Henry Ford Hospital Medical Journal

Volume 21 | Number 2 Article 6

6-1973

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Henry Ford Hosp. Med. Journal
Vol. 21, No. 2, 1973

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A detailed analysis is presented of 321 patients with clefts of the lip and/or palate treated at Henry Ford Hospital. Comments are made on past and future trends in the management of these complex entities.

Roy D. McCLURE was the first surgeon to repair a cleft palate at Henry Ford Hospital. In 1917, shortly after the institution opened its doors, Dr. McClure closed a moderate-sized palatal defect in a 1½-year-old girl. Although the surgery went well with encouraging results, subsequent cases ended in frequent frustrations for Dr. McClure, one of the most accomplished surgeons of his era, and he ultimately abandoned the field of palate surgery.

Despite growing knowledge of the biology of cleft palate and increasing subspecialization in its care, many of the frustrations which Dr. McClure felt so keenly have persisted to this day. There have been triumphs, but progress has come in slow, hesitant steps. Although the Ford Hospital experience has not been as extensive as that of some other cleft palate centers, it illustrates the various parameters of this challenging problem.

Background

The palate is a structure peculiar to mammals. Likewise the lips, while present in rudimentary form in lower species, do not attain their true anatomic development until the mammalian stage is reached. Each of these

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structures represents a biologic adaptation to the needs of the species. Lips are necessary to grasp the nipple of the mammary gland and to provide an air seal. An extensive hard and soft palate is required to shut off the nasal cavities and nasopharynx so that sufficient negative pressure can be generated for sucking. Clefting of either the lip or palate creates functional problems of nutrition in both the neonatal and postnatal periods.

Emotionally, few experiences are as disheartening as those of the mother whose newborn's lip or palate is cleft. Etiologically, these developmental errors can be fixed at certain pivotal points in facial development, when either the lip processes fail to fuse, or else the palatal shelves fail to form in the midline. A myriad of combinations is possible, from a relatively minor notching of the soft palate to the grotesque bilateral clefts of both lip and palate. The most common entities are either unilateral clefts of the lip or clefts of the secondary (posterior) palate.

Study Data

As of June 1972, 362 patients with at least one of the cleft entities had been evaluated at this institution. Of these 362 children, reliable data was available on 321. See Table 1. Roughly 65% underwent their primary surgery here, another 25% had only their secondary revisions here, while the remaining 10% had no operative intervention. The most common anomaly encountered was the single cleft of the secondary palate, or that portion of the palate posterior to the incisive foramen. Complete unilateral clefts of both the lip and palate also showed a significant incidence, as did unilateral clefts of the lip alone. Generally, the more complicated the anomaly the more likely was there referral for secondary revision. In those diagnoses where unilaterality was a factor, left-sided lesions predominated. Males predominated in all categories having any statistical validity. The family history could be accurately assessed in 168 patients, and in 13% of these it was positive.

As might be expected with defects originating from developmental arrest in the first trimester of gestation, cleft patients displayed a high incidence (12.5%) of associated congenital anomolies. Prematurity was the most commonly encountered single entity, followed closely by mental retardation. When evaluated in terms of system involvement, musculoskeletal defects (18 cases) were most numerous along with neurologic lesions (17 cases) and cardiac anomalies (15 cases). This latter category accounted for the highest postnatal mortality (30%), principally from Tetralogy of Fallot and great vessel transposition.

Cleft palate care has been a shared responsibility over the years. With the increasing compartmentalization of surgical endeavors, however, the initial interest of general surgeons gave way to that of oral surgeons and, more recently at Henry Ford Hospital, of plastic surgeons. Of the 321 cases, 201 were handled by oral surgeons, 104 by plastic surgeons, 10 by general surgeons and 6 by others. The combined case load of these latter two specialties reached a peak in the 1950's when 113 patients were seen. In recent years there has been a tapering off of the total case load, due in large measure to dispersion of the available clinical material among an increasing number of specialists interested in these modalities.

Cleft Palate

Repair of a cleft palate relies on soft tissue cover of the bony defect. In prac-

TABLE 1
DISTRIBUTION OF DIAGNOSES

	Involvement			Laterality		Sex	
	primary procedure	secondary procedure	evaluation only	right	left	male	female
Unilateral lip & palate	42	34	4	26	54	46	34
Bilateral lip & palate	10	14	2			17	9
Secondary palate:							
hard & soft	65	19	13			65	74
soft only	34	1	7				
Unilateral lip	34	4	4	15	27	27	15
Submucous cleft	4		4			4	4
V-P insufficiency	6					2	4
Other palate	9	10	1			11	9
TOTAL	**204**	**82**	**35**			**172**	**149**

tically all instances, this tissue originates from areas adjacent to the cleft. The classic repair is the von Langenbeck, where relaxing incisions are made along either inside (lingual) gum margin, and the intervening palatal soft tissue is undermined and raised as two mucoperiosteal bipedicle flaps. These are each moved medially and approximated in the midline. The raw donor areas which remain laterally are left to granulate.

