The Effect on Middle Ear Disease of Fracture of the Pterygoid Hamulus during Palatoplasty

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Since 1878 when Alt (*1*) noted hearing improvement following treatment of otorrhea associated with cleft palate, hearing loss and ear disease have been subjects for extensive investigation in children with cleft palate. A high incidence of both chronic otitis media and hearing loss in the child with cleft palate has been confirmed (*6, 8, 11, 12, 13, 14, 15*).

The extent of the problem as presented in the literature varies with the age group studied, the criteria for hearing loss, the socio-economic group and geographic distribution of population. Authorities generally agree that the hearing loss is usually of a conductive nature and typically involves both ears.

Among the commonly proposed etiologies for the high incidence of aural pathology in cleft palate patients is that of abnormal structure and function of the palatal musculature which is intimately related to the nasopharyngeal end of the Eustachian tube. During normal swallowing, the tensor veli palatini, and possibly the levator veli palatini, open the lumen of the Eustachian tube and allow ventilation of the middle ear. Most authors agree that in cleft palate there is impaired middle ear ventilation on the basis of tubal dysfunction. The course and action of the tensor veli palatini can be altered at the time of surgical repair of the palatal cleft by

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division of its tendon or by fracture of the pterygoid hamulus, around which the tendon passes.

The result of fracture of the pterygoid hamulus during palatoplasty in terms of the course of middle ear pathology has not been conclusively evaluated. Experimental studies indicating that middle ear disease should develop following division of the tensor or hamulotomy (*7, 10*) are in contrast to the clinical report by Bennett, et al (*2*) that less ear disease and improved hearing function followed division of the tensor tendon.

A controlled prospective study designed to evaluate the relationship of hamulus fracture to the post operative state of middle ear disease was started in 1963 at the Cleft Palate Clinic of the Children's Hospital of Philadelphia. This paper gives the results of that study.

Materials and Methods

115 children undergoing palatoplasty at the Children's Hospital of Philadelphia during the seven year period 1963–1969 were entered in the study. This allowed a three-year follow up period for ear evaluation. At the time of soft palate repair, either the right or the left pterygoid hamulus was fractured. The side of fracture was randomized. If the operation was performed in an even month (Feb, April, etc.), the left side was fractured. In odd months, a right hamulotomy was done. All patients received a unilateral hamulotomy consisting of a partial or greenstick fracture of the hamular process of the pterygoid performed by the surgeon with his finger or by use of a periosteal elevator. The opposite hamulus as well as the tensor veli palatini tendon were not disturbed. The ear contralateral to the hamulus fracture was considered as a control in each child.

The patients were studied for ear disease and hearing loss by clinical otologic examination and audiogram when possible pre operatively, and within the first, second or third post operative years. The authors responsible for clinical ear evaluation (S.E.S.) and audiologic follow up (R.A.W.) were not aware of the side of hamular fracture at the time of their evaluation.

Otologic evidence of ear disease was considered to be present if the patient had a history of active otitis media during the followup year in which he was studied or if on physical examination he evidenced tympanic membrane fullness, yellow or red color, opacification or loss of translucency, impairment to motility by pneumatic otoscopy, otorrhea, perforation or cholesteatoma. Intensive prophylactic care of the ear disease was provided by myringotomy and antibiotic treatment when indicated.

Audiograms were performed when possible during the preoperative and follow up periods by using a standard clinical audiometer and speech reception threshold (SRT) recordings were made. Hearing loss was recorded in one of the four categories listed in Table 1. All records of loss are of a conductive nature ranging from 10 decibels to greater than 50 decibels in those recorded as abnormal.

TABLE 1. The severity of hearing loss was recorded by speech reception threshold and listed in one of four groups according to degree of air-bone conductive loss.

group	*degree of loss*	*air-bone gap*
I	Normal	0 to 10 dB
II	Mild	11 to 30 dB
III	Moderate	31 to 50 dB
IV	Severe	51 to more dB

Results

Of the 115 children entered in the study, 26 were later excluded because of inadequate followup data. Those excluded were patients who were followed by otolaryngologists outside the clinic group, patients who moved to another city with followup at another institution and patients who failed to return postoperatively for examination.

All 89 patients composing the study group, were tested at least once by audiometry or otologic examination during the three year follow up period.

