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VELOPHARYNGEAL COMPETENCE
A retrospective study of the outcome of primary cleft palate surgery

by

Sharon Hundert 

A thesis submitted to the Faculty of Graduate Studies and Research in partial fulfillment of the requirements for the degree of Master of Science in Speech-Language Pathology

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Edmonton, Alberta

Spring 2001

University of Alberta

Library Release Form

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Title of Thesis: Velopharyngeal Competence: a retrospective study

Degree: Master of Science

Year this Degree Granted: Spring 2001

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ABSTRACT

This retrospective study of data for 161 subjects was completed to determine which independent variables sex, cleft type, age at surgery, surgical procedure, surgeon and/or the presence of fistulae or dehiscence were predictive of the outcome measure, velopharyngeal competence, after primary palate repair. The association of syndromes or sequences relative to the outcome measure was also investigated. Results revealed that three variables were significant predictors of velopharyngeal competence: fistulae ($p < 0.001$), dehiscence ($p < 0.005$) and total cleft palate ($p < 0.05$). Fistulae and dehiscence were also predictive together ($p < 0.0001$). Subsequent classification analyses revealed weak classification abilities for all three of these variables. Sequences and/or syndromes were associated with incompetent VPC ratings. The results of the investigation are discussed with respect to current literature and future research. Study limitations are also reviewed.

DEDICATION

To the many children and their families who I have had the privilege of working with, during my years of affiliation with the Cleft Lip and Palate Clinic and to Myrna Siegenberg, my colleague, mentor and friend.

ACKNOWLEDGEMENTS

I would like to express my appreciation and gratitude to my supervisor, Dr. Anne Rochet, for her support in carrying out this research as well as for her mentorship throughout my Master's program. Neither would have been possible without her patience and commitment.

My appreciation is also extended to my other committee members. My many thanks to Dr. Todd Rogers and his students at CRAME, who were able to teach me the finer points of statistics. Dr. Sharon Warren, through her research design course, gave me the basis to develop the proposal for this project. Dr. Gordon Wilkes, both committee member and colleague, has shared both his wealth of knowledge in the area of cleft palate as well as his sense of humour over the last four years.

The biggest thank you is for my family, who carried on in my absence for the last four years in order for me to realize my dream.

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PROBLEM STATEMENT

One of the main objectives of cleft palate surgery is to create a velopharyngeal mechanism that functions adequately during speech. From 60% to 80% of patients exhibit velopharyngeal competence (VPC) for speech after primary palate repair (McWilliams, Morris and Shelton, 1984). For the remaining 20% to 40% of patients (Witt and Marsh, 1997), the result of surgery with respect to speech is less than satisfactory, and further intervention is required. The challenge is to determine how to achieve a successful outcome of primary palatal surgery and which factor or combination of factors contributes to this result. Hence the purpose of this study was to predict the outcome of primary palate repair based on the variables sex, cleft type, age at surgery, surgical procedure, surgeon and/or post surgical morbidity.

LITERATURE REVIEW

Velopharyngeal competence (VPC) is defined as the ability to control air pressure and airflow for speech and sound-emission patterns which affect aspects of both articulation and resonance (Philips, 1980). Subjective and objective means have been used to measure VPC. The degree of need for secondary management after primary palate repair has been employed as an indicator of the degree of velopharyngeal competence (Marrinan, Labrie, and Mulliken, 1998; LaRossa, Randall, Cohen, and Cohen, 1990). In these instances, criteria for secondary management may vary from patient to patient.

Ordinal subjective rating scales, based on the perceptual evaluation of articulation, intelligibility, and resonance, have also been utilized to assess the degree of velopharyngeal competence (Copeland, 1990; Brothers, Dalston, Peterson, and Lawrence, 1995). While perceptual evaluation is subjective in nature, there are observable characteristics of speech that may complement perception sufficiently to suggest how well the velopharyngeal mechanism is functioning. The Weighted Values for Speech Symptoms Associated with Velopharyngeal Incompetence (McWilliams and Philips, 1979; Philips, 1986) is such a tool. It relies on the clinician's subjective perceptual assessment of a speech sample. Specific characteristics of articulation and resonance are weighted in order to derive a numerical score. This score is converted to an ordinal scale of VPC. The value of this screening tool is that it takes into account both articulation and resonance as well as

their relationship to VPC. This screening tool correlates with the results of instrumental assessments such as videofluoroscopy and pressure-flow measurements during speech (Philips, 1980). These assessments, in addition to the perceptual evaluation, provide information necessary for making decisions regarding the need for secondary management of velopharyngeal incompetence.

Many variables affect the outcome of palatal surgery and VPC. Researchers and clinicians have focused on the effects of patient-related variables, and those related to the surgical repair itself. The relationship between VPC and patient characteristics, such as sex, cleft type, age at surgery and the presence of a syndrome, has been investigated. Studies have also examined the influence of specific surgical procedures, surgeons' skill levels, and post-surgical morbidity on the outcome of palatal surgery.

There are known male-female differences in the distribution of certain cleft types. Isolated cleft palate occurs more frequently in females, while clefts of the lip with or without cleft palate are more prevalent in males (McWilliams, et al., 1984). There is some evidence that sex-related differences may influence a child's potential for speech proficiency. In a longitudinal study of successful outcome of primary palatoplasty, over time, females tended to show greater improvements in articulation and oral-nasal resonance balance than males (Hardin-Jones, Brown, Van Demark, and Morris, 1993).

The type of cleft and its severity have been linked to velopharyngeal competence. Speech of patients with repaired clefts of the soft palate, viewed as the least extensive cleft type, has shown greater improvement over time in comparison to the speech of persons born with other cleft types (Hardin-Jones et al., 1993). Patients requiring secondary surgical management are more likely to have total clefts of the lip and palate rather than clefts of the palate only (Van Demark and Hardin, 1985). On the other hand, Morris et al. (1993) reported an unusually high number of their patients with isolated clefts of the palate required secondary surgery for VPI. There is also evidence that clefts in which there is an absence of attachment of the palatal shelves to the nasal septum (vomer bone) have resulted in less favourable VPC outcomes. This may give rise to a new concept of severity, based on vomeric attachment and its contiguous muscular complex, rather than extent of cleft in an anterior-posterior dimension (Marrinan et al., 1998).

Early surgery, performed prior to twelve months of age, has been reported to positively influence the development of speech and to be associated with fewer compensatory articulation patterns regardless of cleft type (Dorf and Curtin, 1982). Palatal closure at an earlier age is assumed to be beneficial for establishing normal structural relationships and physiologic activity (McWilliams, et al., 1984; Kaplan, 1981). This, in turn, is thought to facilitate the learning of normal patterns of velopharyngeal movement (Shprintzen, 1990) and more normal patterns of speech (Dorf and Curtin, 1982; Randall, LaRossa, Fakhraee, and Cohen, 1983).

The presence of a syndrome may affect the outcome of surgery. In a study conducted by Witt, Myckatyn, Marsh, Grames,and Dowton (1997), patients presenting with palatal clefts associated with a syndrome were more likely to require management of VPI than their nonsyndromic counterparts. The results also revealed differences in the frequency of VPI between subjects with syndromic and nonsyndromic Robin sequence.

Different surgical procedures have yielded different success rates in terms of VPC. When compared with other surgical procedures retrospectively, the Furlow palatoplasty has shown a greater percentage of successful outcomes (McWilliams et al., 1996; Grobbelaar, Hudson, Fernandes, and Lentin, 1995; LaRossa, Randall, Cohen, and Cohen, 1990). Less improvement in speech ratings over time and the need for more frequent secondary management has been reported for the Von Langenbeck bipedicle flap procedure in comparison to the VY pushback (Van Demark and Hardin, 1985, Hardin-Jones et al., 1993). Although the Intravelar Veloplasty (IVV) has been an accepted part of primary palatal repair for over twenty years, there is evidence to suggest the benefit of this procedure upon VPC is minimal (Marsh, Grames, and Holtman, 1989).

A surgeon's training and skill also play a role in the result of the primary repair (Bardach and Salyer, 1995; Rintala and Haapanen, 1995) and the occurrence of post-surgical morbidity (Cohen et al., 1991). Witt, Wahlen, Marsh, Grames, and Pilgram (1998) reported that the cumulative number of surgeries performed by a single surgeon over a twelve-year period, rather than the annual frequency of performing the operation, was the key to the surgeon's improvement. Deficiencies in surgical outcome in other areas of comparably difficult

surgery have consistently been ascribed to low-volume (presumably less-experienced) operators (Williams, Shaw, Sandy, and Devlin, 1996). It could be hypothesized, therefore, that this would also be true for the outcome of cleft palate surgery, which is technically challenging.

