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Tympanometric Evaluation in Pediatric Cleft Palate Patients: Pre- and Postoperative Analysis

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Abstract

Many disabilities are found in children born with cleft palate. Abnormal palatal function, structural defects of the upper jaw and abnormal dental development give rise to difficulties of mastication, swallowing and speech. Of late studies have been focused on the audiological aspect of the overall disability. Due to the cleft palate impaired Eustachian tube function is common which subsequently leads to middle ear disease and hearing loss.

Keywords: Tympanometry; Middle ear pressure; Cleft palate

Introduction

Children born with cleft palate often experience multiple disabilities, including impaired palatal function, structural jaw defects, and abnormal dental development. These issues contribute to difficulties in mastication, swallowing, and speech. Recent studies have increasingly focused on the audiological impact of cleft palate. Impaired Eustachian tube function is common, often leading to middle ear disease and associated hearing loss. Otitis media with effusion (OME) is frequently observed in children with cleft palate, with hearing loss ranging from mild to severe but typically of moderate degree. Several techniques have been employed to assess middle ear function in cleft palate patients, including pneumatic otoscopy, audiometry, and impedance studies. Among these, impedance audiometry provides the most reliable information about middle ear conditions, as confirmed by exploratory paracentesis. Tympanometry, a component of impedance audiometry, is an objective, rapid, and non-invasive test that effectively detects middle ear effusion and other abnormalities, with a Type B tympanogram demonstrating a 90% predictive value for diagnosing middle ear effusion. Studies suggest that early surgical repair of cleft palate significantly improves Eustachian tube function, reducing the incidence of middle ear disease. This study prospectively evaluated 21 cleft palate patients and compared their audiological parameters with a control group of normal children. Follow-up tympanometric assessments were performed to observe changes in middle ear function post-surgery.

Aims and Objectives

1. To assess middle ear function using impedance audiometry in children with cleft palate and compare the results with normal children using the following parameters:

a) Static compliance
b) Middle ear pressure
c) Tympanogram shape

d) Acoustic reflex

2. To evaluate changes in middle ear function following cleft palate repair in the late postoperative period.

Review of Literature

The development of cleft palate

Clefts of the palate and/or lip are among the most common congenital deformities. The embryological development of the lip and palate occurs in two phases: the primary palate and the secondary palate. The failure of palatal shelf elevation, mesodermal deficiency, excessive resistance from the tongue, and other genetic or environmental factors can contribute to cleft palate formation. Various syndromes, nutritional deficiencies, and radiation exposure have been implicated in this anomaly (Figure 1).

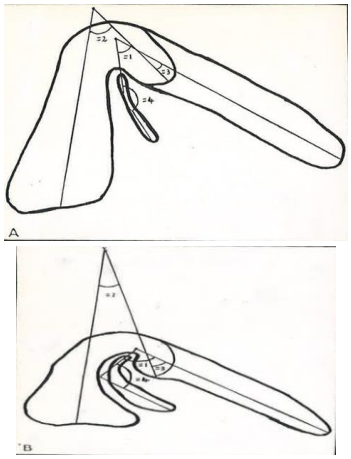


Figure 1: *SCHEMATIC DRAWING OF ANGLES.*

Angle 1 is between axial lines through the tensor veli palatine (TVP) muscle and though the superior portion of the Eustachian tube (ET).
Angle 2 is between the axial lines though lateral lamina and though medial lamina of the cartilage.
Angle 3 is between the axial lines though TVP muscle and though lateral lamina of cartilage.
Angle 4 is between the axial lines though superior and inferior parts of the ET lumen.
A) Children with cleft palate
B) Normal Children