Valid audiograms were available for 40 children during the first post operative year, while 46 had an accurate otologic examination recorded. Thirty-five of these also had audiograms. Between one and two years following surgery, 56 had a documented ear examination (46 of which also had audiograms) and 54 audiograms were done. In the third follow up year, 41 ear examinations and 53 audiograms were performed. The following examinations are shown in Figure 1.

The study group included 57 male and 32 female children. The majority (41) had Veau Class II clefts, while 27 were in the Veau Class III category, 14 Veau Class IV and 7 Veau Class I. Most were operated between 13 and 18 months of age. Thirty-eight were in this group, while 19 were closed in the 19 to 24 month age period. Therefore, 64% were operated between one and two years of age (Figure 2). There were two immediate complications. One patient required transfusing for operative hemorrhage. A second patient with Pierre Robin Syndrome required tracheostomy.

Of the 89 included in the study group, records were available on 63 children to evaluate the preoperative status of middle ear disease. 79% demonstrated evidence of otitis media preceding surgery. All children received otologic examination at surgery, 93% manifesting ear disease. A myringotomy was carried out in 95% of the group at the time of soft palate closure.

The right pterygoid hamulus was fractured in 44 patients, the left in 45.

In an effort to determine the effect of hamular fracture on the course of middle ear disease, pathological findings in the ear on the side of hamulotomy were compared with disease on the non-fractured side and the data

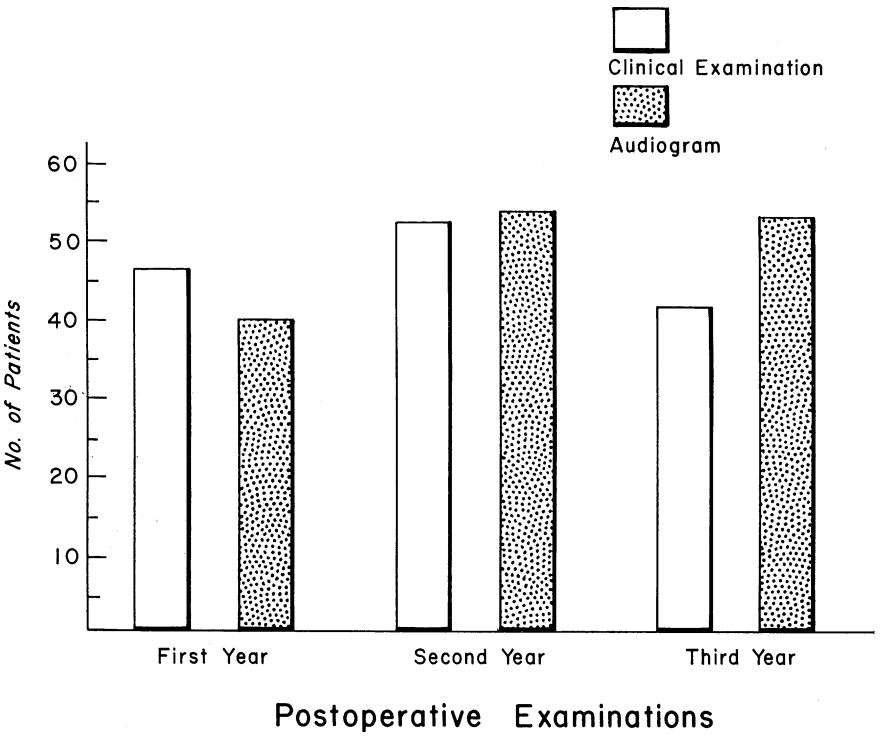

FIGURE 1. Number of clinical otologic and audiometric examinations done in each of the three post operative years.