This repair permits generous medial mobility, but, because most cleft palates are short in the anterior-posterior dimension, when repaired they frequently do not close off the nasopharyngeal space during speech. To overcome this deficiency the various pushback procedures (Wardill, Veau-Wardill, etc.) superimpose an additional anterior release on the basic von Langenbeck bipedicle. This converts it into two single, proximally-based pedicles which can be moved posteriorly. The raw granulating area now left is mainly in the anterior palate.

All these repairs entail considerable dissection in mobilizing their respective mucoperiosteal flaps. It has subsequently been documented[1] that the operative trauma attendant upon these techniques can seriously jeopardize the growth potential of the facial and dental skeletons. In addition, the raw surfaces left in the flap donor areas frequently heal with heavy scarring and subsequent contracture, thus setting in motion an insidious pattern of various dental arch deformities and associated malocclusions.[2]

To forestall these complications, it has become fashionable in recent years to respect the growth dynamics of the developing palatal complex by performing more limited procedures upon the palatal cleft itself.[3] Because of its role in determining early speech patterns, the soft palate is the only anatomic area that

TABLE 2
RESULTS OF PALATE REPAIR BY DIAGNOSIS AND SURGICAL METHOD

		Original procedure				
		von L.: 1-stage	von L.: 2-stage	push-back	direct approx.	unknown
Diagnosis	Unilateral lip, palate	17	12	12	3	36
	Bilateral lip, palate	3	4	3		16
	Secondary palate	39	2	21	17	18
	Soft palate	20	3	7	4	8
Results	no complications	42%	19%	29%	50%	2%
	fistula	31%	33%	31%	12%	56%
	dental abnormality	27%	48%	37%	7%	53%
	speech deficit	16%	14%	28%	31%	24%

demands closure at an early age. Its relative laxity and lack of bony attachment make repair by direct approximation a virtually atraumatic technique. The cleft of the hard palate can usually be occluded by a self-retaining dental appliance until enough facial growth has occurred to allow closure with minimal risk of later hypoplasia.

Table 2 summarizes, within a few broad categories, the various techniques used for the different cleft entities, along with their success or failure rates. The one-stage von Langenbeck was most commonly employed typically for clefts of the secondary and soft palates. The two-staged von Langenbeck (stage one being a delay procedure) was employed in the more extensive clefts, which probably explains the 42% vs 19% difference in success rates between the one- and two-stage operations.

Direct approximation of cleft margins had the highest overall success rate (50%), but this is because this closure method was used for the less serious lesions. And finally, the low success rate (2%) for procedures in which the primary technique was not documented reflects the fact that most of these patients were referred for manifested secondary complications.

Success/failure rates could not be correlated with patient age at time of palate repair. The primary procedures were carried out anywhere from three weeks of age to three years of age, but the mean age in the series falls between 11½ months and 13 months.

Operative complications were few. Most represented technical failures during the immediate post-operative period, such as dehisences of palate repairs (5 cases) or lip repairs (4 cases), or disruption of a recently completed pharyngeal flap. Major complications in the form of hemorrhage (3 cases) or airway obstruction (1 case) have occurred in only 1.4% of the total number of

TABLE 3
TREATMENT OF PALATAL FISTULAS

		unilateral lip & palate	bilateral lip & palate	secondary palate	TOTALS
Method	bipedicle flap	15	1	9	
	direct approx.	6	2	0	
	unknown	7	2	5	
	TOTAL	**28**	**5**	**14**	**47**
	recurrences	7	3	4	14 (30%)
	2nd recurrences	2	2	1	5 (11%)

patients operated upon. There has been no significant morbidity from these, nor have there been any operative deaths.

Although there is potential for long-term complications from this type of surgery, they are usually of three types: (1) fistula formation between nose and mouth, due mainly to partial disruption of the original repair; (2) abnormalities of the dental arch; and (3) poor speech. No clear pattern emerges from misfortunes incident upon the original procedures, but two trends are noteworthy: (1) speech results were not improved following pushback procedures despite the rationale of posterior displacement of tissue, and at the cost of a high rate (37%) of arch deformities; and (2) the incidence of dental maldevelopment was significantly lower in cases repaired by direct approximation than in cases repaired by other means.