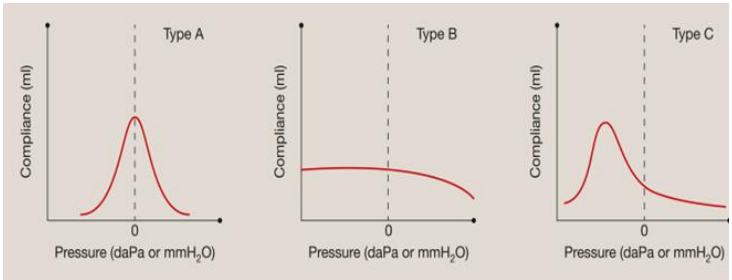
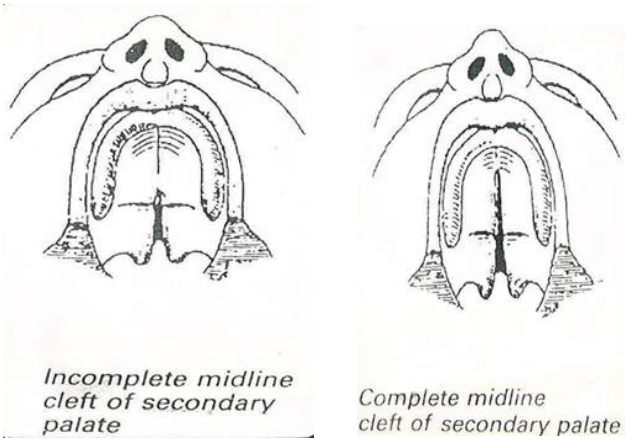


Figure 2: *Tympanogram Shapes: Jerger classification categorizes tympanograms into Type A (normal), Type B (indicative of OME), and Type C (suggestive of negative middle ear pressure).*



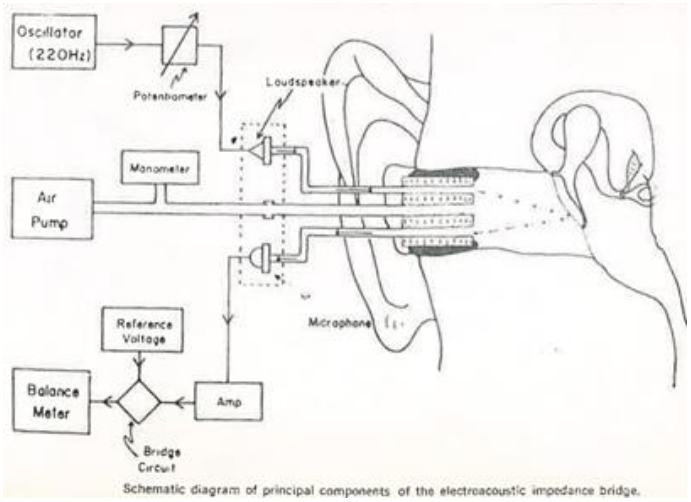


Figure 3: *Case Selection Tympanometer Schemtic Diagram of the Electroacoustic Impedance Bridge.*

Anatomy of the Eustachian tube in cleft palate

In cleft palate, palatal muscle attachments are abnormal. Autopsy studies indicate that tensor veli palatini and levator veli palatini muscles exhibit hypoplasia and atypical insertions, affecting Eustachian tube function. Experimental studies in animal models demonstrate that the tensor palatini muscle widens the Eustachian tube canal. In cleft palate cases, abnormalities in Eustachian tube morphology contribute to impaired function, increasing susceptibility to middle ear diseases.

Mechanism of otitis media with effusion (OME) in cleft palate

Middle ear disease in cleft palate patients is attributed to Eustachian tube dysfunction. The traditional "ex-vacuo" theory suggests that inadequate tubal opening results in negative middle ear pressure, leading to OME. Abnormal tubal insertion, smaller tubal lumina, and inflammation-related obstructions further contribute to dysfunction. Studies report a nearly universal incidence of middle ear effusion in cleft palate infants.

Factors influencing the occurrence of OME in cleft palate

1. **Age:** The incidence of OME is highest between 3 to 4 years and tends to decline after 5 to 6 years.
2. **Severity of the Cleft:** Patients with bilateral cleft lip and palate (BCLP) or unilateral cleft lip and palate (UCLP) show higher OME incidence compared to isolated cleft palate (ICP).
3. **Surgical Timing:** Early closure of cleft palate is associated with better Eustachian tube function and reduced middle ear pathology.

Methods of Assessing Middle Ear Function

Various techniques have been employed, including:

- Otoscopic examination (pneumatic otoscopy and microscopy)
- Pure tone audiometry (less reliable in young children)
- Impedance audiometry (preferred method, including tympanometry, static compliance, middle ear pressure measurements, and acoustic reflex testing)

Tympanometry parameters

- **Static Compliance:** Reflects tympanic membrane and ossicular mobility, with normal values between 0.35 and 1.40 ml.
- **Middle Ear Pressure:** Normal range is +50 to -50 mm H2O; in young children, +25 to -100 mm H2O is considered acceptable (Figure 2).
- **Tympanogram Shapes:** Jerger classification categorizes tympanograms into Type A (normal), Type B (indicative of OME), and Type C (suggestive of negative middle ear pressure).