The two primary categories of post-surgical morbidity, the presence of fistulae or dehiscences, may affect velopharyngeal function. The presence of post-operative fistulae has been observed to affect velopharyngeal function and characteristics of resonance and articulation (Isberg and Henningsson, 1987; Henningsson and Isberg, 1987). There is a reported correlation between the presence of hard palate fistulae and the degree of velopharyngeal incompetence during both radiographic studies and perceptual speech evaluations (Isberg and Henningsson, 1987). There is also a relationship between the presence of a fistula and characteristics of disordered resonance, reduced intraoral air pressure, and nasal air emission (Henningsson and Isberg, 1987; Shelton and Blank, 1984), which are known correlates of velopharyngeal incompetence. It can be presumed, then, that a similar relationship would exist for dehiscence and speech, although there are no specific reports in the literature.

Clinicians and researchers alike are obsessed with the quality of the outcome of primary palatal surgery. The surgical result significantly affects orofacial growth and development, speech development, appearance, and sense of well being of the patient (Roberts, Semb and Shaw, 1991; Stal; Klebuc, Taylor, Spira and Edwards, 1998). One of the primary goals of cleft palate research is to determine what constitutes the most efficacious treatment for a particular cleft type with respect to both the timing and type of surgical procedure. To this end, the Cleft Palate-Craniofacial Journal has published over 200 papers on some aspect of treatment outcome since 1964 (Witt and Marsh, 1997). The timing of surgery, cleft type, and surgical procedure have each been important considerations at one time or another. The statistical significance of these and other variables has varied from study to study, making it difficult to differentiate those variables that would be the most sensitive early predictors of successful outcome of primary palatoplasty. As well, research has often failed to examine how the relationship among the independent variables would affect outcome.

There continues to be debate as to how best to study cleft palate surgery and its effect on VPC. Errors

in methodology render questionable the reliability and validity of existing studies and influence the credibility of their results as well as the degree to which they can be generalized (Roberts et al., 1991). It is argued by some that prospective, longitudinal, randomized clinical trials (RCT) are necessary to obtain meaningful conclusions from research (Witt and Marsh, 1997; Roberts et al., 1991). While studies of this nature are considered the gold standard, there are matters related to ethics, expense, and the complexity of the process which are difficult to ignore (Berkowitz, 1995; Roberts et al., 1991). An alternative to the RCT is the retrospective research study. It is economical in terms of the time and cost required to complete (Berkowitz, 1995). At the same time, there is concern regarding lack of complete information about subjects as well as lack of equivalency of groups under study, which can create biases (Roberts et. al., 1991). Despite this concern, a retrospective study provides an important historical overview of the evolution of clinical practice as therapies and protocols change. Finally, a retrospective study allows a potentially large sample of subjects and a number of variables to be studied in a short period.

There remains a caveat that only 60 to 80% of all patients will have a competent velopharyngeal mechanism after primary palatoplasty (McWilliams et. al., 1984). Previous research has examined the outcome of cleft palate surgery with respect to subjective judgments regarding characteristics of articulation and resonance related to velopharyngeal incompetence and the need for secondary surgery. Although a number of variables has been studied, their association with the successful outcome of surgery has not been consistent from study to study. The designs of the studies have also affected their validity and reliability. Existing databases are considered important sources of information readily available for retrospective research regarding the outcome of primary palate surgery. It is essential to examine surgical outcomes relative to velopharyngeal function based on the combined salient perceptual characteristics of articulation and resonance rather than on individual features. Additionally, it is important to demonstrate more than an association between VPC and patient- or surgery-related variables. It is critical to analyze the ability and strength of these variables both individually and as a group, to predict VPC. This study was undertaken to utilize available retrospective data to investigate the ability of patient- and surgical variables to predict

VPC.

PURPOSE

The purpose of this study was to predict the outcome of primary palatoplasty with respect to velopharyngeal competence (VPC) in order to inform current and future surgical practice. The research question was: Can the outcome of surgery, measured by VPC, be predicted from sex, cleft type, age at surgery, surgical procedure, surgeon, and/or post-surgical morbidity?

STUDY DESIGN

A retrospective study was carried out. Charts of children registered with the Cleft Lip and Palate Clinic at the University of Alberta Hospital since 1984 were reviewed and data were collected for one dependent variable and seven independent variables.

VARIABLES

The dependent variable, velopharyngeal competence (VPC) at age four or the earliest possible sample time, was the measure of surgical outcome in the study. The score obtained on the Weighted Values for Speech Symptoms Associated with Velopharyngeal Incompetence, hereinafter referred to as "Weighted Values" (McWilliams and Philips, 1979; Philips, 1986) represented the analog of VPC.

Seven independent variables were considered: (1) cleft type, (2) sex, (3) age at primary surgery, (4) surgical procedure, (5) surgeon, (6) dehiscence, and (7) fistula(e). Additional documentation was collected regarding the presence of syndromes with respect to the outcome measure, VPC.

SUBJECTS

The clinical records of 495 children registered with the Cleft Lip and Palate Clinic at the University of Alberta Hospital constituted the pool of potential subjects for this study. Sources of information on the study variables within the children's charts included initial referrals, operative reports, clinical notes, and assessment reports. Charts eligible for review were screened according to the following inclusion and exclusion criteria.

Inclusion Criteria

Charts of patients who underwent primary palatal repair between 1985 and 1995 were included.

Patient diagnoses consisted of syndromic as well as non-syndromic overt cleft lip and palate or cleft palate only. Among these charts, there was evidence that velopharyngeal competence had been assessed at a minimum patient age of four years, either in the form of a VPC score obtained on the Weighted Values instrument (McWilliams and Philips, 1979; Philips, 1986) or in an assessment profile that contained sufficient information to derive a Weighted Value.

Inclusion of patients with diagnoses of syndromic and nonsyndromic clefts allowed for the most comprehensive study sample. Assessment data at a minimum age of four years were chosen so that some stability in children's articulation and language development could be assumed (Shprintzen, 1990).

Exclusion Criteria

Charts were excluded from the review process if they had missing or inadequate data regarding any one of the following: velopharyngeal function by age four, operative procedures and post-operative outcome, or management. Charts of potential patients who exhibited dysarthria, anarthria, dyspraxia, and/or sensori-neural hearing loss were excluded. In these cases, the outcome measure of VPC was considered to be ambiguous with respect to the relative influence of these conditions versus the effects of craniofacial deficit and primary palatoplasty.

Charts of patients with cleft lip only were excluded, as this condition was not pertinent to the surgical field or the outcome measure of VPC. Charts of patients presenting with submucous cleft palate or occult submucous cleft palate also were not reviewed. These covert clefts could not be included due to differences in their underlying dysmorphology, dysfunction, diagnosis, and form of management. In contrast to the identification of an overt cleft, a diagnosis of submucous or occult submucous cleft palate was not always made at birth. The age of primary repair and the management techniques used for children in the submucous cleft palate category also varied considerably from those of the overt cleft palate group. In some cases, prosthetic rather than surgical management of a submucous or occult submucous cleft palate was the preferred method of treatment.

Finally, charts of patients with a post-surgical dehiscence of the palate or palatal fistulae that had been

repaired before the criterion age of assessment of VPC also were excluded from the study. The repair of these dehiscences and fistulae constituted a secondary surgical procedure, which put these cases beyond the scope of the current study.

PROCEDURE

DATA COLLECTION

The hospital charts of 495 patients were reviewed. The charts of patients who met the inclusion criteria were set aside for analysis. A code number unrelated to the patient's hospital identification number was assigned to each chart.

Dependent Variable

Velopharyngeal Competence. Information regarding VPC was obtained from speech evaluation reports in each patient's chart. A VPC score was derived with the Weighted Values tool by evaluating characteristics of articulation, resonance, voice, anatomy, and vegetative function that were related to velopharyngeal competence (see Appendix A). A patient's status was classified according to the following four-point ordinal scale:

1. Competent (a score of 0)
2. Borderline competent (a score of 1-2)
3. Borderline incompetent (a score of 3-6)
4. Incompetent (a score of 7 or more).

Independent Variables

Cleft Type. The Kernahan classification (Kernahan, 1971) was used to document both cleft type and degree of clefting. In this system, cleft type, based on embryological development, is described according to involvement of both the primary and secondary palates or the secondary palate only. Degree of clefting is documented as total or subtotal. The classification includes the categories below (see Appendix B):

1. Total cleft of the secondary palate
2. Subtotal cleft of the secondary palate

3. Bilateral total cleft of the primary and secondary palates

4. Unilateral total cleft of the primary and secondary palates.

Patient data representing both right and left unilateral clefts of the lip and palate were recorded without reference to laterality, as the side of the cleft lip, and when affected, the alveolus were not pertinent to the outcome measure of VPC. Data for patients presenting with subtotal cleft lip were included in the categories of total cleft palate or subtotal cleft palate, depending on the extent of the palatal cleft. Subtotal clefts of the lip are not relevant with respect to VPC particularly when they do not extend into the alveolar process.