Therapeutic regimens for complications of palate repair underscore the aphorism that "a cleft palate patient is a patient for life". For example, 47 palatal fistulas were repaired by the methods summarized in Table 3. There was an overall recurrence rate of 30% and, after further repair, a second recurrence rate of 36%, or 11% of the original total. Further reconstruction beyond the second recurrence has been unrewarding.

Similarly, 42 patients embarked on protracted courses of orthodontic treatment for moderate-to-severe occlusal abnormalities. These measures were carried out between the ages of 7 and 19.

Considerable effort has been expended on rehabilitating the speech patterns of these patients. Speech therapy has been necessary in practically all children, particularly when the hypernasality resulting from nasal escape distorts communication. In cases where the response has been minimal, surgical measures have been required to permit closure of the nasopharyngeal space. Eighteen such patients have had later operative intervention in the form of a pushback procedure (3 patients) or a pharyngeal flap, based either superiorly (12 patients) or inferiorly (3 cases). Reliable criteria to assess speech improvement are difficult to establish, but clinical evaluation has determined a success rate of roughly 70% for these procedures.

TABLE 4:
RESULTS OF LIP REPAIR

	Original lip repair			
	straight line	quadrilateral flap	triangular flap	advancement-rotation
total procedures	27	29	7	22
known results	**15**	**20**	**6**	**19**
good result	33%	30%	50%	37%
scarring of lip	14%	10%	17%	10%
vermillion irregularity	40%	40%	33%	37%
tight lip	14%	20%		16%

Cleft Lip

While palate defects pose problems mainly of distorted physiology, cleft lips are a blend of both the functional and the cosmetic. The upper lip contains musculature whose integrity is essential for maintaining the subtle topography of mid-facial features. Disregard of these muscular dynamics in the course of reconstruction dooms the patient to various contractures which distort the lip into a flat band of scar. Early cleft lip repairs consisted merely of straight line closures. The scar contractures that ensued highlighted the need for procedures which broke these lines of tension, and hence there evolved the various local flap operations.[4,5] Although these went far toward recreating the normal lip fulness, they generally failed to capture the subtle shadings of contour present in the mid-lip. Millard's advancement-rotation flap repair[6] has done much to redress the balance by integrating lateral tissue into the elements that create the philtral columns and the cupid's bow of the vermillion-cutaneous border.

These trends are underscored in analyzing those clefts of the lip whose primary procedures have been identified. Of 85 such cases, 5-year followups are available in 60 (Table 4). As in any assessment of cosmetic features, evaluation tends to be subjective, so that the data in Table 4 reflects a range within each category. There is a suggestion that the triangular flap repair produces the best result, but this sample is a small one. The advancement-rotation method of Millard shows an encouraging success rate, and, although the figures do not give it a clear mandate, this technique seems to give the repaired lip an attractive dimension that the other techniques do not.

In a significant majority of cases (66% in this series), the lip defect was associated with a corresponding cleft in the alveolar arch. In the normal individual, the pressure of the overlying lip musculature moulds the dental arch into its physiologic shape. Where this shaping force is absent, the medial (or premaxillary) alveolar segment tends to wing out, while the lateral or buccal

TABLE 5
EFFECT OF APPROXIMATION OF ALVEOLUS UPON DENTITION

	TOTAL	unilateral lip	bilateral lip	incidence of occlusal abnormalities
repair, soft lip only	97	84	13	42%
approximation of alveolus	33	21	12	82%

TABLE 6
INFLUENCE OF ALVEOLAR CLEFT ON SUCCESS OF SOFT TISSUE REPAIR OF LIP

	total, known results	good result	scarring of lip	vermillion irregularity	tight lip
soft lip only	32	28%	23%	34%	15%
lip & alveolus	85	36%	14%	24%	26%

segment collapses inward. Early attempts to insure anatomic union of these alveolar segments involved herculean efforts to approximate the alveolar stumps surgically with wire or horsehair sutures. However, the extensive dissection necessitated by these procedures invariabley damaged osseous growth centers, so that malunions and abnormal dentition frequently resulted. In recent years, greater recognition has been given to the shaping effect of the intact lip.[7,8] Direct intervention in the process of bony union has fallen out of fashion.

The increased occurrence of complications following direct closure of the alveolar cleft is documented in Table 5. Incidence of occlusal abnormalities was almost twice as high where there was surgical closure of the alveolus as where there was closure of the soft tissue cleft only.