Age of Closure of Cleft Palate and Its Impact on Middle Ear Function and Hearing

The optimal age for cleft palate closure remains debated, with studies suggesting that early closure (before 4 months) significantly improves middle ear function, while delays beyond 18 months correlate with increased otitis media with effusion (OME) and potential hearing loss. Studies indicate that closure before 6 years enhances Eustachian tube function and reduces adult hearing loss. The D.V. Dado protocol recommends early cleft palate repair with intra-velar veloplasty, ideally before 12 months. For complete clefts, closure is advised after primary palate healing but before the first birthday. Some advocate early soft palate closure while delaying the hard palate to prevent mid-facial growth attenuation. A study comparing early vs. late hard palate closure found no significant difference in conductive hearing loss, but sensorineural hearing loss was higher in the late closure group, indicating long-term risks. A multicenter trial revealed that 97% of cleft palate infants had OME pre-surgery, with persistent OME in 80% of non-ventilated ears post-repair, showing no significant difference between early and late closure. Despite surgical closure, hearing issues may persist, possibly due to surgical trauma (e.g., hamular fracture). To mitigate this, pressure equalization tubes, first described by Armstrong (1954), are widely recommended. Studies show a high incidence of mucoid middle ear fluid in cleft infants, suggesting routine examination with myringotomy and ventilation tube insertion during reconstructive surgery to prevent chronic ear issues, ossicular damage, and complications such as cholesteatoma. Management strategies include myringotomy with tube insertion for severe deafness and unilateral ventilation to balance hearing restoration with minimal tube-related complications.

In conclusion, early cleft palate closure, combined with proactive otologic management, is crucial to minimizing long-term auditory complications.

Surgical techniques for palatal cleft Repair

The following surgical techniques are commonly employed for cleft palate repair, often combined with intravelar veloplasty:

Two-Flap V-Y Pushback Technique

- The infant is positioned with head and neck hyperextended for optimal access.
- Mucoperiosteum is infiltrated with 0.5% lignocaine + epinephrine (1:200,000) to minimize blood loss.
- Key Steps:
  - S-shaped incisions along the Pterygomandibular raphe, curving around the maxillary tubercle to the canine tooth.
  - Fracture of the Pterygoid hamulus for mobilization.
  - Nasal mucosa is freed and closed.
  - The palate is reconstructed in layers.

Furlow's Double Opposing Z-Plasty

- Used for soft palate closure with mirror-image Z-plasties on both the oral and nasal sides.

- The palatal musculature is repositioned to form an overlapping muscle sling, improving function.
- Hard palate is closed without pushback or lateral relaxing incisions.

Von-Langenbeck Repair

- Incision pattern: Medial to the alveolar sulcus, extending to the maxillary buttress and hamulus.
- Flaps are elevated without complete muscle dissection.
- Key Steps:
- Mobilization of nasopharyngeal mucosa from the medial pterygoid plate.
- Midline suturing of muscle layers.
- Nasal mucosa everted with horizontal mattress sutures.
- Oral mucosa closure follows.

Each technique is selected based on the cleft's severity and anatomical considerations to optimize speech outcomes and velopharyngeal function.

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Materials and Methods

Subjects

The study group included children with isolated cleft palate admitted for surgical repair. Exclusion criteria included tympanic membrane perforation, ventilation tubes, or other congenital anomalies. A total of 37 patients were examined, with 21 eligible for inclusion. A control group of 21 normal children was selected (Figure 3).

Procedure

A detailed history was taken, focusing on aural symptoms. Otoscopy and impedance audiometry were performed one day before surgery. Follow-up assessments were conducted at three months postoperatively. Otoscopic findings included tympanic membrane dullness, absence of light reflex, reduced mobility, and presence of air-fluid levels. Tympanometric parameters were recorded with A GRASON-STADLER (GSI) 39 .and analyzed.

Preoperative Assessment

- Detailed history, focusing on aural symptoms.
- Otoscopy and impedance audiometry performed one day before surgery.

Postoperative Assessment

- Follow-up after 3 months, reassessing middle ear function

Observations

Preoperative observations

A total of 37 cleft palate patients, ages ranging from 11 months to 14 years, were selected. Out of these, only 21 patients who returned for postoperative follow-up were included in the study. A total of 21 subjects aged between 10 months and 12 years were selected as controls. (Table 1-3).

