Clinical Studies of the Efficacy of Speech Appliances Compared to Pharyngeal Flap Surgery

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The rehabilitation of cleft palate children and adults who present, after primary surgical closure, persistent velopharyngeal insufficiency for speech is a clinical problem which occurs with some frequency. The management of such problems at some treatment centers might be approached generally through the construction of a prosthetic speech appliance. Secondary surgical procedures might almost routinely be used at other centers. At many centers the team members are rightly concerned with establishing criteria for the selection of cases for these alternative procedures.

The pharyngeal flap surgical technique which was re-introduced in the United States in the late 1940's appears now to be the most frequently used secondary surgical procedure for the correction of velopharyngeal incompetences for speech. Moran (*3*), Conway (*1*), Dunn (*2*), and others advocated this operation in the early 1950's. The operation had previously been popularized by Rosenthal (*4*) in 1924 but had apparently been generally abandoned. Some surgeons who used this operation in the 1920's and 1930's discontinued its use because of the tendency of the flap to tube and shrink causing a return of velopharyngeal insufficiency.

Since 1950 the pharyngeal flap operation with various modifications has apparently been used so widely that Webster and others (*5*) proposed a system of classification of the various methods of utilizing posterior pharyngeal tissue so that the operation might be better clinically evaluated. However, objective evaluations of the benefits and the complications following pharyngeal flap operations as compared to treatment of similar clinical problems through prosthetics are still lacking in the literature.

This paper will discuss some of the advantages and disadvantages of these two approaches based on the findings of four clinical studies carried out by the investigator over the past 10 years. The findings of each study, of course, apply only to the specific cases in each group. In such studies, subject variables of type and severity of clefts, timing of surgery, age, etc., can be described but not easily controlled for comparison with other groups. All generalizations, therefore, need to be very cautiously extended

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to other groups of individuals. On the other hand, the four studies present carefully validated and detailed information concerning the efficacy of speech appliances and pharyngeal flap treatment on a total group of 255 cleft palate individuals. The total group might be considered a homogeneous clinical population in that all cases had the common problem of velopharyngeal incompetency before treatment. The studies will be briefly presented here to form a basis for the discussion which will also draw upon clinical experience with cleft palate speech therapy.

Clinical Study 1: Speech Appliance, Longitudinal

The first study was an appraisal of speech appliance rehabilitative treatment of 163 cleft palate subjects treated at the Northwestern University Cleft Lip and Palate Institute. Longitudinal data were collected on each of the subjects. A detailed initial study included case history, cephalometric, dental, orthodontic, medical, surgical, and detailed clinical speech evaluations. The cases were all selected for speech appliance treatment by a decision of the cleft palate team.

Each case was re-evaluated at approximately six month intervals for periods ranging up to 10 years from the time of placement of the appliance. Data recorded and accumulated over this period of time have recently been studied by comparing previously recorded pre-appliance speech, physiological, and cephalometric data with post-appliance data. The frequency of complications, adjustments, need for new appliances, failures, etc., were tabulated for the study population for presentation in the form of group statistics.

Subjects. Table 1 shows that the study group consisted of 163 cases of which 84 were males, and 79 were females. These cases ranged in age from six to 78 years, with a mean age of 24 years. They represented a distribution of all types of cleft conditions involving the soft palate. The group includes 74 cases born with clefts of the secondary palate only and 86 with combined clefts of the primary and secondary palates. Three cases presented problems of congenital palatal insufficiency without clefts.

Only 15 of the 163 cases had not had surgery prior to the recommendation for and the construction of the prosthetic speech appliance. Seventy-

TABLE 1. Distribution by sex and type of cleft of 163 subjects who received speech appliance rehabilitative treatment.

Cleft Type	*Male*	*Female*	*Total*
Palate Only			
Soft Palate	15	1	16
Hard and Soft Palate	43	15	58
Prepalate and Palate			
Unilateral	21	40	61
Bilateral	3	22	25
Congenital Palate Insufficiency	2	1	3
Total	84	79	163

three cases had had only one or two palatal operations, 62 cases had from three to six palatal operations, and 13 had from six to 19 palatal operations before their initial evaluations. One case had surgical redivision of the soft palate to facilitate placement of the speech bulb.