Sex. The sex of each patient was documented.

Age at Primary Surgery. A child's age at primary surgery was calculated in months, based on the date of surgery recorded on the operative report. The data for this variable were then grouped into binary categories:

1. Surgery at or before 12 months of age

2. Surgery at or after 13 months of age.

Surgical Procedure. Information regarding the type of surgical procedure performed was obtained from the operative report and the name of the procedure was recorded. The description of the surgical procedure was compared to the operational definitions of the procedures provided by Witt and Marsh (1998). Descriptions of these procedures are provided in Appendix C. The following categories of procedures were used:

1. Von Langenbeck Palatoplasty

2. Von Langenbeck Palatoplasty + Intravelar Veloplasty

3. VY Palatoplasty

4. VY Palatoplasty + Intravelar Veloplasty

5. Furlow Palatoplasty

6. Other.

Surgeon. The primary surgeons were identified from the operative reports. Data were collected regarding the number of surgeries completed by each surgeon. Surgeons were then placed into one of two categories based on the percentage of surgeries completed over the 10-year sampling period for the study:

1. High-volume practitioner
2. Low-volume practitioner.

Surgeons completing 20% or more of the surgeries were considered high-volume practitioners. Those completing fewer than 20% were placed in the low-volume category. This figure was based on a high-volume practitioner completing more than 30 surgeries over the ten-year study period. This took into consideration the influence of cumulative surgeries performed by a surgeon on outcomes of VPC (Witt et al., 1998).

Dehiscence. Post-operative discharge summaries and plastic surgery reports from clinic assessments were reviewed for information regarding the occurrence of unrepaired dehiscences. Dehiscence was classified according to the extent of the cleft that had reopened following surgical repair. The following categories were used:

1. No dehiscence
2. Subtotal
3. Total.

"Total" described dehiscence of both the soft and hard palates, while "subtotal" identified dehiscence involving only the soft palate.

Fistula(e). Information regarding unrepaired fistulae was obtained from post-operative discharge summaries and plastic surgery reports from clinic assessments. Fistula(e) location was classified relative to three positions:

1. In the hard palate
2. At the border of the hard and soft palates
3. In the soft palate.

Residual alveolar clefts that had not been surgically repaired, were not included in the fistula category

or in the analysis because they were not pertinent to the outcome measure, VPC.

Syndromes and Sequences. The ancillary data regarding syndromes and sequences were obtained from clinic assessments as well as reports received following referrals for genetics assessment. Syndromes and sequences were classified according to the following three categories:

1. Syndrome or sequence present
2. Syndrome or sequence not present
3. Presence of syndrome or sequence not confirmed.

DATA ANALYSIS

Descriptive Statistical Analysis

Frequencies for the independent variables were tabulated to identify the demographic characteristics of the study sample. Sample totals for these variables from 1985 to 1995 were computed. The number of subjects diagnosed with syndromes and sequences was also counted when data were available.

The frequencies of VPC ratings were tabulated for each of the independent variables. When data were available, frequencies of VPC among patients with diagnoses of clefts associated with syndromes or sequences were calculated separately.

Inferential Statistical Analysis

A significance level of $p < .05$ was used for all inferential statistics. Two discriminant function analyses of the independent predictor variables with respect to the dependent variable were performed. Prior probabilities were set proportional to the number in each category of VPC.

A zero-order discriminant function analysis was completed for the dependent variable and each of the independent variables separately. Variables reaching statistical significance then were entered into a stepwise discriminant function analysis. This analysis assessed the relative importance of the effect of each of the predictors on the outcome measure, VPC, and selected the most useful discriminating variable(s) based on the Wilks's Lambda values. This multivariate statistic is an inverse measure ranging from 0 to 1, with values closer to 0 denoting a stronger ability to discriminate groups and predict outcomes (Klecka, 1980).

Classification analyses were completed in order to assess the accuracy of both the zero-order and stepwise discriminant function analyses' results. Comparisons were made between the actual and predicted classifications of subjects for each level of VPC in the form of a classification matrix. The matrix showed the number of correctly classified cases on the diagonal. Results were reported as both raw data and percentages. The overall percentage of correct classification for all the levels of VPC combined was based on the sum of the correctly classified cases divided by the total number of cases.

The Pearson chi-square analysis was used to test for associations between a diagnosed syndrome or sequence and VPC status. Due to the limited data regarding sequences and syndromes, the dependent variable, VPC, was treated as a binary variable for this analysis. That is, a competent variable was created that included both competent and borderline competent VPC ratings. An incompetent variable contained the VPC ratings of incompetent and borderline incompetent.

RESULTS

EXCLUSIONS

Of the 495 charts reviewed for the study, 313 were rejected based on the exclusion criteria. One hundred and eight patients presented with clefts of the lip only. Five patients were recorded as having submucous cleft palates. Five patients were diagnosed with submucous cleft palates and clefts of the lip. Fifteen patients were deceased prior to age four. Ten patients presented with dysarthria or dyspraxia, and sensori-neural hearing loss was diagnosed in 16 patients. Revisions of cleft palate repairs that had dehisced, and fistula repairs prior to age four were detected in 16 patients. An additional 138 patients were excluded for the following reasons: no operative reports were available (6 patients); speech assessments were completed prior to age four (39 patients); a VPC score was unavailable or could not be derived based on the chart information (29 patients); and children had been lost to follow-up (64 patients). These exclusions left a potential sample of 182 subjects for study.

SAMPLE REDEFINITION

Upon reviewing the data, the Principal Investigator noted that the sample required redefinition based

on the independent variable, surgical procedures, and the dependent variable, VPC, due to sample size limitations. Redefinition of the independent variable surgical procedures was necessary because few subjects had undergone surgical procedures other than the VY Pushback plus Intravelar Veloplasty. A decision was made to retain the 137 subjects who had undergone the VY Pushback plus Intravelar Veloplasty as well as the 24 who had undergone the Von Langenbeck plus Intravelar Veloplasty procedure. The remaining 21 subjects, who had undergone VY Pushback alone (7), Furlow (7), and other (7) palatoplasties, were excluded from the study. The statistical analyses were completed on a final sample size of 161 subjects.

The data for the dependent variable VPC were originally classified as a four point ordinal scale. Two of these levels, competent and borderline competent, were collapsed into one level, "competent". The rationale for grouping these levels was based on the opinion and experience of the Principal Investigator. Clinically, patients who are considered competent or borderline competent are more similar than those who are incompetent or borderline incompetent. Patients with VPC ratings of competent and borderline competent are considered to have successful surgical outcomes and are not candidates for further physical intervention related to VPC.

CHARACTERISTICS OF STUDY SAMPLE

Table 1 contains the data regarding the characteristics for the final study sample (N = 161). Frequencies are reported for the three levels of the dependent variable VPC, seven independent variables (sex, cleft type, age at surgery, surgical procedure, surgeon, dehiscence, and fistulae), the ancillary data regarding syndromes and sequences, and the independent variables relative to the three levels of VPC. The frequencies are expressed in percentages, with actual numbers contained in parentheses.