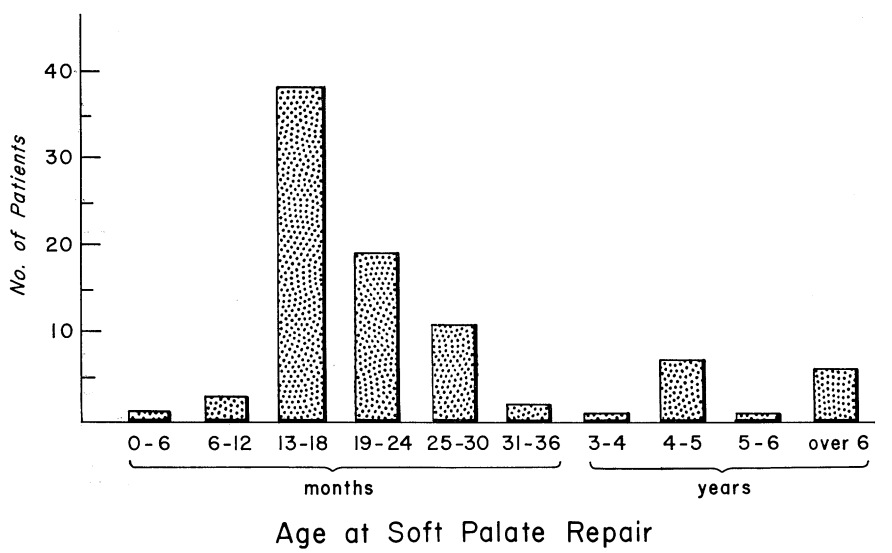

FIGURE 2. Age of the patient at the time of palatal surgery and hamulus fracture. Sixty-four percent were operated on between the ages of 12 and 24 months.

evaluated as follows:

1. Individual comparison of the course of disease in the ear on the side of hamulotomy with the control ear following surgery. An increase, decrease or lack of change in findings over the control ear was recorded.

2. Group comparison of side of hamulotomy and the control ear.

3. Effect of hamulotomy on the group with preoperative evidence of middle ear disease.

4. Effect of hamulotomy on the group with evidence of middle ear at surgery.

5. Effect of hamulotomy on the severity of hearing loss as recorded by audiograms.

1. Individual Evaluation. When each child was evaluated individually and the subsequent course of ear disease in the ear on the side of hamulotomy was compared with the contralateral ear, the following results were obtained. 64 patients showed no difference in audiogram and 65 demonstrated no difference in clinical evaluation. The ear on the side of hamular fracture showed less severe disease than the control side by audiogram in eight patients and by clinical examination in four. The ear on the side of hamular fracture showed more severe disease in nine patients by audiogram and in five clinically. If the ear was judged worse by one parameter and unchanged by the other over the control, the patient was considered to be worse by comparison. Figure 3 summarizes the data. By this criterion, 66 children were judged to have no difference in ear disease, 12 were found to have more severe disease in the ear on the side of hamulotomy and 11 were found to have more disease in the ear opposite to the side of hamular fracture. These data show no statistically significant difference between the two ears.

2. Group Comparison. The patients undergoing right hamulotomy were evaluated individually for evidence of ear disease or hearing loss in both the right and left ear during the first, second and third post operative years. An identical evaluation process was then applied to the left hamulotomy group. In each subgroup, no significant difference was noted in the incidence of clinically documented historical or otologic evidence of otitis media or in audiographic evidence of hearing loss. When both groups were combined and the data evaluated for the total series, the difference was even less significant. During the three-year period, a total of 147 audiograms were recorded for the ear on the side of hamulotomy, 69 of which showed at least mild hearing loss. Clinically, 75 of 143 examined had evidence of otitis media. In the non-fractured group, 70 of 147 audiograms were positive for hearing loss, while 72 of 143 ear examinations were positive for ear disease. The data, detailed in Table 2, show no significant difference between these groups.

3. Preoperative Ear Disease. When the 49 patients in whom satisfactory documentation of otitis media preceding surgery were evaluated, the results were similar. 93 of 159 exams on audiogram were positive on the

