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Oral Health–Related Quality of Life and Self-Rated Speech in Children With Existing Fistulas in Mid-Childhood and Adolescence

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Abstract

Objective—To report the associations of oro-nasal fistulae on the patient-centered outcomes oral health–related quality of life and self-reported speech outcomes in school aged-children.

Design—Prospective, nonrandomized multicenter design.

Setting—Six ACPA-accredited cleft centers.

Participants—Patients with cleft palate at the age of mixed dentition.

Interventions—None.

Main Outcome Measures—Prevalence of fistula and location of fistula (Pittsburgh Classification System). Patients were placed into one of three groups based on the following criteria: alveolar cleft present, no previous repair (Group 1); alveolar cleft present, previously repaired (Group 2); no congenital alveolar cleft (Group 3). Presence of fistula and subgroup classification were correlated to oral health–related quality of life (Child Oral Health Impact Profile [COHIP]) and perceived speech outcomes.

Results—The fistula rate was 5.52% (62 of 1198 patients). There was a significant difference in fistula rate between the three groups: Group 1 (11.15%), Group 2 (4.44%), Group 3 (1.90%). Patients with fistula had significantly lower COHIP scores ($F_{1,1188} = 4.79$; $P = .03$) and worse self-reported speech scores ($F_{1,1197} = 4.27$; $P = .04$). Group 1 patients with fistula had the lowest COHIP scores ($F_{5,1188} = 4.78$, $P = .02$) and the lowest speech scores ($F_{5,1188} = 3.41$, $P = .003$).

Conclusions—Presence of palatal fistulas was associated with lower oral health–related quality of life and perceived speech among youth with cleft. The poorest outcomes were reported among those with the highest fistula rates, including an unrepaired alveolar cleft.

Keywords

fistula; speech; quality of life; cleft palate

It is reported in the literature that the incidence of oronasal fistulas in children with clefts varies widely from a low of 0% to as much as 75% of patients (Losee et al., 2009). This wide range likely reflects differences in presurgical and surgical protocols, surgical techniques, surgical skills, variability of cleft severity within the cleft population, and recording and reporting between centers. When present and symptomatic, the existence of oro-nasal fistulas can result in the distortion of speech, nasal air escape, nasal regurgitation of liquids and food, and hearing loss (Muzzaffar et al., 2001).

Various approaches have been taken to describe fistulas based on type, location, and size. The most comprehensive summary of fistula description has been provided by Smith et al. (2007) and Losee et al. (2009) in their Pittsburgh Fistula Classification System, which identifies seven possible fistula locations: (1) uvular, (2) soft palate, (3) junction hard/soft palate, (4) hard palate, (5) junction primary/secondary palate (Veau IV clefts), (6) lingual alveolar, and (7) labial alveolar (Smith et al., 2007). This classification system includes any residual oro-nasal communication as well as fistula “type” primarily based on the reason for its occurrence. The most commonly understood reason for the presence of a fistula is the unintentional occurrence resulting from breakdown following a previous surgical repair that was intended to result in separation of oral and nasal cavities. This type is in contrast to the intentional occurrence of fistula or persistent oro-nasal communication that exists prior to any surgery intended to close it. The most common examples of intentional fistulas are cases of delayed palate closure and delayed closure of the cleft alveolar ridge, as in the case of secondary alveolar bone grafting.

Orthodontic treatment, especially maxillary expansion, has been shown to exacerbate the symptoms associated with fistulas by uncovering covert unintentional fistulas that are asymptomatic and not clinically evident due to palatal scarring and constriction or by increasing the size of fistulas that are already symptomatic (Abyholm et al., 1979). These can occur at any of the seven locations of the Pittsburgh system but are most frequently seen in locations 1 through 5. However, the same sequelae of expansion can occur in cases of intentional fistulas in the area of the unrepaired alveolar ridge when patients are being prepared for secondary alveolar bone grafting (Mercado and Vig, 2009). These fistulas typically occur at locations 6 and/or 7 of the Pittsburgh system.

Regardless of the type or location of residual fistulas, the potential problems with speech and nasal regurgitation of food and liquids may negatively impact a patient’s quality of life (QOL). Although several studies examine outcomes and alveolar fistulas, few studies have examined patient-centered outcomes. In short, scant data exist about speech and related QOL impact from a patient’s perspective. There has also been no assessment regarding the relationship of intentional fistulas or persistent oro-nasal communications on speech and QOL in patients with clefts. Knowledge of the effect of intentional persistent oro-nasal communications on patients, their speech, and their QOL are crucial when providing patient-centered care. For example, fistula may be of little concern to the surgeon, but from the

patient's perspective it may significantly affect QOL. Conversely, additional surgery may be considered necessary by the cleft team to improve the sequelae of fistula, but surgery may represent an additional burden to the patient. The purpose of this investigation was to assess the oral health-related quality of life (OHRQOL) and self-rated speech in youth who were candidates for fistula repair. Our research questions are intended to examine prevalence and type of fistulas observed in this large sample of school-aged children with nonsyndromic cleft lip and palate (CLP) or cleft palate only (CPO) and the association of fistulas on both OHRQOL and perceived speech.