Table 1

Sample Characteristics (N=161) for the Dependent Variable, Independent Variables and Ancillary Data

Variable	% (n)	% (n) Competent	% (n) Borderline Incompetent	% (n) Incompetent
Sex				
Male	60.9 (98)	64.3 (63)	21.4 (21)	14.3 (14)
Female	39.1 (63)	49.2 (31)	30.2 (19)	20.6 (13)
Cleft Type				
Unilateral cleft primary and secondary palates	36.6 (59)	66.1 (39)	25.4 (15)	8.5 (5)
Total cleft secondary palate	26.1 (42)	54.8 (23)	16.7 (7)	28.6 (12)
Bilateral cleft primary and secondary palates	22.4 (36)	58.3 (21)	27.8 (10)	13.9 (5)
Subtotal cleft secondary palate	14.9 (24)	45.8 (11)	33.3 (8)	20.8 (5)
Age at Surgery				
≤ 12 months of age	59.6 (96)	61.5 (59)	25.0 (24)	13.5 (13)
≥ 13 months of age	40.4 (65)	53.8 (35)	24.6 (16)	21.5 (14)
Surgical Procedure				
VY Pushback + IVV*	85.1 (137)	59.1 (81)	25.5 (35)	15.3 (21)
Von Langenbeck + IVV*	14.9 (24)	54.2 (13)	20.8 (5)	25.0 (6)
Surgeon				
Low volume practitioner	67.7 (109)	56.9 (62)	23.9 (26)	19.3 (21)
High volume practitioner	32.3 (52)	61.5 (32)	26.9 (14)	11.5 (6)
Dehiscence				
No dehiscence	83.9 (135)	62.2 (84)	25.2 (34)	12.6 (17)
Partial dehiscence	16.1 (26)	38.5 (10)	23.1 (6)	38.5 (10)
Fistulae				
No fistulae	62.7 (101)	64.4 (65)	13.9 (14)	21.8 (22)
Fistulae	37.3 (60)	48.3 (29)	43.3 (26)	8.3 (5)
in hard palate	32.9 (53)	54.7(29)	37.7 (20)	7.5 (4)
at border of hard and soft palates	2.5 (4)	0	75.0 (3)	25.0 (1)
in soft palate	1.9 (3)	0	100.0 (3)	0
Syndromes/Sequences				
Syndrome/sequence present	13.7 (22)	27.3 (6)	45.5 (10)	27.3 (6)
Syndrome/sequence not present	9.9 (16)	62.5 (10)	18.8 (3)	18.8 (3)
Syndrome/sequence unconfirmed	76.4 (123)	63.4 (78)	22.0 (27)	14.6 (18)
VPC ratings for total sample		58.4 (94)	24.8 (40)	16.8 (27)

*IVV = intravelar veloplasty

DESCRIPTIVE STATISTICAL ANALYSES

VPC. Ratings of competent occurred most frequently (f = 94), followed by borderline incompetent (f = 40), and incompetent, (f = 27).

Sex. Males comprised a larger portion of the sample. Both males and females demonstrated competent ratings most frequently in comparison to the other two levels of VPC. Ratings of incompetent were least frequent for both sexes.

Cleft Type. Data regarding cleft type revealed unilateral total cleft of primary and secondary palates to be the most frequently occurring diagnosis; the subtotal cleft palate group was the least frequent. Competent ratings were more frequent than the other two ratings of VPC for all cleft types. Borderline incompetent ratings also were more frequent than incompetent ratings for all cleft types with the exception of total clefts of the palate. For this cleft type, incompetent ratings were more frequent than borderline incompetent ratings.

Age at Surgery. The mean age at the time of surgery for the sample was 12.79 months, (SD = 2.58 months). Primary palatoplasty was completed by 12 months of age more often than at 13 months and older. The mean age at surgery for the early age group was 11.58 months (SD = .61 months), with an intervention range from 10 to 12 months. For children who were 13 months and older, the intervention range was from 13 to 32 months, with a mean age at surgery of 14.57 months (SD = 3.28 months). Late repair was exceptional, with only 3.7% of those in the older intervention group undergoing surgical management after 17 months of age. Both age groups exhibited greater frequencies of competent ratings than the other two ratings of VPC, followed by ratings of borderline incompetent and incompetent.

Surgical Procedure. Of the two surgical procedures, the VY Pushback with Intravelar Veloplasty was used much more frequently than the Von Langenbeck with Intravelar Veloplasty. The VY Pushback plus Intravelar veloplasty procedure demonstrated ratings of competent most frequently, followed by borderline incompetent and incompetent. For the Von Langenbeck plus Intravelar Veloplasty procedure, ratings of competent and incompetent were more frequent than borderline incompetent ratings.

Surgeon. Data for 11 surgeons were included. Percentage of surgeries completed by individual surgeons ranged from .6% to 32.3% (mean 9.4% surgeries, median 4.9% surgeries). The low-volume practitioners included the 10 surgeons who completed less than 20% of the total number of procedures. Together these surgeons accounted for the majority of surgeries. Only four surgeons used both the VY Pushback plus Intravelar Veloplasty and the Von Langenbeck plus Intravelar Veloplasty procedures. Surgical outcomes for both the high- and low-volume practitioners were associated with VPC ratings of competent more frequently than ratings of borderline incompetent and incompetent. Borderline incompetent ratings occurred more frequently than incompetent ratings for both groups as well.

Dehiscences. A large majority of the charts reviewed recorded no dehiscence. Partial dehiscence was recorded infrequently and no total dehiscences were recorded. Subjects without palatal dehiscence demonstrated competent VPC ratings most frequently, followed by borderline incompetent and incompetent ratings. Subjects with dehiscence demonstrated equal frequencies of competent and incompetent ratings. Children with dehiscences presented with these two VPC ratings more often than borderline incompetent ratings.

Fistulae. The greatest number of fistulae occurred in the hard palate. Few fistulae were reported on the border of the hard and soft palates or in the soft palate. Children, both with and without fistulae, presented with competent VPC ratings more often than borderline incompetent or incompetent ratings. For children with fistulae in the hard palate, the competent VPC ratings were most frequent, followed by ratings of borderline incompetent and incompetent. Subjects with fistulae in the border of the hard and soft palates obtained VPC ratings of borderline incompetent and incompetent only. Borderline incompetence was the only VPC rating achieved by subjects with fistulae in the soft palate.

Syndromes and Sequences. Only a small portion of the sample was assessed for the presence of a sequence or syndrome. Of those who were assessed for a genetic condition, more subjects were diagnosed with a syndrome or sequence in addition to the cleft in comparison to the number who were without an additional diagnosis. Pierre Robin Sequence was the most frequently reported diagnosis. Only one

occurrence of this sequence was reported to be syndromic, however. The second most common diagnosis was fetal alcohol syndrome. Aperts, Treacher-Collins, CATCH-22, Van der Woude, and Williams were the other syndromes reported. The subjects diagnosed with a syndrome or sequence more frequently received a VPC rating of borderline incompetent than competent or incompetent ratings. Subjects for whom syndromes or sequences were absent or unconfirmed, presented with higher frequencies of competent than borderline or incompetent ratings.

INFERENTIAL STATISTICAL ANALYSES

Discriminant Function Analysis

The following results were obtained from the zero-order discriminant function analysis and the stepwise discriminant function analysis.

Zero Order Discriminant Function Analysis

At the zero order level, there were three significant predictors of VPC: dehiscence, fistulae, and total cleft palate.

Dehiscence. The independent variable, dehiscence, was statistically significant as a predictor of VPC ($\chi^2 = 11.020$, $df = 2$, $p < .005$). The Wilks's lambda of .933 revealed that dehiscence was not a strong predictor, however, despite reaching statistical significance. Although dehiscence correctly predicted competent VPC ratings more frequently than borderline incompetent or incompetent VPC ratings, the classification results revealed that overall 58.4% of the original VPC ratings were correctly classified. The specific classification results are reported in Table 2.

Table 2

Classification Results of Dehiscence Discriminant Function Analysis

			Predicted Group Membership			
		VPC	Competent	Borderline Incompetent	Incompetent	Total
Original Ratings	Count	Competent	84	0	10	94
		Borderline Incompetent	34	0	6	40
		Incompetent	17	0	10	27
	%	Competent	89.4	0	10.6	100.0
		Borderline Incompetent	85.0	0	15.0	100.0
		Incompetent	63.0	0	37.0	100.0

Fistulae. The independent variable, fistulae, was a statistically significant predictor of VPC ($\chi^2 = 19.701$, $df = 2$, $p < .001$). Although this independent variable reached statistical significance, the Wilks's lambda value of .883 revealed that fistulae was not a strong predictor of VPC. All of the subjects with competent ratings were correctly classified, but none of the borderline incompetent or incompetent cases were correctly classified. The predicted membership for all of the subjects was competent, with a resulting overall correct classification rate of 58.4% for the original VPC ratings. The classification results appear in Table 3.

Table 3

Classification Results of Fistulae Discriminant Function Analysis

			Predicted Group Membership			
		VPC	Competent	Borderline Incompetent	Incompetent	Total
Original Ratings	Count	Competent	94	0	0	94
		Borderline Incompetent	40	0	0	40
		Incompetent	27	0	0	27
	%	Competent	100.0	.0	.0	100.0
		Borderline Incompetent	100.0	.0	.0	100.0
		Incompetent	100.0	.0	.0	100.0

Total Cleft Palate. Total cleft palate was the only cleft type identified as a significant predictor of VPC ($\chi^2 = 6.385$, $\underline{df} = 2$, $\underline{p} < .05$) on the basis of the zero order discriminant function analysis. The Wilks's lambda of .960 revealed total cleft palate to be the weakest of the three significant predictors of VPC, however. As with fistulae, only the competent subjects were correctly classified by total cleft palate and all of the borderline incompetent or incompetent subjects were incorrectly predicted to be competent. Again, the overall correct classification rate was 58.4%. These classification results are contained in Table 4.