PROCEDURE. Initial clinical evaluations of each of the 163 cases indicated that all presented problems of velopharyngeal incompetency for speech. Incompetency was determined from voice and speech tests, tests of nasal emission, and cephalometric studies of the palate. Additional data included intraoral examinations with recorded descriptions of specific muscle function. In most of the 163 cases the deficiencies were judged to be too extensive for functional surgical reconstruction with the secondary techniques then used at the center.

Without exception, the 163 cases presented speech disorders. Hypernasal resonance distortion of voice was recorded for 106 cases, and distortion of consonant sounds from audible nasal emission was noted in 84 cases; all 163 presented one or both of these speech symptoms of velopharyngeal insufficiency. It should be pointed out that some cases presented nasal emission distortion without obvious hypernasal resonance distortion, particularly if they had deviations of the nasal structures. Others presented hypernasal distortion without detectable nasal emission of the pressure consonants, particularly those who frequently substituted glottal catches for pressure consonants (plosive and fricative sounds). Articulation errors, exclusive of distortions from nasal emission, were found in 92 cases. Phonatory voice disorders of hoarseness or extreme aspirate quality were recorded for 54 cases.

FINDINGS. For simplicity of presentation, findings are briefly presented for this and the pharyngeal flap studies in terms of a) the correction of velopharyngeal insufficiency, b) the correction of speech disorders, and c) ensuing complications.

Correction of velopharyngeal insufficiency. The records indicate that velopharyngeal insufficiency for speech was corrected in 151 cases (92.6%) of the study group. In 88 cases no further adjustments in the size or shape of the speech bulb were necessary after the initial construction and placement of the appliance. However, in 16 cases the speech bulb was not closely fitted at first but rather under-extended in order to develop tolerance of the subject for the prosthesis. For these 16 cases, the speech bulb was later properly adjusted for 10, but six cases did not tolerate a muscle trimmed bulb which could give them good resonance balance. They remained mildly hypernasal. In 53 cases, the speech bulb had to be made somewhat smaller a short time after the placement of the appliance because of the development of muscle activity in the nasopharynx.

In all, there were 12 cases who failed to achieve velopharyngeal function after the speech appliance was made for them. Of these, six cases rejected the use of the prosthesis after it was made. They either complained of discomfort or refused to use the appliance for other reasons. As mentioned previously, an additional six cases failed to achieve good ad-

justment of the speech bulb due to tolerance problems which were not solved.

Correction of speech disorders. Speech problems directly related to velopharyngeal valving (the problems of hypernasality and distortion from nasal emission) were eliminated in 147 cases (90.2%) of the study group. As mentioned previously, 12 cases failed to achieve good velopharyngeal function. An additional four cases appeared to have maintained some hypernasality on a functional basis.

Diagnosable speech disorders of either articulation, phonation, or resonance balance persisted in 66 of the 163 cases (40.5%) of the study group. This large percentage failed to achieve speech free from any distortions mainly due to the persistence of functional articulatory and voice disorders. The majority of these cases were still receiving speech therapy and were in the process of improving their speech skills. All but 12 cases had the structural adequacy to achieve speech free from defects.

Complications. A review of this large group of cases suggests that the most frequent problem encountered in carrying out the prosthetic treatment was the postponement of appliance construction after determining the need for treatment. Postponements occurred mainly in order to provide needed dental or orthodontic treatment which was prerequisite to prosthetic management. Such delays in construction of speech appliances occurred in 106 cases (65%) of the study group.

The need for regular adjustments of the appliance and sometimes for new appliances required long-term supervision of the cases so habilitated. Adjustments after the initial placement of the appliance were needed and obtained in 150 cases (92%). Interestingly enough, only 15 cases (9.2%) had an entirely new appliance after periods of time ranging from two years to 30 years. Two of these 15 cases (young children) lost their appliances and therefore needed a second appliance. These needs are not truly complications, but rather possible disadvantages of following prosthetic rather than surgical treatment.