Methods

School-aged youth (ranging in age from 7.5 years to 18 years) evaluated from six multidisciplinary cleft/craniofacial centers (New York University Langone Medical Center in New York, NY; Lancaster Cleft Palate Center in Lancaster, PA; Children's Hospital of Pennsylvania in Philadelphia, PA; University of Illinois at Chicago Craniofacial Center in Chicago, IL; Children's Healthcare of Atlanta in Atlanta, GA; and University of North Carolina Craniofacial Center in Chapel Hill, NC) participated in an observational study of QOL. Inclusion criteria included age, speaking and reading English or Spanish, and having CLP or CLO. Any individual having a syndrome or a midline cleft was excluded. Consents and assents were obtained according to the institutional review boards at all sites. Each participant was evaluated by team clinical specialists to determine cleft status and make surgical recommendations, if indicated. Cross-sectional clinical data at baseline included cleft type, presence of alveolar cleft, previously repaired or unrepaired alveolar cleft, and presence of fistulas. For this investigation, any communication between oral (palatal or labial) and nasal cavities was considered a fistula even if related to an unrepaired alveolar cleft. When present, fistulas were classified according to the Pittsburgh Fistula Classification System (Losee et al., 2009). Furthermore, intentional fistulas were coded as such if they were the result of no attempt at alveolar repair at the time of the assessment; unintentional fistulas were coded as such if they resulted from previous failed attempts at palate and alveolar repairs. The study population was additionally categorized according to the following: congenital alveolar cleft present with no previous alveolar repair (AC), congenital alveolar cleft present with previous alveolar repair performed (ACR), no congenital alveolar cleft (NoAC). The three groups were further coded for presence (F+) or absence (F-) of fistulas, resulting in a total of six groups. Participant demographic characteristics and psychosocial functioning measures were collected in person during clinic visits via self-report or interview.

Self-Report Measures

Brief Demographic Questionnaire—This questionnaire included information about the child's gender, age, race, academic grade of child, and ethnicity.

OHRQOL—At baseline, patients completed the Child Oral Health Impact Profile (COHIP; Broder and Wilson-Genderson, 2007; Dunlow et al., 2007), a validated, 34-item self-report measure with five discrete dimensions using a five-point Likert-type scale: 1 = oral health, 2 = function well-being (e.g., chewing, talking), 3 = treatment expectations, 4 = environment

(school or job), 5 = social/emotional well-being (anxiety, attractiveness, happiness). For the purpose of this study, only the total COHIP scores are reported. Higher scores indicate higher QOL.

Speech—Patients used a 4-point extent of difference (EOD) ordinal scale to self-rate speech. The scale consists of (1) normal—not different from others, (2) mildly different from others, (3) moderately different from others, and (4) severely different from others. This scale has been used in other studies (Strauss and Broder, 1988; Broder et al. 1994).

Data Analyses

Descriptive statistics (means, frequencies) were calculated for patient demographic and clinical characteristics. Chi-square tests with Fisher exact tests of proportion are reported for categorical data comparisons, including the presence or absence of fistula between the AC, ACR, and NoAC groups and type of fistula between groups (intentional/unintentional). The Fisher exact test is appropriate given the small and uneven cell sizes for the fistula-present groups. Means for continuous variables (COHIP and speech rating) are assessed using generalized linear modeling (GLM), which is analogous to analysis of variance with correction for unbalanced data. AC and NoAC, AC and ACR, and fistulas present/fistulas absent are compared on scores for patient-reported OHRQOL and self-rated speech. Pairwise group comparisons were performed to detect differences among the groups with an alpha correction for multiple comparisons applied to keep the overall *P* value at .05. All mean values reported are least-squares means resulting from the GLM; least-squares means are adjusted for all elements in the model.

Results

The mean age for the children in the study was 11.6 years $\pm$ 3.1 years. More than half of the sample (56%) was male. Of the participants, 76% had a diagnosis of cleft lip and palate, and 24% had cleft palate only. With respect to ethnicity, the majority of the sample was white (68%); 16% Hispanic or Latino, 12% other, 11% African American, and 10% Asian. More than half of the sample (55%) reported having private insurance. The average number of prior surgical procedures was 2.7.