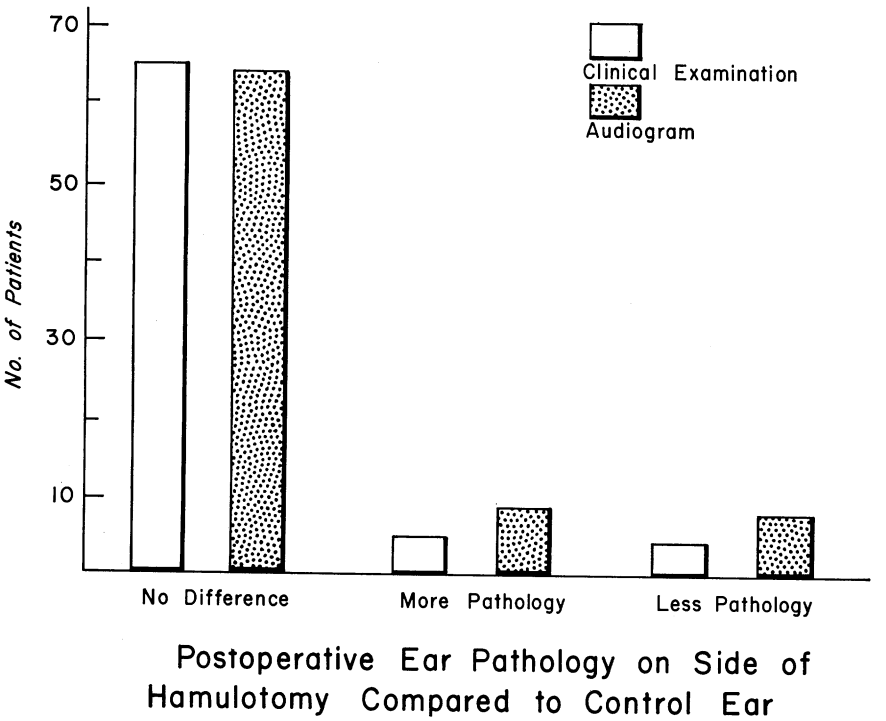

FIGURE 3. Evaluation of each child individually demonstrates no difference in the development of middle ear disease on the side of hamulus fracture compared to opposite ear.

side of hamular facture, while 94 of 154 showed evidence of ear disease in the opposite or control ear.

4. EAR DISEASE AT SURGERY. Of the 100 ears in 51 patients which showed evidence of middle ear disease at surgery, usually on the basis of positive myringotomy results, 50 were on the side of hamular fracture and

TABLE 2. Table comparing the total number of abnormal examinations on the side of hamulus fracture with those obtained by evaluation of the opposite ears. There is no statistically significant difference in the figures below.

method and time of evaluation	*side of hamulotomy*		*control side*	
	no. exam.	*no. pos.*	*no. exam.*	*no. pos.*
clinical examination first year	46	24	46	25
audiogram first year	40	15	40	17
clinical examination second year	56	27	56	28
audiogram second year	54	28	54	30
clinical examination third year	41	24	41	19
audiogram third year	53	26	53	23

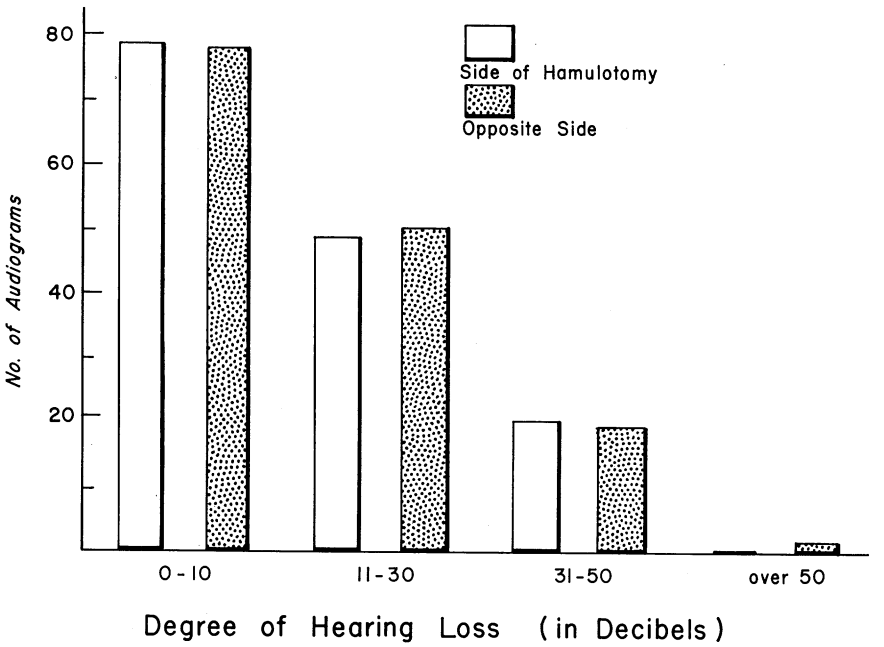

FIGURE 4. Severity of hearing loss in the 89 patients in this study. Only one examination showed a hearing loss of greater than 50 decibels. Perhaps this reflects prompt and active care of middle ear disease in these patients.