Other complications that occurred infrequently included: a) retention problems, particularly for edentulous patients, b) caries or peridontal problems in patients with poor oral hygiene, c) tooth eruptions and changing dentition in younger cases requiring prosthetic changes, d) breaking and damaging of appliances through careless handling, and e) failure to come in for needed adjustments.

It should be pointed out that in no case was there evidence of obstruction of the eustachian tubes, nor was there evidence of infectious processes related to the use of speech appliances. There was no finding of any carcinogenic irritations. There were no breathing complications related to the use of speech appliances.

Clinical Study 2: Pharyngeal Flap, Cross-Sectional

In 1959 a group of 27 cases that had previously been treated by pharyngeal flap surgery by a single surgeon at a clinic in Boston, Massachusetts,

were recalled for individual examinations by the investigator at an average of four years after they had received their surgery. Complete pre-operative clinic records including intraoral photographs were reviewed on each case. The main purpose of this study was to test the report of a surgeon that a very wide epithelized pharyngeal flap could correct the tendency of the flap to diminish in size over a period of time.

PROCEDURE. Each case was examined individually. Diagnostic articulation tests, special clinical tests for nasal emission and hypernasal resonance, and direct examination of the structure and function of the organs of speech were carried out and recorded on prepared forms. Judgments regarding resonance balance and phonatory voice quality were determined from sustained isolated vowels and during connected speech. Information from each direct evaluation was categorized on a speech appraisal form under the following categories: a) organic speech problems, such as velopharyngeal insufficiency, occlusal and dental hazards to speech, and hearing loss and b) functional speech problems, such as gross sound substitutions, voice adjustments, and developmental speech disorders.

Hi-fidelity tape recordings were also made of the connected speech of each subject. The tape recordings of each patient's connected speech were later re-evaluated by two experienced speech pathologists for both articulation and voice judgments. These judges agreed 90% of the time with the specific articulation evaluations of the investigator and 94% of the time on voice judgments. Tapes were played backwards on judgments regarding hypernasality to eliminate contamination of nasality judgments from articulation errors.

SUBJECTS. Table 2 shows that the group included 15 males and 12 females, 13 of whom were born with clefts of the palate only and the remaining 14 with combined clefts of the pre-palate and palate. Ages ranged from two years nine months to 52 years, with a mean age of 14.3 years. The total group included 27 subjects: nine of whom had received the pharyngeal flap as a primary closure technique for clefts involving the palate; the remaining 18 had the technique as a secondary operation for the correction of gross velopharyngeal insufficiency after previous surgery.

TABLE 2. Distribution by sex and type of cleft of 27 subjects who had received pharyngeal flap surgery an average of four years prior to their evaluation.

Cleft Type	*Male*	*Female*	*Total*
Palate Only			
Soft Palate	0	2	2
Hard and Soft Palate	4	7	11
Prepalate and Palate			
Unilateral	7	2	9
Bilateral	4	1	5
Total	15	12	27

FINDINGS. *Correction of velopharyngeal insufficiency.* Velopharyngeal insufficiency for speech was judged corrected in 24 of 27 cases (89%) in the study group. However, an additional four cases with mild hypernasality were also found where the pharyngeal flap was used as a primary operation and a hard palate obturator was not functionally fitted at the time of the study.

Correction of speech disorders. Three cases presented speech problems of moderate to severe hypernasal distortion directly related to velopharyngeal insufficiency for speech. An additional four cases presented speech deviations of mild hypernasal distortion due to non-functioning obturators. The remaining 20 cases were free from speech problems related directly to velopharyngeal insufficiencies.

Only three cases were completely free from any speech deviations due to the persistence of functional articulation, phonation, or resonance abnormalities of speech. However, in 10 cases (37%), remaining articulation distortions were apparently directly related to dental or occlusal hazards, and in two cases (7%), to hearing impairments.

Functional speech problems were common in the study group. Sixteen of the 27 cases (59%) still used many glottal stops or pharyngeal fricatives which distorted their speech and marked them as cleft palate speakers. Fourteen cases (52%) had voice problems other than hypernasality which affected their speech intelligibility. Nine cases (33%) had functional articulation abnormalities.