Distribution of Fistulas and Fistula Type

The overall fistula rate for participants in the entire sample with fistulas was 5.52% (62 of 1198 participants; Table 1). There was a significant difference in the distribution of fistulas across the groups, $\chi^2(2) = 29.06$, $P < .0001$. The AC group had the highest percentage of participants with fistulas, 11.15% (31 of 278 patients); the ACR group had a fistula rate of 4.44% (24 of 551 participants); and the NoAC group fistula rate was the lowest at 1.90% (7 of 362 participants).

Of the 40 fistulas in the 31 AC patients, 11 (two Type 6 and nine Type 7) would be considered intentional fistulas (Table 2). The remaining 29 AC F (+) patients, all 24 AC F (+) patients, and all seven NoAC F (+) patients would be classified as unintentional fistulas. The distribution of these unintentional fistula rates across groups is statistically significant,

$\chi^2(2) = 24.42, P < .00001$, with AC F (+) demonstrating a slightly higher prevalence than both ACR F (+) and NoAC F (+).

The distribution of fistula types varied by group (Figure 1). The majority of fistulas in the NoAC F (+) patients involved the hard and/or soft palate (Types 1, 2, and 3), and in the majority of AC F (+) and ACR F (+) patients involved the alveolar ridge (Types 5, 6, and 7).

Group Differences

Means testing via GLM revealed that there was a significant difference in the mean ages between the six groups for age ($F_{5,1197} = 31.93, P < .001$). Contrasts were specified to examine the age differences between the groups. AC participants (mean age 9.9 years) both with and without fistulas (mean ages 9.5 years and 9.9 years, respectively) were the youngest ($P < .001$), followed by NoAC participants (mean age 11.6), both with and without fistulas (mean ages 11.7 years and 11.5 years, respectively) ($P < .001$). ACR participants (mean age 12.6 years) with and without fistulas (mean ages 12.6 years and 12.6 years, respectively) were the oldest. All subsequent GLM analyses were controlled for age. The influence of gender was examined and not found to be significant. For the sake of parsimony given the small cell sizes, age was the sole covariate in the GLM model.

OHRQOL

The overall OHRQOL COHIP scores and EOD speech scores are shown in Table 3. A test of the main effect of fistulas comparing the 1136 participants without fistulas to the scores for the 62 participants with fistulas revealed that those with fistulas had significantly lower COHIP scores ($F_{1,1188} = 4.79; P = .03$). A test of the main effect of group ($F_{2,1187} = 3.84, P = .04$) revealed that AC participants had the lowest average COHIP score (90.65), followed by ACR participants (96.4), and NoAC participants had the highest average COHIP score (99.45). The omnibus test comparing the COHIP scores of the six groups ($F_{5,1188} = 4.78, P < .001$) was significant, and the post-hoc pairwise comparison of the means revealed that the COHIP scores for AC F (+) were significantly lower than scores for the other five groups.

Speech

A test of the main effect of fistulas comparing the 1136 participants without fistulas to the scores for the 62 participants with fistulas showed that the those with fistulas had significantly worse self-reported speech scores ($F_{1,1197} = 4.27; P = .04$). A test of the main effect of group ($F_{2,1187} = 3.84; P = .04$) revealed that AC participants had the poorest speech ratings (2.26) when compared with ACR participants (1.99) and NoAC participants (2.0), but the latter two groups were not significantly different from each other for self-rated speech. Direct comparison of the means for all six groups revealed that speech ratings ($F_{5,1188} = 3.41, P = .003$) for AC F (+) were significantly worse than speech ratings for the three nonfistula groups, but not statistically significantly different from the two other groups with fistulas. AC F (–) participants had the best speech scores, which were significantly better than AC F (+), AC F (–), and NoAC F (+) participants.

Discussion

The presence of persistent oro-nasal fistulas presents a known challenge to many cleft palate team members, such as surgeons attempting fistula closure, orthodontists planning tooth movement or maxillary expansion, and speech pathologists addressing persistent hypernasal resonance. Most important, however, these residual fistulas, whether unintentional or intentional, represent potentially negative defects for the well-being of our participants. Although this impact of fistulas on participants has long been acknowledged and accepted, no known published empirical evidence exists documenting the consequences on participants' OHRQOL and perceptions of their own speech. In addition, a number of our treatment options in cleft care, such as delayed alveolar cleft closure until the time of mixed dentition, may be associated with presence of intentional oro-nasal communications. Orthodontic expansion can be associated with uncovering covert or exacerbating overt fistulas, making them more symptomatic (Abyholm et al., 1979). This large population study of youth with clefts from six U.S. cleft centers provided an opportunity to assess the impact of oro-nasal fistula at the time of mixed dentition on oral health and perceived speech results. Given the importance of holistic outcomes in cleft care, this report is timely and relevant (Broder, 2014).