50 were on the contralateral or control side. This chance occurrence provided a natural basis for comparison. On the side of fracture 152 post operative evaluations were recorded, 83 or 54% showing evidence of disease. In the contralateral ears, 56% or 90 of 162 examinations recorded either clinically or audiometrically were positive for middle ear pathology.

5. Severity of Hearing Loss. On the side of hamulotomy, 78 of the total 147 audiograms were normal, compared to 77 of 147 on the opposite side (Figure 4). Forty-nine on the fractured side and 50 of the control ears showed mild loss. Moderate damage was recorded in the ear on the side of fracture in 20, in 19 on the opposite side. Only one audiogram demonstrating an air-bone conductive gap greater than 51 decibels was recorded, this on the side in which no fracture was done. In summary, 47% of the audiograms recorded on the side of fracture showed evidence of at least mild hearing loss, compared to 48% on the contralateral studies.

Discussion

Although a portion of the tensor veli palatini muscle originates from the greater wing of the sphenoid bone and from the scaphoid fossa at the root of the pterygoid process, the origin of a part of the muscle from the Eustachian tube has been classically described by Graves and Edwards (*5*) and by McMyn (*9*). As this flat muscle approaches the pterygoid

hamulus, it narrows into a strong tendon that bends around the hamulus in a deep notch on its lateral side and from its vertical position enters into a horizontal plane. The horizontal part of the muscle expands in a fan-like manner to become the palatine aponeurosis which fuses to both the posterior border of the hard palate and the aponeurosis of the other side. Those fibers originating from the anterolateral membranous wall of the Eustachian tube serve to retract this part of the wall away from the cartilagenous posteromedial wall, thus opening the tubal canal (Figure 5).