Complications. Two adult cases who presented moderate hypernasality appeared to have been less successful because of conditions of chronic rhinitis which led the surgeon to widen the orifices.

Speech problems due to malocclusions and hearing loss limited the actual speech improvement obtained by all but three subjects since adequate orthodontic and speech therapy facilities were not available to all subjects after surgery.

Clinical Study 3: Pharyngeal Flap, Longitudinal

A second and more extensive study of the efficacy of pharyngeal flap surgery was carried out at Northwestern University Cleft Lip and Palate Institute from 1954 to 1961. All cases were treated by one surgeon with a very wide pharyngeal flap designed specifically to leave an epithelized orifice of approximately 3 mm on each side of the flap which could be obturated by the mesial movement of the salpingopharyngeal fold.

PROCEDURE. Pre-operative descriptive data were obtained from detailed direct clinical examinations on all cases selected for this operation. An evaluation of the immediate effect of surgery was made through a comparison of these data with identical two week post-operative evaluation data. In each case, evaluations included a cephalometric study, hi-fidelity tape recordings of connected speech, intraoral examinations with recordings of judgments of muscle activity, measurements of perforations, and clinical articulation and voice tests of speech proficiency.

A detailed surgical report was added to the files in each case by the surgeon. Included in these were observations of muscle activity following stimulation of the palate and pharynx after each patient was brought from deep to light anesthesia.

Thereafter, direct clinical evaluations were carried out at six month intervals on each case. At the termination of the study, information was charted in chronological order for periods of time ranging from two to six years for individual cases. The data charted for a total of the 40 patients included: a) the biometric measures of velopharyngeal area from 196 cephalometric x-rays, b) information from 40 surgical records, c) 290 separate speech evaluations made by three different judges on 104 tape recordings, and d) 220 direct clinical speech evaluations and descriptive judgments regarding the structure and function of the organs of speech by two speech pathologists.

Reliability Studies. Reliability of the investigator's judgments regarding resonance voice problems was determined in three ways. First, the judgments were compared with another set of judgments made independently by another speech pathologist. Of 120 pairs of judgments, the two judges agreed 100% of the time about presence or absence of hypernasality or hyponasality and 94% of the time on the degree of hypernasality (mild, moderate, or severe). Secondly, the investigator and two other speech therapists separately rated relatively long tape recorded samples of speech including sections of clinical speech tests. Agreement ranged from 92% to 98%. Thirdly, comparison of the investigator's direct judgments and judgments from tape recordings revealed 94% agreement.

Reliability of articulation judgments was determined on five cases from simultaneous but separate direct evaluations of two judges. The two judges agreed 98% of the time about the presence of error sounds and 91% of the time about the specific errors found.

Subjects. Table 3 shows the sex distribution and the type of cleft conditions present for the 40 subjects studied in detail in the manner described above. The study group was composed of 22 males (55%) and 18 females (45%). The mean age of this group was 16.6 years and ranged

TABLE 3. Distribution by sex and type of cleft of 40 subjects studied before and after pharyngeal flap surgery.

Cleft Type	*Male*	*Female*	*Total*
Palate Only			
Soft Palate	4	2	6
Hard and Soft Palate	7	7	14
Prepalate and Palate			
Unilateral	10	9	19
Bilateral	0	0	0
Velopharyngeal Insufficiency without Cleft Palate	1	0	1
Total	22	18	40

from four to 45 years. All of these subjects had velopharyngeal incompetency before surgery. Cephalometric measurements of the narrowest port of the nasopharynx on x-ray films exposed while each subject was producing the vowel /i/ after the plosive sound /p/ revealed deficiencies in velopharyngeal valving ranging from 6 to 20 mm with an average of 10.45 mm.

Thirty-four subjects had received the operation as a secondary surgical procedure. Five other subjects, who had previously used prosthetic appliances, received the operation as the primary closure of a palatal cleft. One subject received the operation to correct velopharyngeal insufficiency secondary to polio. Of the 39 cleft cases, 20 of the subjects had been born with clefts of the secondary palate only; of these, six involved the soft palate only and 14 involved the hard and soft palate. All 19 of the remaining cases had combined unilateral complete clefts.