The results indicate that the presence of oro-nasal fistulas had a statistically significant negative impact on OHRQOL and perceived speech outcomes. Our comparative analysis of participants who did not undergo previous alveolar reconstruction (AC) with participants who did have previous alveolar reconstruction (ACR) and participants who had no alveolar cleft (NoAC) demonstrates a decrease in the prevalence of oro-nasal fistulas with the highest incidence in AC. There are two likely explanations for this pattern. First, AC with no previous alveolar repair would be the only group with the addition of intentional fistulas in the area of the alveolar ridge (11 intentional fistulas in addition to the 29 unintentional fistulas in this sample). Second, significant age differences between groups were found. Many AC participants who averaged 9.9 years had unrepaired alveolar clefts that are usually in some stage of orthodontic treatment in preparation for secondary bone graft surgery, normally carried out at approximately the same age. Because maxillary expansion is typically part of that preparation and can uncover or exacerbate unintentional covert fistulas (Abyholm et al., 1979; Mercado and Vig, 2009), an increased prevalence of fistulas at this age and stage of treatment is not unexpected. Furthermore, it is also standard protocol in many centers to combine alveolar bone grafting with repair of any unintentional fistulas to minimize surgeries for patients. Thus it is not unexpected to find a lower unintentional fistula rate in a group of patients who had also previously undergone alveolar repair versus a higher rate in patients yet to have the bone graft surgery.

The OHRQOL and perceptions of speech across these three groups follow an inverse relationship to the prevalence of fistulas: Outcome scores are poorest in AC participants (unrepaired alveolar cleft with the highest fistula rate) and best in NoAC participants (no congenital alveolar cleft with the lowest fistula rate). In the subgroup analysis, the poorest OHRQOL scores and perceived speech scores were in AC F (+) participants. These data suggest that oro-nasal fistulas have a significant, measurable, and negative effect on the QOL and speech in children with a cleft. Furthermore, delay of alveolar cleft repair to the time of

mixed dentition may have a negative impact on patients' well-being and perceived speech, at least up to the point of alveolar repair. Interestingly, the results of this investigation also suggest a positive effect of alveolar and fistula repair, whether done as a primary or delayed procedure, because individuals in the ACR group with significantly better QOL and speech scores included all participants with previous alveolar repair, regardless of the age at repair. However, verification of this observation is not possible with this cross-sectional study but will be examined through longitudinal follow-up of patients postoperatively. Nonetheless, the possible benefits of alveolar repair as a primary procedure, reducing the chance of negative impact of intentional fistulas and exacerbation of unintentional fistulas during mixed dentition preparation prior to secondary bone grafting, need to be considered in treatment approaches. Thus the question of whether primary or delayed alveolar cleft closure would be the better treatment approach is further complicated by this consideration.

Although these data suggest that primary alveolar reconstruction might benefit children with cleft of the primary palate from the standpoint of the effects of fistulas on QOL and self-rated speech, this study only measured a limited number of outcomes related to fistulas affecting the primary and secondary palates. There are other clinical variables associated with the timing and choice of palate and alveolar surgeries that warrant consideration. These issues include facial growth, dental arch relationship, dental development, coordination of orthodontic care and surgery, and perceived burden of care and/or patient and parent satisfaction. In addition to taking measures to minimize growth disturbances, reduce the numbers of surgeries, improve maxillary arch form and speech quality, and so on, our treatment choices must take into account the effects they may have on patients' OHRQOL. In light of the results of this study, anything that can be done to reduce the occurrence of fistulas, to repair fistulas at the earliest possible time, and to use with caution procedures known to exacerbate the symptoms of existing fistulas becomes even more important. These steps may include using surgical procedures that have the lowest risk of unintentional fistulas and minimizing the time delay in the repair of intentional fistulas with full appreciation of the possible negative psychological, social, and speech consequences.

In short, this study is not intended to promote a specific type of treatment plan for alveolar repair nor does it suggest one technique over another. The effects of specific alveolar repair techniques on fistula formation, OHRQOL, and perceived speech results were not analyzed in this study but might be a topic of future research. Our goal was to demonstrate the potential effects of oro-nasal fistula, of any type or cause, on perceived speech results and patients' well-being. Traditionally, the assessment and relevance of patient-oriented outcomes has been given little attention (Broder and Wilson-Genderson, 2007).