Two patients in the cleft palate group developed a central perforation by the time of postoperative follow-up. The ages of symptomatic children ranged from 11 months to 6 years.

Otoscopic examination criteria

Presence of dullness
Absence of cone of light
Decreased mobility

Based on these criteria, 29 ears exhibited otoscopic evidence of fluid. In the control group, there was no significant age-related difference in mean static compliance among the three age groups (Table 4).

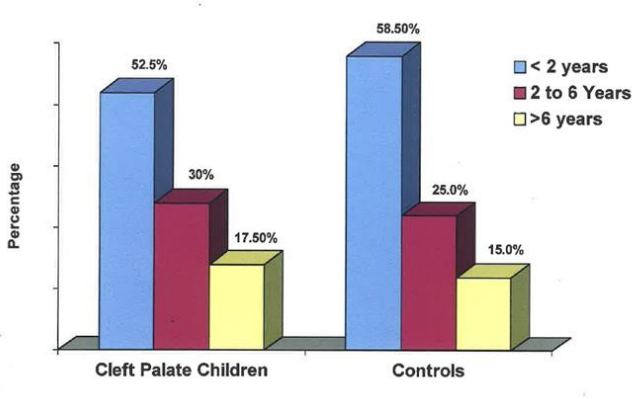


Table 1: *Age Distrubution of Study Group and Control Group.*

Age group in Years	Cleft Palate Children	%	Controls	%
< 2 Years	21	52.5	24	58.5
2 to 6 Years	12	30	11	26.8
> 6 Years	7	17.5	6	14.6

Findings

Significant difference in static compliance between cleft palate and controls across all age groups. No significant difference between control groups (Tables 5,6). Statistically significant differences in tympanometric curves between controls and cleft palate children across all age groups (Tables 7,8).

Improved: B or C curves changed to A; B curve changed to C.
Worsened: A or C curve changed to B.

Postoperative changes

28 B curves changed to A.

3 C curves changed to A.

2 C curves changed to B.

Improved: Middle ear pressure changing from negative toward zero.

Worsened: Increasing negative middle ear pressure (Table 9).

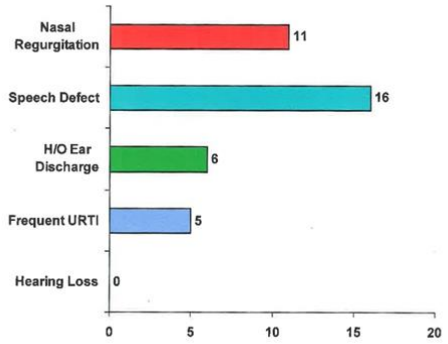


Table 2: *Distribution of Symptoms among the Cleft Palate Patients.*

SYMPTOMS	NUMBER
HEARING LOSS	NIL
FREQUENT URTI	5
H/O EAR DISCHARGE	6
SPEECH DEFECT	16
NASAL REGURGITATION	11

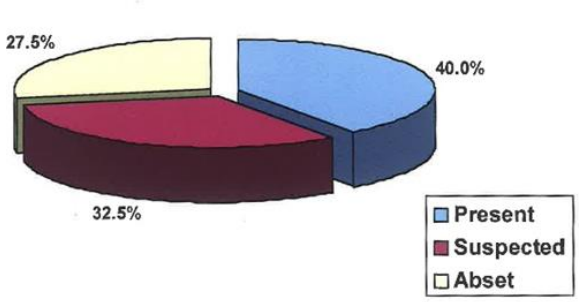
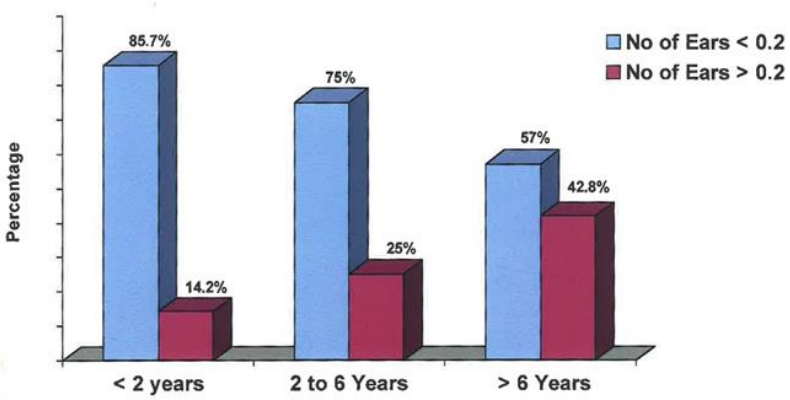