Table 4

Classification Results of Total Cleft Palate Discriminant Function Analysis

			Predicted Group Membership			
		VPC	Competent	Borderline Incompetent	Incompetent	Total
Original Ratings	Count	Competent	94	0	0	94
		Borderline Incompetent	40	0	0	40
		Incompetent	27	0	0	27
	%	Competent	100.0	.0	.0	100.0
		Borderline Incompetent	100.0	.0	.0	100.0
		Incompetent	100.0	.0	.0	100.0

Stepwise Discriminant Function Analysis

A stepwise discriminant function analysis was completed using the three independent variabales (dehiscence, fistulae, and total cleft palate) that reached statisticall significance in the zero order analysis. Table 5 contains the results of this analysis. Only fistulae and dehiscence, emerged as significant predictors of VPC.

Table 5

Results of Stepwise Discriminant Function analysis

Step	Variables	Wilks Lambda	df 1	df 2	df 3	Exact F	df 1	df 2	Significance
1	Fistulae	.883	1	2	158	10.491	2	158	.000
2	Dehiscence & Fistulae	.824	2	2	158	7.992	4	314	.000

The results of a subsequent classification analysis revealed that these two independent variables were not strong predictors of VPC, however. Classification was correct for only 59.0% of the original grouped cases. Table 6 contains the classification results. Children with competent VPC ratings were most often correctly classified based on predictions using fistulae and dehiscence.

Table 6

Classification results for the Stepwise Discriminant Function analysis (N = 161)

			Predicted Group Membership			
		VPC	Competent	Borderline Incompetent	Incompetent	Total
Original Ratings	Count	Competent	84	4	6	94
		Borderline Incompetent	34	3	3	40
		Incompetent	17	2	8	27
	%	Competent	89.4	4.3	6.4	100.0
		Borderline Incompetent	85.0	7.5	7.5	100.0
		Incompetent	63.0	7.4	29.6	100.0

Chi-Square Analysis

Results of the Pearson chi-square analysis for associations between syndromes or sequences and VPC status was statistically significant ($\chi^2 = 4.716$, $\underline{df} = 1$, $p < .05$, $n = 38$). A significant association was present between subjects with a diagnosis of a syndrome or sequence and a VPC rating of incompetent.

DISCUSSION

The purpose of the study was to document the outcome of primary palate repair with respect to VPC in the hope of informing future surgical practice. More specifically, the question was whether the independent variables, sex, age at time of surgery, surgeon, dehiscence, or fistulae could predict VPC. Given the ready availability of data for these variables, this prediction, if confirmed, would be useful for long-term planning and follow-up with respect to speech and plastic surgery needs.

Discriminant function analyses were used to investigate the ability of the seven independent variables to predict patients' VPC outcomes and classify them accordingly. Three variables reached statistical significance in the inferential analyses. Dehiscence and fistulae were significant predictors of VPC in both the zero order and the stepwise discriminant function analyses. Total cleft palate was the only other significant predictor of VPC at the zero order level.

The chi-square analysis of the ancillary data for syndromes and sequences, collected in addition to the data that constituted the seven independent variables, demonstrated a significant association between syndromes and sequences and velopharyngeal incompetence.

The following discussion will examine the influence of fistulae, dehiscence and total cleft palate on VPC. Findings regarding the association between syndromes and sequences and VPC will also be reviewed.

FISTULAE AND DEHISCENCE

The fistulae and dehiscence variables were significant as predictors of VPC for both the zero order and stepwise discriminant function analyses, although their high Wilks' lambda values suggested weak classification abilities. Nevertheless, their significance as predictors is both sensible and robust, based on evidence from both clinical practice and the research literature with respect to their effects on the perceptual characteristics of speech, oral pressure, airflow, and adequacy of velopharyngeal function.

Fistulae are holes that develop in the repaired palate, most often at places of extraordinary tension, such as along suture lines or at hard-soft tissue junctions. They are usually classified, as they were in this study, according to location (i.e. in the hard palate, at the border of the hard and soft palates, or in the soft

palate). They can also be described according to their dimensions, both length and width. Dehiscence refers to a breakdown of the surgical wound associated with a palatal repair. It is usually recorded as "total" or "subtotal" (partial). The "subtotal" category may be further defined to indicate the location and extent of dehiscence. Such additional definitions are useful because some wound breakdowns or fistulae may be benign with respect to their effect on speech, while others may have a devastating influence because their location or their dimensions affect speech production.

Cohen et al. (1991) and Emory et al. (1997) reported fistula rates of 23.0% and 11.5% in their study samples respectively, less frequent than the 37.3% reported for the current study. In this study and the research by Cohen et al. (1991), fistulae in the hard palate were most common, with an almost equal distribution of fistulae at the hard and soft palate junction and in the soft palate. Emory et al. (1997) reported equal frequencies of fistula at all three locations. Additionally, 3.5% of their sample presented with total palatal disruption, another term for total dehiscence, in comparison to a rate of 9.0% (16/177) for the current study.

The effect of fistulae and dehiscence must be considered during the perceptual evaluation of speech and resonance. Certain components of the Weighted Values, namely reductions in oral air pressure and the presence of facial grimacing, nasal air turbulence, compensatory articulations, hypernasal resonance, and nasal regurgitation are susceptible to the influence of these post-surgical problems. The presence of fistulae or dehiscence can affect a speaker's ability to impound oral air pressure to produce plosive consonants (i.e., /p, b, t, d, k, g/) or to drive air across an intraoral obstacle to produce fricatives (e.g., /s, z/) or affricates (i.e., /tʃ, dʒ/). Air pressure bleeds off and airflow may escape through a fistula or dehiscence, thereby decreasing available oral air pressure required for accurate production of both plosive and fricative sounds. An air leak can encourage facial grimacing as a speaker attempts to reduce nasal air emission. Nasal air turbulence, associated with a leak through a fistula or dehiscence in the soft palate or uvula, may be audible in the form of snorting or bubbling noises.

Compensatory adjustments in the articulation of phonemes made with anterior points of

articulation (i.e., /p, b, s, z, t, d/) occur primarily when fistulae are present in the hard palate. These phonemes are produced with compensatory points of articulation posterior to the fistulae, in the area of the posterior hard palate or the velum. Compensatory glottal stops or pharyngeal fricatives are substituted in severe cases, when palatal fistulae are large or dehiscence is extensive. Fistulae and dehiscence can affect acoustic characteristics of speech in addition to the aeromechanical characteristics of airflow. There may be hypernasal resonance, particularly for high vowels (i.e., /u, i/), as a result of sound energy being passively transmitted through the palatal tissue barrier that offers less impedance at the site of the fistula or dehiscence. Nasal regurgitation of foods or liquids, through fistulae in the hard palate or a dehiscence in the soft palate, is subsumed among the Weighted Value criteria as well. Though a non-speech problem, it is indicative of the patency of the defect and thus its ability to affect the aeromechanics, acoustics, and articulation of speech .

There is evidence in the literature to support some of the clinical findings regarding the effect of fistulae on speech and velopharyngeal function. Henningson and Isberg (1987) studied the relationship between fistulae in the hard palate and perceptual characteristics of speech similar to those used in the Weighted Values. Using a five-point subjective rating scale, they examined oral-nasal resonance balance, oral air pressure, nasal emission, and compensatory articulations in 10 subjects with fistulae in the hard palate under open and covered conditions. They reported a statistically significant improvement ($p \leq 0.01$) in oral-nasal resonance balance, an increase in the availability of oral air pressure and a reduction in nasal air escape, when speakers produced consonants anterior to the covered fistulae, regardless of the size of the fistulae. The reduction of oral air pressure during production of anterior consonants for open-fistulae conditions, based on the five-point rating scale, showed a moderate correlation with both the increased hypernasality and increased audible nasal escape. Henningson and Isberg (1987) concluded that fistulae of the hard palate, regardless of size, could cause hypernasality, weak pressure consonants and audible nasal escape separate from incompetence related to the function of the velopharyngeal mechanism.

Shelton and Blank (1984) provided further evidence supporting the influence of fistulae on the

aeromechanics of speech. They examined intraoral air pressure and nasal airflow data for patients with oronasal fistulae of varying sizes during production of anterior consonants /p, f, s/. Their findings revealed a systematic variation in intraoral air pressure and nasal airflow with the fistulae open as opposed to covered, which appeared related to fistula size. Nasal airflow was present during the open condition for all fistulae with the exception of the smallest, while only the largest fistulae affected a patient's ability to generate the intraoral air pressure necessary for adequate articulation. It was hypothesized that patients with moderately sized fistulae were able to produce adequate intraoral air pressure by increasing respiratory drive. In these cases, a fricative noise was sometimes perceived as air was lost through the fistulae and the increased oral air pressure drove it fast enough to create turbulent flow. This research demonstrated that palatal fistulae of different sizes can affect intraoral air pressure and nasal airflow in ways similar to varying degrees of velopharyngeal incompetence.