This prospective multicenter trial on OHRQOL and perceived speech is one of the largest of its kind. Although we demonstrate statistically significant negative associations between oro-nasal fistulas and QOL impacts, there are limitations to this study when interpreting the results. This study is observational and nonrandomized and treatment protocols for cleft palate repair reconstruction varied across the six study centers with regard to the use of presurgical orthopedics, surgical techniques, and orthodontic care plans. These variables were not recorded as part of our study protocol. Therefore, we cannot comment on the effects of surgery or orthodontic care on the results reported here. Although oro-nasal

fistulas negatively impact QOL and perceived speech, the timing of repair of the alveolus may result in other functional problems that could have negative sequelae that are not assessed in this report. We note that many participants were in mixed dentition, and it is possible that some oro-nasal fistulas had been noted and repaired prior to examination for this study.

In summary, the participants from these centers had fistula rates at the very low end of the range reported by Losee et al. (2009). This low fistula rate prevented any comparative statistical analysis on the effects of fistula location on speech and QOL. Furthermore, because this study did not record the type alveolar surgeries performed on the study participants, one cannot draw conclusions regarding specific surgical techniques nor the protocols on the prevalence of fistula formation.

Conclusion

This investigation into the effects of fistulas on the OHRQOL and self-reported speech ratings of a large sample of patients with clefts revealed a significant negative association on both outcome measures. This effect linked the numbers of fistulas present with poorer total OHRQOL and speech scores. The highest prevalence of fistulas was found in the subgroup of patients who did not undergo previous alveolar reconstruction. The findings should be taken into account when planning surgical, orthopedic, or orthodontic treatment protocols and the effects they may have on a patient's QOL.

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FIGURE 1.

Percentage of fistula types of all fistulas within each group. All second fistulas occurred in cases of alveolar cleft present with no previous repair (AC) (Types 2, 5, 6, and 7) and cases of alveolar cleft present and previously repaired (ACR) (Type 3).

TABLE 1

Sample Description by Age and Fistulae

	AC*	ACR	NoAC	Total
Total patients, N	278	551	369	1198
Mean age (SD), y	9.9 (2.4)	12.6 (3.1)	11.5 (2.9)	11.6 (2.9)
Patients without fistulas, n (%)	247 (89)	527 (96)	362 (98)	1136 (95)
Mean age (SD), y	9.9 (2.4)	12.6 (3.0)	11.5 (3.2)	11.6 (2.9)
Patients with fistulas, n (%)	31 (11)	24 (4)	7 (2)	62 (5)
Mean age (SD), y	9.5 (2.4)	12.6 (3.4)	11.7 (1.9)	11.5 (2.8)
Total fistulas, N	40	25	7	72

† + = second fistulas in nine AC patients and one ACR patient.

* AC = alveolar cleft present, no previous repair; ACR = alveolar cleft present, previously repaired; NoAC = no congenital alveolar cleft; SD = standard deviation..

TABLE 2

Fistula Location by Group

	Patients With Fistulas	Total Fistulas, n	Type						
			1	2	3	4	5	6	7
AC *	31	40	6	3(+3) [†]	0	8	7(+2)	1(+1)	6(+3)
ACR	24	25	0	1	5(+1)	1	8	3	6
NoAC	7	7	2	1	3	1	0	0	0
Total	62	72	8	8	9	10	17	5	15

* AC = alveolar cleft present, no previous repair; ACR = alveolar cleft present, previously repaired; NoAC = no congenital alveolar cleft.

[†] += second fistulas in nine AC patients and one ACR patient.

TABLE 3

Overall Oral Health–Related Quality of Life Child Oral Health Impact Profile (COHIP) and Self-Rated Speech Scores

	AC*	ACR	NoAC	Total
Total patients, N	278	551	369	1198
Patients without fistulas, n	247	527	362	1136
Mean (SD) COHIP	94.9 (17.9)	96.2 (18.8)	100.1 (17.7)	97.2 (18.3)
Mean (SD) speech score	2.11 (.96)	1.89 (.87)	2.04 (.98)	2.0 (0.93)
Patients with fistulas, n	31	24	7	62
Mean (SD) COHIP	86.4 (23.6)	96.5 (26.1)	98.8 (24.5)	91.8 (24.5)
Mean (SD) speech score	2.42 (1.0)	2.08 (1.1)	2.00 (1.0)	2.2 (1.0)

* AC = alveolar cleft present, no previous repair; ACR = alveolar cleft present, previously repaired; NoAC = no congenital alveolar cleft; SD = standard deviation.