Table 3: *Otoscopic Findings in Cleft Palate Patients.*

OTITIS MEDIA WITH EFFUSION	NUMBER OF EARS	PERCENTAGE
PRESENT	16	40
SUSPECTED	13	32.5
ABSENT	11	27.5



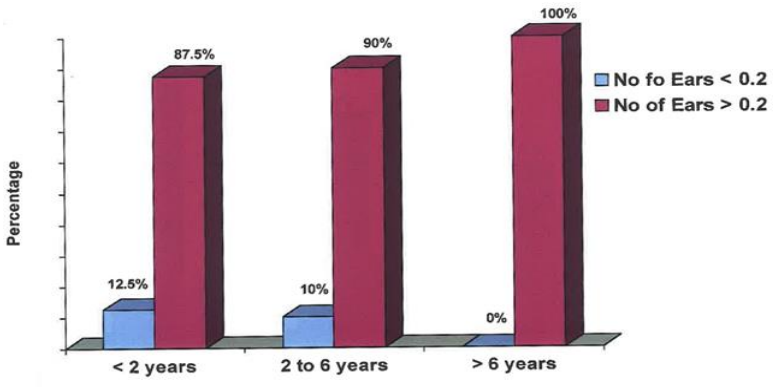
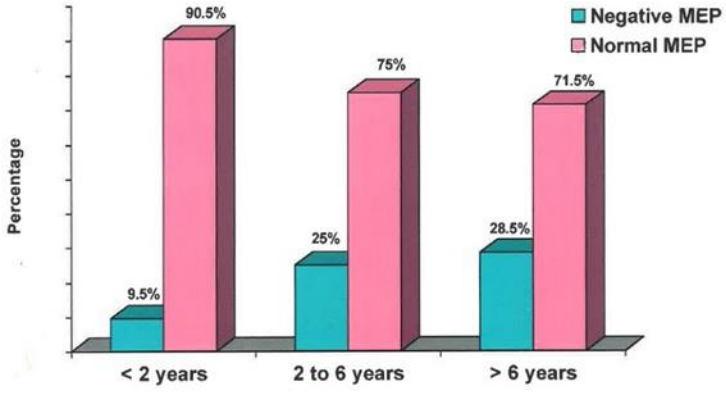


Table 4: *Static Compliance of Controls and Children with Cleft Palate According to Age.*

Age group in Years	Cleft Palate				Controls			
	No. of Ears	%	No. of Ears	%	No. of Ea	%	No. o	%
< 2 Years	18	8	3	14	3	12.	2	87.5
2 to 6	9	7	3	25	1	9.1	1	90.9
> 6 Years	4	5	3	42	0	0	6	100



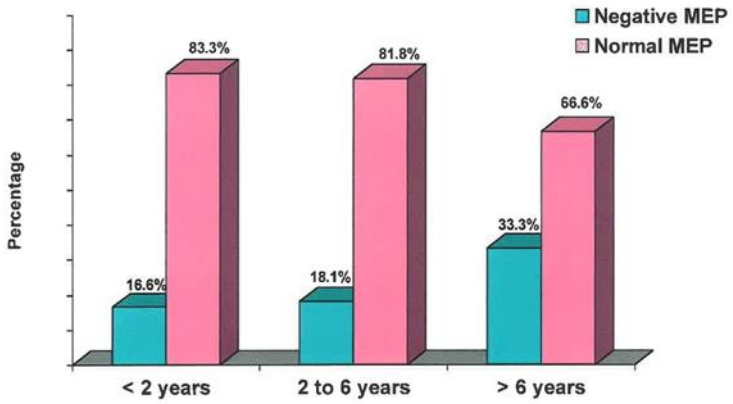
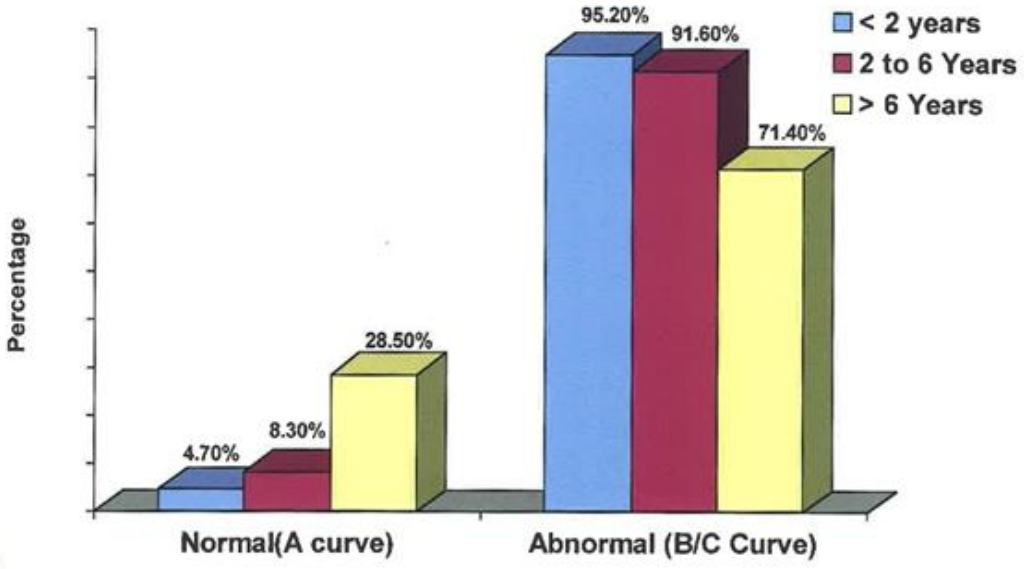