Visualization techniques have also demonstrated that fistula size affects velopharyngeal function. Isberg and Henningson (1987) used cineradiographic studies to demonstrate the effect of fistulae on velopharyngeal activity in 10 subjects with fistulae in the hard palate. A five-point subjective rating scale was used to evaluate movements of the velum and lateral pharyngeal walls during articulation of consonants anterior and posterior to the fistulae, in open and covered conditions. For open fistulae, there was a statistically significant ($p \leq 0.05$) correlation between activity of the lateral pharyngeal walls and both the width and size of the fistulae. Subjects with fistulae that were wider and larger in size presented with poorer lateral pharyngeal wall motion than those with fistulae that were narrower and smaller. The fistulae associated with poor- to no- lateral pharyngeal wall motion were similar in size, expressed in square millimeters, to velopharyngeal openings related to ratings of borderline incompetence and incompetence (Warren, Dalston, Morr, Hairfield, and Smith, 1989).

Changes that speakers make in the presence of a fistula or dehiscence, which affect oral air pressure, nasal air escape, oral-nasal resonance balance and pharyngeal muscle function, appear similar to the compensatory responses that speakers use in the presence of velopharyngeal incompetence as described

by Warren's speech regulation control theory (Warren 1986; Warren et al., 1989). Warren has postulated that speakers attempt to maintain a regulated homeostasis with respect to air pressure for speech in the presence of velopharyngeal incompetence. Furthermore, the degree of incompetence or the size of the fistulae create different magnitudes of error and provoke a variety of compensatory mechanisms to regulate the system for maintenance of aerodynamic stability (Warren, 1986). The cineradiographic evidence of Isberg and Henningson (1987) and the aerodynamic data of Shelton and Blank (1984) have demonstrated that speakers increase respiratory muscle activity to increase airflow rate and maintain the intraoral air pressure and velar resistance necessary for speech production in the presence of small velopharyngeal openings or small fistulae. As incompetence increases due to larger velopharyngeal openings or fistulae, increasing respiratory muscle activity is not sufficient to maintain the intraoral air pressure and velar resistance required for speech. Other compensatory strategies are therefore employed, often at the expense of speech performance (Warren, 1986). These strategies consist of facial grimacing, which increases nasal airway resistance, and compensatory articulations (e.g., glottal stops, velar or pharyngeal fricatives) that minimize the effects of decreased intraoral pressure, increased nasal airflow and increased hypernasal resonance.

While the preceding discussion reveals that there is evidence to suggest that fistula size affects speech regulation control and VPC, there is little information regarding the effect of fistula position. The current study, unlike other studies regarding fistulae (Henningson and Isberg, 1987, Isberg and Henningson, 1987, Shelton and Blank, 1984), included data for soft palate fistulae and those at the junction of the hard and soft palates. All of the subjects, with these types of fistulae in the current study, achieved either borderline incompetent or incompetent VPC ratings. Although there were no data available regarding the size and shape of these fistulae in comparison to those in the hard palate, an inherent difference may explain the poor VPC ratings. During speech, fistulae in the hard palate are static with respect to shape and size, as they are not influenced by the movements of surrounding muscles (Shelton and Blank, 1984). This may not have been the case, however, for the fistulae contained in the soft palate or at the junction of the hard and

soft palates in the current study. These fistulae were of a more dynamic nature because of their soft-tissue boundaries. The movement of the velar musculature during speech may have directly affected their size and shape in ways that had a negative influence on both speech aeromechanics and VPC. Prospective research examining the position of fistulae and their influence on VPC ratings would be beneficial in planning for secondary management.

In summary, although the categories of fistulae and dehiscence were weak predictors of VPC in the current study, there is evidence in the literature to suggest that these defects have the potential to undermine speech aeromechanics, acoustics, and VPC ratings. Clinical findings regarding the susceptibility of certain components of the Weighted Values to the presence of fistulae and dehiscence are supported by the literature pertaining to perceptual characteristics (Henningson and Isberg, 1987), aeromechanics of speech (Shelton and Blank, 1984) and direct visualization of pharyngeal wall function (Isberg and Henningson, 1987). The theory of speech regulation control (Warren, 1986; Warren et al., 1989) provides an explanation for the mechanism of compensation for the speech problems resulting from fistulae and dehiscence. There is also evidence to suggest that the size of fistulae or dehiscence is influential in determining the manner of compensation as well as the VPC rating. As there were no data from the current study regarding the dimensions of the fistulae or the extent of the dehiscence that occurred in the study sample, conclusions could not be drawn with respect to this issue. In view of the importance of this variable in the literature, it will be important for future research to include data regarding both fistula size and degree of dehiscence. This will be beneficial in determining which post-surgical problems are the greatest threats to VPC and ultimately require further management.

TOTAL CLEFT PALATE

Results of the zero order discriminant function analysis revealed total cleft of the secondary palate was the only cleft type to reach statistical significance as a predictor of VPC, although the high Wilks' lambda value (.960) and weak classification results (58.4%) indicated that total cleft palate was not a *strong* predictor of VPC. Nevertheless, its significance warrants brief discussion relative to the results of other

research that has focused on issues regarding the anatomy and physiology of a cleft (Van Demark and Hardin, 1985; Morris et al., 1993; Marrinan et al., 1998) and its relationship to VPC.

Traditionally, the classification of clefts has been based on the extent of the cleft in an anterior-posterior direction (Kernahan, 1971; Berlin, 1971) and has been used to define severity (McWilliams, Morris and Shelton, 1984). Van Demark and Hardin (1985) asserted that subjects with more severe clefts (i.e., those involving both the lip and palate) had a greater risk of VPC requiring secondary surgeries than subjects with less severe clefts (i.e., those of the hard and soft palates or the soft palate only). The results of the current study are in opposition to their findings. In the present sample children with incompetent VPC ratings had total clefts of the palate (i.e., involving the entire hard and soft palates) more often than the other types of palatal clefts. The lack of agreement between the findings of the current study and those of Van Demark and Hardin (1985), raises questions about the limitations of the classification systems as well as the underlying nature of the total cleft palate and its influence on surgical outcome.

Morris et al. (1993) discussed the possibility of anatomical and physiological differences in clefts that include the velum which might affect surgical outcome. Their study of subjects with isolated clefts of the palate (i.e., all cleft types excluding those of the lip and palate) revealed VPC results similar to those found in the current study. Thirty-four per cent of 58 subjects in their study presented with incompetence requiring secondary surgery, a higher "failure rate" than that exhibited by subjects with either unilateral or bilateral clefts of the lip and palate. The authors questioned whether there was less soft tissue in the palate-only group or a difference in the velar tissue that resulted in a shorter, less mobile velum after primary repair, which ultimately affected velopharyngeal function. This report by Morris et al. (1993) reflected a shift in thinking from concentrating on the anterior-posterior extent of the cleft deformity to examining the cleft's influence on the functional potential of the velar muscles.

Marrinan et al. (1998) postulated that the muscles of the velum as well as the size, position, and physiology of the cleft palate and its potential for function after primary repair, rather than the severity of the skeletal deformity alone, might determine the success of surgical repair and ultimately VPC. Marrinan et

al.'s (1998) examination of the need for secondary surgery based on surgical technique, age at repair, and cleft type revealed results similar to those of the current study. Their findings demonstrated that there was an association between the need for secondary surgery and cleft type when the cleft types were grouped based on the concept of vomeric attachment. Patients with clefts without vomeric attachment to the palatal shelves (i.e., bilateral clefts of the lip and palate and total cleft palates) had less successful primary palatoplasty outcomes than those with such an attachment (i.e., unilateral clefts of the lip and palate and clefts of the soft palate). Marrinan et al. (1998) hypothesized that the lack of vomeric attachment to the palatal shelves results in a shorter palate. The palatal muscles are also affected; the levator palatini muscles are no longer in close apposition to each other and are positioned more anteriorly when vomeric attachment is absent.