The role of an associated alveolar cleft in the final appearance of the overlying soft tissue repair is of considerable interest. Presumably the deforming forces of the underlying skeletal defect would make success more difficult. Yet Table 6 shows the overall success rate was higher in patients with clefts of both the lip and the alveolus, than it was in patients with clefts of the soft lip only. However, tightness of the lip, a

key element in the final appearance of the structure, was a more significant postoperative factor in instances where the dental arch had been involved.

Revisions of previous unilateral lip repairs have been performed in 47 of these 85 patients, and second and third revisions have been necessary in 18. Abbe flaps, wherein a wedge of tissue pedicled on a labial vessel in the lower lip is transferred to the upper lip, have been performed in an additional seven patients with uni-lateral lip repairs, and in eight patients with previous bilateral lip closures. The average interval has been 12 days between original procedure and division of pedicle.

Ear Disease

Care of the cleft palate anomaly touches multiple systems, a fact particularly evident in otologic disease. Numerous studies have cited the high incidence of serous otitis media and associated hearing deficits in children with clefts of the palate.[9,10] A prime etiologic factor is disruption of the tensor palati, a muscle whose belly originates at the midline of the intact soft palate and whose tendon swings around the hook of the hamulus to insert at the pharyngeal orifice of the eustachian tube. Clefting of the soft palate causes loss of the mechanical advantage necessary for the tensor palati to open the eustachian orifice and thereby decompress the middle ear. Unfortunately, recognition of this relationship has come relatively late. Prior to 1950, only 10 cases of otitis media were diagnosed in patients comprising the present series, whereas 47 cases have been documented since that time. The majority of these have been treated medically, but 23 have required myringotomies at least once. Obviously an increased awareness of the relationship between cleft palate and ear disease has been responsible for the higher diagnosis rate.

At the same time the operative rate for documented cases of tonsillitis and/or adenoiditis has dropped. Prior to 1950 tonsillectomy and/or adenoidectomy was performed in 11 patients, 15% of the cases having clefts of the palate. Since 1950, the corresponding figure has fallen to 10%. This is partly due to less frequent surgical intervention in children with recurrent throat infections. However, it also reflects an increased appreciation of the role that the adenoid bulk plays in closing off the nasopharynx during speech. It is now accepted practice in cases requiring surgery to perform a lateral band adenoidectomy,[9] leaving residual tissue in the midline against which the soft palate can close.

Comment

Cleft palate care offers challenges which are greater in the whole than they are in their respective parts. With rapid advances occurring in each of medicine's various compartments, few specialties or institutions lack the expertise to deal effectively with specific aspects of cleft palate management. The problem has been to coordinate and harmonize the various therapeutic modalities that cross specialty lines. An effective solution has been cleft palate clinics where patients are evaluated by all specialties at the same sitting, and in an organizational framework that insures continuity. Henry Ford Hospital's Cleft Palate Clinic has been in operation since the early 1960's, and offers the services of plastic surgeons, pediatricians, otolaryngologists, oral surgeons, audiologists, speech therapists and social service workers. Currently a core of roughly 40 patients is being followed at either six-monthly or yearly

intervals, with new patients added as they come to the attention of the Clinic. Specific procedures such as operations or courses of speech therapy are carried out in the intervals between the bimonthly Clinics.

Precise patterns of inheritance for cleft lip and palate disorders have not been firmly established. Despite lack of a genetic base, a familial tendency can be seen. Incidence is high in certain inbred communities, such as the Navajo Indians, and the deformity is seen more frequently in families with strong histories in previous generations. Increasing social mobility and more readily available genetic counseling may be expected to reduce the prevalence of these anomalies. Contrary to the Scandinavian experience, for example, the incidence of cleft lip/palate is decreasing in the U.S.

At the same time, cleft palate care is being spread among an increasing number of institutions, so that the exposure of any one center is being proportionately constricted. There is a certain peril in this trend. As with any disease of similar complexity, therapeutic success varies in direct relation to the frequency with which the disease is encountered. Unfortunately, few hospital centers in this country can approach the cumulative experience of centers in other nations where affected patients are concentrated in one institution. For instance, Fogh-Anderson[11] has treated over 4,000 cases in 30 years at Copenhagen's Diakonissestiftelsens Hospital, to which every cleft palate patient in Denmark is referred. Sheer numbers are of themselves no guarantee of superior medical care but, other things being equal, they certainly help.

Acknowledgment

I appreciate the advice and help of Drs. A. P. Kelly and D. M. Ditmars Jr in the preparation of this paper.

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