Table 5: *Distribution of Middle Year Pressure in Controls and Cleft Palate Children According to Age.*

Age group in Years	Cleft Palate Children				Controls			
	Negative MEP	%	Normal MEP	%	Negative MEP	%	Normal MEP	%
<or= 2 Years	2	9.52	19	90.5	4	16.6	20	83.3
2 to 6 Years	3	25	9	75	2	18.1	9	81.8
> 6 Years	2	28.6	5	71.43	2	33.3	4	66.6



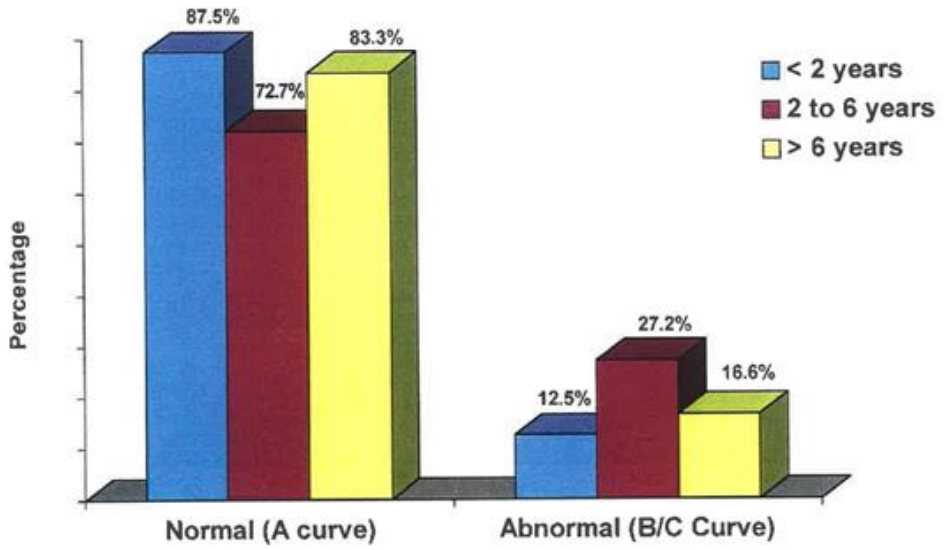


Table 6: *Distribution of Tympanometric Curves According to Age.*

Age group in Years	Cleft Palate Children				Controls			
	Normal (A curve)	%	Abnorma (B/C Curve)	%	Normal (A curve)	%	Abnormal (B/C Curve)	%
< 2 Years	1	4.7	20	95.20	21	87.5	3	12.5
2 to 6 Years	1	8.3	11	91.6	8	72.7	3	27.2
> 6 Years	2	28.5	5	71.4	5	83.3	1	16.6

Table 7: *Comparision of Static Compliance between Pre-Operative and Third Month Post-Operative in Cleft Palate Patients According to Age.*