FINDINGS. *Correction of velopharyngeal insufficiency.* Cephalometric studies, clinical speech and voice tests, and clinical case study evaluations all demonstrated that velopharyngeal insufficiency was eliminated in all of these 40 cases. The cephalometric measures revealed that a measurable thinning of the posterior end of the flap ranging from 1 to 3 mm did occur in 30 to the 40 subjects over a period of one to three years.

Correction of speech disorders. Table 4 presents some of the data which led to this conclusion regarding correction of velopharyngeal insufficiency. Inspection of Table 4 reveals that immediately following surgery, only two cases (5%) showed a persistence of the problem of nasal emission on pressure consonant sounds. This problem was completely eliminated by one year after surgery and did not return in any of the cases, some of which were studied for six years. Similarly, hypernasal resonance distortion persisted in only three cases after surgery and was completely eliminated in all cases before the end of the study.

Overcorrection of the velopharyngeal insufficiency changed the resonance balance in speech from hypernasality to hyponasality in 29 cases (72.5%) following surgery. As these cases were followed, excellent resonance balance was achieved in nine of the 29 hyponasal cases and the remaining cases in the group showed improvement in resonance balance.

Speech studies indicated that articulation and phonation defects generally persisted after surgery and sometimes caused greater distortions

TABLE 4. Ratings of nasal emission, hypernasality, and hyponasality for 40 subjects before surgery, immediately after surgery, one year after surgery, and at final evaluation.

Problem	*Before Surgery*	*After Surgery*	*One Year After Surgery*	*Final Evaluation*
Nasal emission	40	2	0	0
Hypernasality	40	3	2	0
Hyponasality	0	29	27	15

of intelligibility than they did before correction of velopharyngeal incompetency. Although the structure was now corrected so that the subjects could be taught to articulate correctly, their errors were occasionally more prominent in connected speech.

Complications. Several complications of debatable significance resulted from the overcorrection of the velopharyngeal insufficiency in this study group. Twenty-nine of the 40 cases were made hyponasal in resonance balance. Twenty cases began mouth breathing and 18 cases began snoring after the procedure. These problems all lessened in degree with time.

Clinical Study 4: Pharyngeal Flap, Problem Cases

This third study of cases treated by pharyngeal flap surgery includes data from 25 problem cases examined at three different centers over a period of six years. The patients had been treated by surgeons from all sections of the United States and one from Europe. Clinical evaluations were carried out at periods of time ranging from two months to 25 years after surgery and included the same tests reported for the speech appliance study.

SUBJECTS. Table 5 shows that the study group included 20 males and five females. They ranged in age from 11 years to 54 years. The mean age of the group was 26 years. Eight cases had been born with clefts of the secondary palate only, and 17 with combined clefts of the hard and soft palates. All but two cases had received pharyngeal flap surgery as a secondary procedure.

These cases presented themselves for re-evaluation after previous treatment in all sections of the United States. One case received his operation in Germany, 25 years prior to the evaluation. They therefore do not represent any meaningful clinic population and are considered only as examples of possible shortcomings and complications of pharyngeal flap surgery.

All but three cases had relatively narrow pharyngeal flaps with lateral orifices that were judged to be wide. Twenty-one were inferiorly based and four superiorly based.

FINDINGS. *Correction of velopharyngeal insufficiency.* Without exception

TABLE 5. Distribution by sex and type of cleft of 25 post-pharyngeal flap problem cases.

Cleft Type	*Male*	*Female*	*Total*
Palate Only			
Soft Palate	0	2	2
Hard and Soft Palate	4	2	6
Prepalate and Palate			
Unilateral	14	1	15
Bilateral	2	0	2
Total	20	5	25

the 25 cases presented problems of velopharyngeal insufficiency for speech. Case histories indicated that six cases had achieved velopharyngeal adequacy for periods of time after surgery ranging from two to six years.

Correction of speech disorders. All of the cases presented speech problems related to hypernasal resonance distortion. Additional functional speech problems were found in 19 cases.