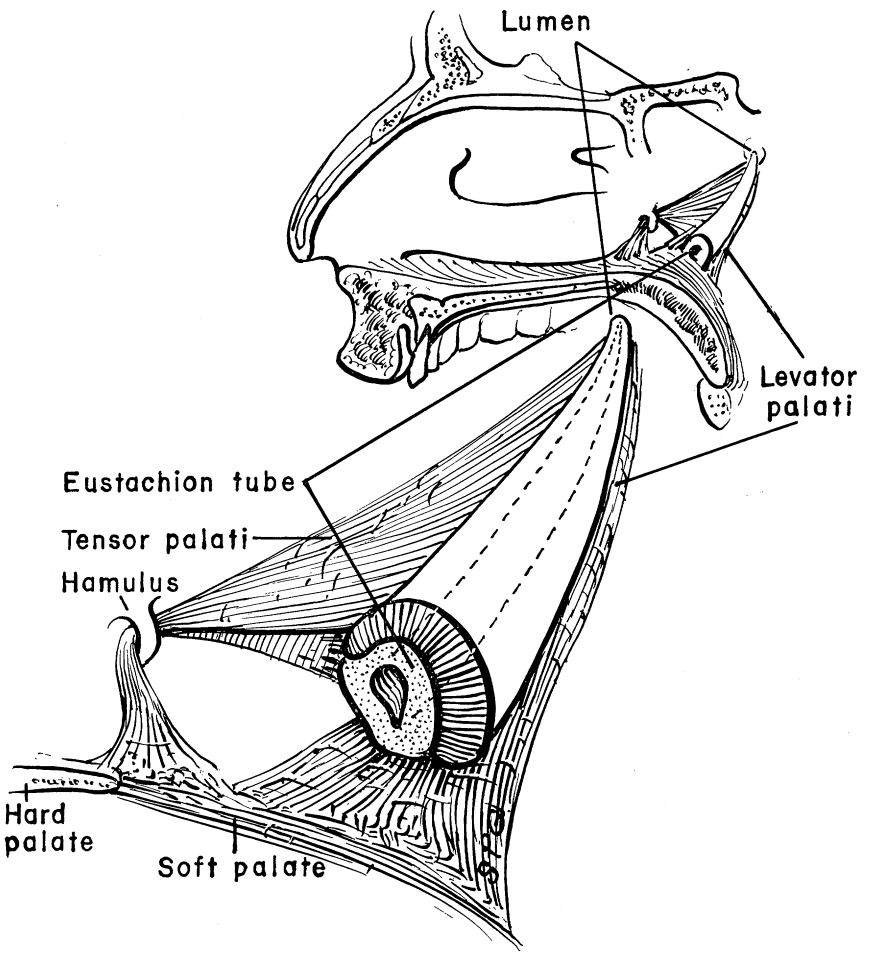

FIGURE 5. Illustration of the origin of the tensor veli palatini from the membranous portion of the Eustachian tube and the relation of its tendon to the pterygoid hamulus. Contraction of this muscle opens the Eustachian tube allowing equalization of pressure in the middle ear with the surrounding atmosphere. In the child with a cleft palate this relationship may be distorted. Fracture of the hamulus process could also interfere with this function. In this study, however, no deleterious effect on middle ear disease of hamulus fracture at the time of soft palate repair could be demonstrated.

This equalizes pressure between the middle ear and the atmosphere, allowing ventilation. It can thus be seen that abnormalities of insertion of the tensor as in cleft palate, poor development of the muscle or surgical damage to the muscle or the pterygoid hamulus could alter Eustachian tube physiology.

Since its introduction by Billroth in 1889 (*3*) surgical fracture of the hamulus as a means of reducing tension at soft palate closure has grown in acceptance and is in widespread use by surgeons performing palate surgery. In a recent questionnaire answered by 101 surgeons performing palate surgery, 42 indicated they routinely fractured the pterygoid hamulus at soft palate closure (*17*). Others did so on occasion but not as a routine.

With the knowledge of the intimate anatomic relationship of the Eustachian tube, the tensor veli palatini and the pterygoid hamulus, surgeons and otolaryngologists have considered the possible harmful effects surgical disturbance of this unit would have on the middle ear. Holobrow (*7*) in 1962 demonstrated that in dogs with normal palate musculature without division of the tensor the air pressure in the middle ear could be returned to normal from an artificially produced positive and negative pressure. When the tensor was divided, air pressures remained unchanged. Odoi et al. (*10*) recently used the cat as an experimental model and demonstrated a three-fold increase in middle ear effusion following hamulotomy compared to a sham-operated group. These experimental studies indicating the possible harmful effect on the middle ear by hamulotomy do not always reflect the technique of hamulotomy done at soft palate repair. They are contrary to the clinical findings of Bennett and co-workers (*2*) that less clinical, otologic and audiologic evidence of ear disease was found in children whose palatal closures included division of the tensor veli palatini compared to an equal number in whom the muscle was not divided.

In our prospective study, the side of hamulotomy was selected at random and was determined only by the date of surgery. All children received a unilateral hamular fracture, the opposite ear serving as an internal control. Therefore, since ear disease in the cleft palate child is usually bilateral, comparison between the operated and the control side appeared to be valid. The bilaterally equal extent of the ear disease in the pre operative and operative periods is further evidenced by comparison of the results obtained when each group was studied separately. Although follow up by clinical examination necessitated subjective evaluation of the state of ear pathology by the otolaryngology group, the evaluation was recorded according to a standard format (*16*). The subjectivity was thought to be minimized by using the opposite ear in each patient as a control, so that both the side of fracture and the control side were subject to the same inherent variations in clinical evaluation and testing.

Since no clear documentation of the effect of hamulotomy on ear disease existed, an impression of the attitude of operating surgeons concerning the

problem was sought through the above questionnaire (*17*). One half of those reporting indicated they were of the opinion that hamular fracture had no effect on Eustachian tube function, 10% indicated a definite effect, 17% thought it sometimes affected function, and the remainder made no commitment.

In the past 20 years, the existence of hearing loss in the cleft palate group has been recognized, but the prevalence of its occurrence is debated. On the average, approximately 50% are thought to have documented hearing loss after the age to two. The reports range from 0% reported by Goetzinger et al. (*4*) through Skolnick's 39.4% (*13*) to the 90% reported by Sataloff and Fraser (*12*) in their original report on the subject. Our data of 47% hearing loss in the ear on the side of hamular fracture compared to 48% in the opposite ear is consistent with the average reported. The severity of the loss, however, is not great, with only one ear of the 294 examined by audiogram showing evidence of greater than 50 decibels air-bone conductive loss. Hopefully, the mild nature of the hearing loss represents the result of continued efforts toward early diagnosis and treatment with myringotomy.