Age group in Years	**Static Compliance**			
	pre-operative		**3 months post-operative**	
	No.	**Mean**	**No.**	**Mean**
< 2 Years	21	0.1143	20	0.228
2 to 6 Years	12	0.1500	11	0.2750
> 6 Years	7	0.2062	7	0.3667

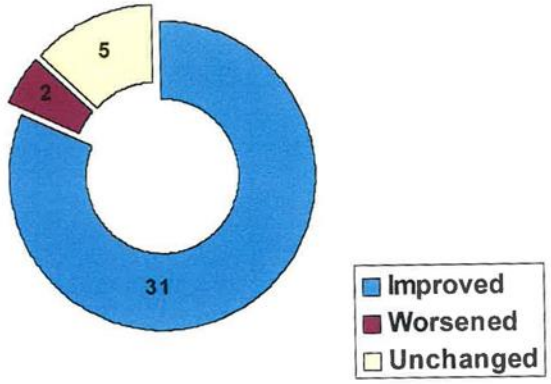


Table 8: *Change in Middle Ear Status According to Tympanometry Pre and Post Operatively.*

	IMPROVED	WORSENED	UNCHANGED
PREOPERATIVELY	31	02	05
TO 3TH MONTH POST OP			

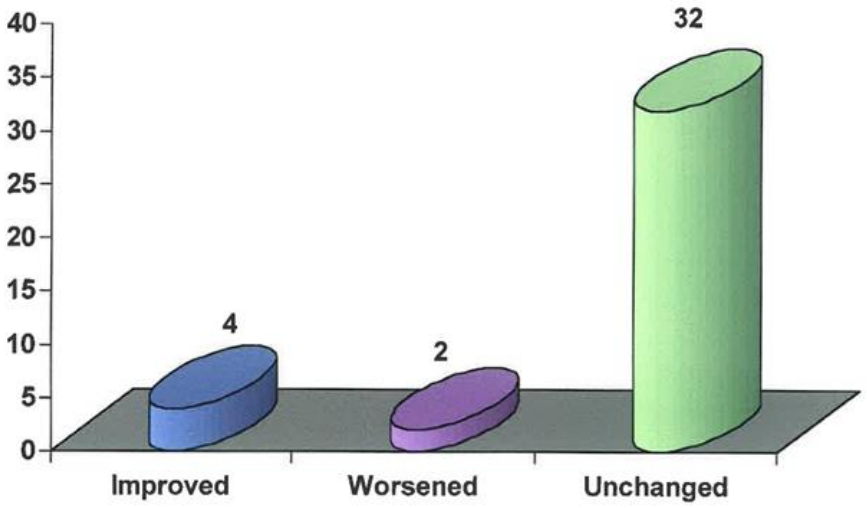


Table 9: *Change in Middle Ear Pressure (Mm Of Water) Preoperatively and Post Operatively.*

	IMPROVED*	**WORSENED****	**UNCHANGED**
PREOPERATIVELY			
TO 3TH MONTH	04	02	32
POST OP			

Results and Discussion

- **Incidence of OME:** 86.2% of cleft palate cases had tympanometric evidence of OME, aligning with previous studies reporting a near-universal presence of middle ear effusion in cleft palate infants.
- **Comparison with Control Group:** Among normal children, 29.4% showed OME, consistent with known age-related variations in middle ear function.
- **Postoperative Changes:** Significant improvement in middle ear function was observed at three months postoperatively, with some cases transitioning from Type B to Type A tympanograms. However, a small percentage worsened, possibly due to postoperative edema.
- **Long-term Follow-Up:** Studies indicate that persistent OME affects approximately 45% of cleft palate patients. Additional interventions, such as myringotomy and ventilation tubes, may be necessary for prolonged middle ear dysfunction.
- **Surgical Timing:** Early palatal repair improves Eustachian tube function and reduces long-term hearing impairment [1-13].

Conclusion

1. **High Incidence of OME:** Cleft palate children have a significantly higher risk of middle ear effusion compared to normal children.
2. **Impaired Middle Ear Function:** Static compliance is poorer in cleft palate patients.
3. **Postoperative Improvement:** Middle ear function improves following cleft palate repair, particularly in the late postoperative period.
4. **Routine Assessment is Crucial:** Regular ENT evaluations are necessary to detect OME early.
5. **Long-Term Monitoring:** Quantitative assessment of middle ear compliance aids in long-term treatment planning.

This study underscores the importance of early surgical intervention and ongoing audiological monitoring in children with cleft palate to optimize middle ear function and prevent long-term hearing impairment.

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