Complications. In 19 of the 25 cases velopharyngeal adequacy had apparently never been achieved. From intraoral examinations it appeared that the narrowness of the flaps prevented contact with the lateral pharyngeal walls and that soft palates were either too immobile or restricted in elevation to seal off the nasopharynx.

Six cases, who were helped by the operation to attain velopharyngeal adequacy, apparently lost this function after limited periods of time.

All cases now presented very complicated rehabilitative problems.

Discussion

Based upon the limited clinical experience presented, the studies to date indicate that either prosthetic speech appliances or broad pharyngeal flap surgery may be used successfully as a secondary procedure to correct problems of gross velopharyngeal insufficiency for speech in cleft palate subjects. Pharyngeal flap surgery or the use of speech appliances may also fail to achieve the desired results.

It would seem that one apparent advantage of the prosthetic approach is the potential for immediate adjustment of resonance balance at the time of placement of the appliance. However, because of tolerance problems, this is not always possible and bulbs may have to be under-extended at first and later modified to achieve good resonance balance. Also, it appears that bulbs which are closely fitted in the nasopharynx at the start, may have to be made smaller after a period of time due to the development of increased muscle activity.

A shortcoming of prosthetic treatment appears to be the frequent need for preparatory orthodontic and dental work. This can be difficult and time-consuming to provide, even in well-staffed clinics in metropolitan areas. Such difficulties are compounded in rural areas. The need for adjustments of both retention devices and speech bulb fittings on prostheses which appear to be necessary for long-term satisfactory use may be a disadvantage both to the patient and to the clinic. Edentulous patients and patients with habits of poor oral hygiene generally present more complications for long-term satisfactory use of prosthesis than patients with good dental hygiene. However, cases with chronic problems of rhinitis or with extensively deficient hard palate structure may be more satisfactorily treated with prosthetic rather than with surgical approaches.

It is generally agreed that treatment with body tissues (surgery) has many psychological advantages for the patient. However, on the basis of existing evidence, providing adequate velopharyngeal valving through

pharyngeal flap surgery presents somewhat of a dilemma. On the one hand, cephalometric and clinical evidence indicates that pharyngeal flaps often gradually diminish in size with time. If the flap is made extremely broad in anticipation of this, obturation of the nasopharynx may occur with the introduction of hyponasality and breathing problems. On the other hand, if a flap is constructed allowing patency of the breathing passages lateral to the flap after surgery, the long-term success of the technique, in terms of speech, depends on increased muscle activity to achieve adequate velopharyngeal valving. Considering only a limited number of unsuccessfully treated pharyngeal flap cases, it appears that a narrow flap attached to a short soft palate often may not achieve the desired goal.

Whenever it can be demonstrated from clinical experience in a cleft palate treatment center that a specific pharyngeal flap operation and prosthetic speech appliance can obtain a comparable high percentage of complete correction of problems of velopharyngeal insufficiencies, a choice should exist between these alternate treatment plans. The physical condition of the patient, his preference, and the factors cited above might determine which approach is better or best-suited for each patient.

Regardless of the approach used, these studies illustrate that speech does not depend solely upon the attainment of velopharyngeal valving. Speech therapy for the correction of the frequent functional articulatory, phonatory, and resonance problems of speech is most often necessary before the potential benefits from successful pharyngeal flap surgery or speech appliances can be obtained. The correction of other structural hazards to clear speech production, severe orthodontic, dental, and hearing problems related to the cleft palate condition, also need to be obtained if the patient is to receive the desired speech, cosmetic, and functional results.

The need for facilities and trained personnel to provide both excellent prosthetic and surgical rehabilitative procedures in cleft palate centers is strongly suggested.

Summary

Four detailed clinical studies concerned with cleft palate patients who presented problems of gross velopharyngeal insufficiency were briefly outlined and presented in order to compare and discuss the efficacy of prosthetic and pharyngeal flap approaches to treatment. The frequency of problems and complications, and the apparent reasons for failures of each approach were discussed. These limited studies suggest certain advantages for both prosthetic and pharyngeal flap treatment and the need for facilities and trained personnel in both prosthetic and surgical handling of such problems at cleft palate centers.

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