Conclusions

From our data, we can conclude that fracture of the pterygoid hamulus and, thus, disturbance of the integrity of the tensor veli palatini tendon during soft palate closure does not significantly alter the state of middle ear disease.

Since the opposite ear in each individual served as a control with which hamulotomy was compared, it can be noted from the lack of superiority on the non-fractured side that elimination of hamulotomy from soft palate closure because of fear of middle ear disease would not be justified.

Summary

An evaluation of the effect of routine fracture of the pterygoid hamulus during soft palate closure on the development and course of middle ear disease and its sequelae is presented. A prospective study alternating right and left fracture of the pterygoid hamulus in a randomized series of 89 patients undergoing soft palate repair between 1963 and 1969 is reviewed. An evaluation of the development of clinical middle ear disease and documented hearing loss by audiogram during a three-year post operative followup period demonstrated no differences between the ear on the side of hamulotomy compared to the opposite ear.

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References

1. Alt, A., Heilunder Taubstummheit erzielte durch Beseitigung einer Otorrhoe und einer angeborenen Gaumenspalte. *Arch für Augen u. Ohrenh. 7,* 211, 1878; and *Schmidt's Jahrbuecher 188.* 277, 1879.

2. BENNETT, M., R. H. WARD, and C. A. TAIT, Otologic-audiologic study of cleft palate children. *Laryngoscope, 78,* 1011–1019, 1968.
3. BILLROTH, T., Ueber Uranoplastik (Krankenvorstellung). *Wien Klin-Wchnschr., 2,* 241, 1889.
4. GOETZINGER, C. P., J. E. EMBREY, and R. BROOKS, et al., Auditory assessment of cleft palate adults. *Acta Otolaryng. 52,* 551–557, 1960.
5. GRAVES, F. O. and L. E. EDWARDS, The Eustachian tube. *Arch. Otolaryng. 39,* 359, 1944.
6. HOLBOROW, C. A., Deafness associated with cleft palate. *J. Laryng. Otolaryng. 76,* 762–773, 1962.
7. HOLBOROW, C. A., Conductive deafness associated with the cleft palate deformity. *Proc. Roy. Soc. Med. 55,* 305, 1962.
8. MASTERS, F. W., H. G. BINGHAM, and D. W. ROBINSON, The prevention and treatment of hearing loss in the cleft palate child. *Plast. Reconst. Surg. 25,* 503–509, 1960.
9. MCMYN, J. K., The anatomy of the salpingopharyngeus muscle. *J. Laryng. 55,* 1, 1940.
10. ODOI, H., G. O. PROUD, and P. S. TOLEDO, Effects of pterygoid hamulotomy upon Eustachian tube function. *Laryngoscope 81,* 1242–1244, 1971.
11. RANDALL, P. and S. STOOL, The high incidence of otitis media in infants with cleft palate. Transactions of the Fourth International Congress of Plastic and Reconstructive Surgery. P 450 Excerpts Medica. Amsterdam 1969.
12. SATALOFF, J. and M. FRASER, Hearing loss in children with cleft palate. *Arch. Otolaryng. 55,* 61–64, 1952.
13. SKOLNIK, E. M., Otologic evaluation in cleft palate patients. *Laryngoscope 68,* 1908–1949, 1958.
14. SPRIESTERBACH, D. C., D. M. LIERLE, K. L. MOLL, and W. F. PRATHER, Hearing loss in children with cleft palates. *Plast. Reconstr. Surg. 30,* 336–347, 1962.
15. STOOL, S. and P. RANDALL, Unexpected ear disease in infants with cleft palate. *Cleft Palate J. 4,* 99–103, 1967.
16. STOOL, S. E., Diagnosis and treatment of ear disease in cleft palate children. Chapter 64, p. 871 in Grabb, W. C. et al., *Cleft Lip and Palate.* Little Brown Company, Boston, 1971.
17. STOOL, S. E., unpublished data, Cleft Palate Clinic, Children's Hospital of Philadelphia.