Kriens' (1990) research regarding the anatomy of the cleft palate with respect to the skeletal defect, palatal shelf inclination, and palatal musculature based on specific palatal measurements also is relevant to the issues of vomeric attachment and velar muscle position. His description of patients with total cleft palate in Pierre Robin Sequence is useful in examining these relationships. Kriens (1990) argued that the cleft associated with Pierre Robin Sequence is the severest form of a cleft of the bony palate, since the palatal cleft is wide and lacks vomeric attachment to the palatal shelves. Additionally, he asserts that the failure to form the velar aponeurosis is the "essence of the velar cleft" (p.294). The aponeurosis, the prerequisite for extrinsic muscular attachment in the medial mass of the velum, normally is positioned horizontally across the velum, between the hamular processes. In the cleft palate patient, the aponeurosis is located almost vertically along the inner aspect of the hamulus. Furthermore, the velopharyngeal fascia is in an abnormal position in the borders of the cleft velar muscles rather than being integrated into the velar aponeurosis. Thus, no intrinsic basis exists to support the union of the velar muscles medially. This soft tissue defect is accompanied by hard tissue malformations in which the inclination of the palatal shelves is steep with a resulting increase in the width of the cleft in both the hard and soft palates.

The presence of Pierre Robin Sequence, associated with a wide, total palatal cleft, would make

repair of the defects of the hard palate and the velar musculature difficult, affecting the outcome of VPC. In fact, in the current study, the majority of the patients with Pierre Robin Sequence had borderline incompetent or incompetent VPC ratings. A comparison of VPC ratings for the subjects with Pierre Robin Sequence with those subjects in the total cleft palate category without the sequence was beyond the scope of the current study. Further investigation is warranted, however, in light of the importance of the anatomical and physiological differences present in the Pierre Robin Sequence population and the resulting effect on surgical outcome and VPC.

In summary, the significance of total cleft of the secondary palate, though weak as a predictor of VPC in this study, has potential to be influential and its value might be stronger in consideration of other factors. The results with respect to incompetent VPC ratings were similar to the outcomes of other research (Morris et al., 1993; Marrinan et al., 1998), which suggest that the reasons for poorer surgical outcomes resulting in poorer VPC ratings in total cleft palate are related to factors in addition to the severity of the bony defect anteroposteriorly. These factors may include the degree of vomeric attachment to the palatal shelves as well as the sagittal dimensions of the cleft, inclination of the palatal shelves, and the orientation of the extrinsic velar muscles. Based on the classification system used in the current study, no conclusions could be made regarding the influence of these factors on the study sample. It will be important in future research of this kind to expand the classification of all cleft palate types to include information regarding these factors. Prospective data should be collected regarding the degree of vomeric attachment to the palatal shelves as well as the dimensions of the palate for all types of clefts. This may provide insight into how these variables affect surgical intervention and may ultimately affect the choice of surgical procedure and the success of surgery as well as outcome for VPC.

VPC AND SYNDROMES AND SEQUENCES

As data for patients with syndromes were limited, a variable syndrome and sequence was not included among the independent variables or in the discriminant function analysis of this study. The syndrome and sequence data that were available were analyzed statistically, however, for the sake of interest and to examine the need for further investigation of these factors.

A chi-square analysis showed a significant association between velopharyngeal incompetence and the presence of a syndrome or sequence. Subjects identified with a syndrome or sequence were more frequently incompetent with respect to VPC than subjects for whom there was no such diagnosis. These findings are in agreement with those of Witt et al. (1997) who reported that 64% of their patients with syndromic isolated clefts of the palate required secondary management of their velopharyngeal dysfunction. The results of the present study should be interpreted cautiously, due to the small sample size and the heterogeneity of the syndrome and sequence group. Nevertheless, these outcomes, in the context of those of Witt et al. (1997) suggest the need for future examination of the presence of a syndrome or sequence as a predictor of VPC.

STUDY LIMITATIONS

"The ideal experimental design would have constant cleft anatomy, all operations performed by the same surgeon, speech evaluations by multiple speech pathologists, instrumental assessment of velopharyngeal function of all patients, and multiple audiological assessments" (Marsh et. al., 1989, p.48). Unfortunately, when data are collected retrospectively in a clinical setting rather than in an experimental one, as they were in this study, there are limitations that will affect the both the internal and external validity of the results. In the current study these limitations included issues related to the sample, as well as measurement and definitions of both the dependent and independent variables.

SAMPLE LIMITATIONS

The sample limitations affected the internal validity of the statistical analyses of some of the independent variables with respect to the dependent variable VPC, the demographics of the sample and

external validity of the results.

Despite the number of charts initially reviewed, the final sample size was small; only 32.52% of the original 495 charts were eligible for inclusion in the study. This small sample size tended to exaggerate the disparity in the frequency distributions of subjects across the independent variables, such as fistulae and dehiscence, which affected both the validity and reliability of the results of the discriminant function analyses. A larger sample size with a minimum of ten subjects in each of the categories of fistulae and dehiscence (Tatsuoka, 1970) might have ensured the robustness of the statistical analysis and help further distinguish the value of these variables as predictors of VPC.

The sample size also affected the analysis of the independent variables, surgeon and surgical procedure. The disparity in the distribution of surgeries completed by low- versus high-volume practitioners in the current study may have influenced the reliability and validity of the discriminant function analysis with respect to this variable. Also, due to the surgeons' preference for one surgical procedure, the VY Pushback plus Intravelar Veloplasty, the significance of the categories other than the VY Pushback plus IVV and the von Langenbeck plus IVV procedures could not be examined. A larger sample size with more equitable representations of the high- and low-volume practitioners and the various surgical procedures would allow for a more robust statistical analysis regarding the relationship of these two variables to VPC. Furthermore, associations of surgical procedures with other variables, such as cleft type and post-surgical morbidity could be examined. Similarly, the association between surgeon and post-surgical morbidity could also be analyzed.

The exclusion criterion for inadequate data may have resulted in sampling bias, which affected the sample demographics. A number of patients (138) were excluded from the study for a variety of reasons related to inadequate data. Patients in this group included those who died, those for whom there were no speech or operative reports, or both, and those who had moved out of the region covered by the clinic or were otherwise lost to follow-up. This form of attrition affects the demographics of the study sample relative to other populations, if categories of the independent variables were more frequently represented in

the lost patients. This may be true of the categories of surgeon, and cleft type relative to sex. It is possible that patients operated on by certain surgeons were excluded from the study more frequently than those operated on by others. On this basis, the surgeons may have been incorrectly classified in the low-volume practitioner category despite having completed the number of surgeries that would have qualified them as high-volume practitioners. Existing databases suggest that clefts involving only the palate occur more frequently in females; however, this was not the case in the current study. Unilateral clefts of the lip and palate occurred more frequently than any other cleft type in the females, followed by total clefts of the palate only. There may have been a higher number of females with clefts of the palate who were eliminated from the study due to attrition, which will ultimately affect the ability to generalize the outcomes of this study to other populations. Sampling bias can be minimized by ensuring the equivalence between groups under study by matching subjects pair-wise on characteristics of gender, age or cleft type (Roberts et al., 1991). In the current study, however, this would likely have further decreased the sample size and affected the strength of the results of the statistical analysis.

MEASUREMENT

Measurement bias associated with surgical procedure coding, the use of the Weighted Values, and hearing loss affected the internal validity of the study.

Coding of surgical procedures presented two inherent difficulties. Firstly, precise identification of surgical procedures in the operative reports was not always provided, which may have compromised the validity of coding this variable. Additionally, although established definitions of operative procedures from the literature were used as references, the extent to which surgeons deviated from the established procedures introduced a systematic error that is inherent in a retrospective study. While operative reports did share common essential elements, there were procedural variations according to surgeons' descriptions. The Principal Investigator attempted to minimize this source of error by participating in a training session with a plastic surgeon specializing in cleft palate repair during which 15 charts that were difficult to code were reviewed to clarify the type of palatoplasty procedure used. After the training session, all the charts were

reviewed a second time to check for errors in the coding of surgical procedures. Analysis of data collected for a single surgeon using multiple procedures or for multiple surgeons performing a single procedure would minimize this form of measurement bias in future studies of this type.

While the use of the Weighted Values rating system for VPC for the duration of the study lends stability to the measurement instrument over time, the application of the instrument and interpretation of its data may have changed. Despite the fact that a single speech–language pathologist, who was experienced in assessing this population (the Principal Investigator), assessed all the subjects included in the study, a single rater's judgment may be unreliable over time (Karnell and Seaver, 1990). In this case there was potential for drift in the investigator's perception of salient characteristics on the Weighted Values associated with a practice effect (Philips, 1980). Internal validity could have been improved by intra-rater and inter-rater reliability checks. To improve intra-rater reliability of the VPC ratings, the Principal Investigator could have re-evaluated 20% of the charts in order to assess the consistency of her application of the Weighted Values criteria across the study. Another individual, experienced in assessing the speech of children with clefts and familiar with the Weighted Values, could have reviewed a random sampling of the charts used in the investigation, in order to assess the reliability of the assigned VPC ratings.

