measured in daPa, Resistance in daPa/ml/min, Dilatory Efficiency is dimensionless

** Fisher's Exact Test