The presence of a conductive hearing loss may have been another issue that confounded VPC ratings. The exclusion criteria for the study were chosen to control for factors other than clefts that would influence the outcome measure VPC. Although one of the means to this end was to exclude patients with sensori-neural hearing losses, this criterion may not have been broad enough with respect to hearing impairment. There were patients in this study sample with hearing losses of a *conductive* nature significant enough to warrant an amplification system and interfere with speech development. It is possible that these patients might have received a VPC rating of *incompetent* due to the influence of their hearing loss on resonance and articulation characteristics of speech, rather than velopharyngeal dysfunction. Their inclusion threatens the internal validity of the assumptions underlying the relationship between the dependent and independent variables and on this basis, they should have been excluded.

OPERATIONAL DEFINITIONS

Definitions of the independent variables surgeon, fistulae and dehiscence, and the dependent variable VPC limit comparisons across studies because of variation between clinical practice and research.

The definition of a high-volume practitioner is variable in the literature. Williams et al. (1996) have referred to low-volume practitioners as surgeons who complete ten or fewer surgeries annually. They further note that these low-volume operators are less likely to be part of a multidisciplinary team and are also less likely to keep standardized patient records. They considered a minimum caseload for a high-volume practitioner to be 20 primary palatal repairs per year. Witt et al.(1998) included surgeons who had completed more that 16 surgeries during a 12 year period in the high-volume practitioner category. For the current study, high-volume practitioners were defined as physicians responsible for a minimum of 20% or 32 of the total 161 procedures included in the study sample. While more stringent than the Witt et al. (1998) definition, the current definition hardly competes with the annual figures defined by Williams et al. (1996). The definition used in the current study is difficult to reconcile due to differences in the population base and the annual number of referrals for the Cleft Palate Clinic catchment area in comparison to those in the literature. A more realistic definition of low-volume practitioner, based on ten or fewer surgeries per year, could be derived from averaging the number of primary cleft repairs completed over the number of years operating. This would take into account both the variability in numbers of surgeries performed annually as well as the number of years a surgeon has been active during a study period.

Issues related to post-surgical morbidity affect the external validity of the results for this variable on VPC. Post-surgical morbidity data were collected for both fistulae and dehiscence and were categorized to reflect the degree of the dehiscence, either subtotal or total, and the occurrence of the fistulae relative to their position in the palate. Comparing the frequencies of these post-surgical problems and their effects on VPC with reports in the literature is difficult due to lack of precise information regarding fistula and dehiscence size. The definition of "subtotal" does not reflect the possible variations in the degree of dehiscence resulting from wound breakdown, from simply an opening in the uvula to a dehiscence of the

entire soft palate. Furthermore, although data were recorded according to fistula position in the palate, there was no mechanism in the current study to relate the size of the fistulae to VPC. As fistula and dehiscence relative to VPC are significant findings, having access to data in patients' charts with respect to fistula size and extent of dehiscence would be worthwhile. This would facilitate comparison with current literature, which describes velopharyngeal function relative to size of fistulae and dehiscence. It would also allow for generalization of the information to other populations of children presenting with similar post-surgical morbidities.

The use of the Weighted Values as a dependent variable measure made comparisons to the current literature difficult. The current study relied on the Weighted Values and a three-level ordinal rating for reporting the outcome, VPC. Although Marrinan et al. (1998) may have documented VPC based on the Weighted Values, their definitive outcome measure was the need for secondary management of velopharyngeal incompetence based on a selected group of perceptual characteristics and not a Weighted Values score, per se. To better compare the results of this study to others that have used secondary management as the outcome measure, subjects' charts could be analyzed for information about the rate of secondary management for children in the borderline incompetent and incompetent categories.

In summary, the value of the results of a retrospective study is linked to the quality of the data (Roberts et al., 1991). Issues related to sample limitations, measurement of the data, and operational definitions in comparison to those already present in the literature, affected the quality of the data analyzed in this study and the validity of its results. The small sample size and the under-representation of categories related to fistulae, dehiscence, surgeon, surgical procedure, specific cleft types for females, and syndromes or sequences influenced the sample demographics and limit the extent to which the results can be generalized to populations who do not share the same characteristics. The small sample size also constrained the performance of statistical analyses that may have been enlightening with respect to the influence of these variables. The adequacy of the information available in the medical records affected the internal validity of the data coded for surgical procedure and VPC. The internal validity of VPC ratings also

was affected by the confounding influence of hearing loss on velopharyngeal function, the subjective nature of the Weighted Values scores, and the failure to assess the reliability of VPC ratings within or between examiners. Finally, differences in definitions for high-volume practitioner, fistulae, dehiscence, and surgical procedure and the outcome measure used in this study in comparison to those employed in other studies posed problems that limited the comparison of these findings to those studies. There are many complexities involved in treating a child with a cleft (Berkowitz, 1995). A retrospective study of this nature stresses the need for standardized practice for all issues related to patient management and documentation. Not only is this beneficial for research, but it is also critical to timely and appropriate patient care.

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APPENDIX A

Weighted Values for Speech Symptoms Associated with VPI

(McWilliams & Philips, 1979; Philips, 1986)

Articulation:
1 point: omission of plosives; omission of fricatives

2 points: reduced oral air pressure on fricatives; nasal turbulence; facial grimacing, intelligibility a concern

3 points: reduced oral air pressure on plosives; pharyngeal turbulence, compensatory articulations

Resonance:
2 points: hypernasal resonance

Voice:
1 point: mildly hoarse

2 points: moderately hoarse

3 points: severely hoarse

Oromotor mechanism:
2 points: nasal regurgitation reported

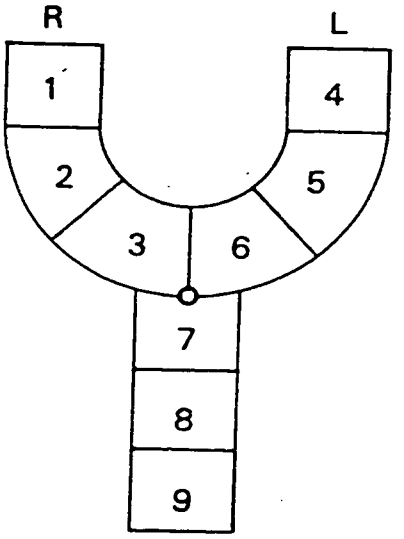
APPENDIX B

Cleft Type Classification

(Kernahan, 1971)

1. Secondary Palate:
    a. total cleft (7-9) including the following:
        i. 1; 7-9 or
        ii. 1-2; 7-9 or
        iii. 4; 7-9 or
        iv. 4-5; 7-9
    b. subtotal cleft (8-9) including the following:
        i. 1; 8-9 or
        ii. 1-2; 8-9 or
        iii. 4; 8-9 or
        iv. 4-5; 8-9

1. Primary and Secondary Palate:
    a. bilateral total cleft including the following:
        i. 1-6; 7-9
    b. unilateral total cleft including the following:
        i. 1-3; 7-9 or
        ii. 4-6; 7-9



APPENDIX C

Surgical Procedures

(Witt and Marsh, 1998)

Von Langenbeck Palatoplasty (VLP) In this procedure, bipedicled mucoperiosteal flaps are raised. Hard palate mucosa is elevated between the bone and the periosteum. After the greater palatine vessels are identified, they are skeletonized and stretched out of the foraminae. The levator palatini muscles are freed from the abnormal attachment at the medial posterior edge of the hard palate. The nasal mucosal layer is closed with inverting suture, then the oral closure is completed.

Veau-Wardill Kilner Palatoplasty (V-Y) In this "pushback" procedure, peninsular flaps are employed. Lateral flaps are elevated and the nasal lining is exposed and freed. The levator palatini muscle is freed and the hamulus is infractured. The nasal lining and muscle is closed. The levator muscle is plicated. The oral mucosa is closed. There is minimal palate exposed.

Furlow Palatoplasty (FP) This procedure is a double-opposing Z-plasty with no relaxing incisions laterally. Primarily a soft tissue operation, there is mobilization of the medial mucoperiosteum. Initially, oral mucosal flaps are marked with levator veli palatini showing through. Oral and nasal flaps are created with levator palatini dissected from the hard palate. The nasal mucosal flaps are approximated. With approximation of the oral mucosal flaps, there is recreation of the levator palatini sling

Intravelar Veloplasty (IVV) Intravelar veloplasty may be employed in addition to either the VLP or V-Y procedures. The muscular insertions are separated from the bone with the muscle then being dissected from the nasal mucosa. The levator veli palatini is completely mobilized and repositioned in a transverse location. It is overlapped and sutured, recreating the levator sling.