

## Early Extrusion of Grommet Tubes and its Impact on Eustachian Tubes of Children

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### ABSTRACT

**Background:** Otitis media with effusion (OME) which also called glue ear is famous in children. Most of children under four years could have OME, but decline beyond six years of age, medical and surgical treatments are present for OME. **Objective:** The aim of the current work was to evaluate the impact of early extrusion of grommet tubes on the eustachian tubes of children and whether this necessitates another intervention or not.

**Subjects and methods** This retrospective cohort study included a total of 191 pediatric patients (aged 3 to 14 years old) who suffered from bilateral otitis media with effusion (OME), not responding to medicinal treatment, and undergone myringotomy with Shepard grommet tubes insertion. It was performed at Department of Otorhinolaryngology, Faculty of Medicine, Benha University, Benha, Egypt. The included subjects were divided into two groups; **Group (A)** included 318 ears with standard extrusion time of grommets (6 to 12 months), **Group (B)** included 64 ears with early extrusion time (before 3 months from grommet tube insertion). Both groups were followed for 6 months after extrusion of the grommet's tubes.

**Results:** At the insertion time the mean ages for group A and B were 5.3 years and 5.1 years, respectively, without statistical differences for age and sex. Adenoidectomy performed in 52.9 % of patients, without statistical difference between groups. Cure rate was 84.9% in group A and 84.4 % in group B, which was comparable.

**Conclusion:** Early extrusion for grommets tube has similar fate to standard extrusion time. No further treatment in early extrusion time grommets until 6 months with treatment and follow up is elapsed.

**Keywords:** Otitis media with effusion, Recurrence, Tympanostomy, Ventilation tubes, Extrusion.

### INTRODUCTION

Otitis media with effusion (OME), is particularly frequent among children, from one to three years of age. The frequency of this problem ranges from 10% to 30% and reaches an incidence of 80% with four years aged children and the signs of acute infection could be absent in OME<sup>(1)</sup>.

The OME has a functional impact of 25 to 30 dB of conductive hearing threshold with effusion in the middle ear<sup>(1)</sup>. Hearing loss is a significant clinical characteristic of OME, produced by diminished tympanic membrane movement and consequent decline in sound transmission. If hearing loss persists, it can have an impact on speech and language development, as well as contribute to behavioral issues in some children<sup>(2)</sup>.

OME symptoms include problems with balance (vestibular) and ear discomfort. Whenever symptoms continue, they might influence a child's everyday activities, social relationships, and emotions, perhaps resulting in an inferior standard of life for the child<sup>(2)</sup>. Antibiotics, decongestants, antihistamines, mucolytics, and steroids are the most commonly used medicinal treatments for OME. These treatments' efficacy has yet to be shown. Ventilation or tympanostomy tube installation, adenoidectomy, or both are surgical options. The risks and benefits of tympanostomy tube placement are fiercely discussed. As a result, OME control remains a source of contention<sup>(3)</sup>.

The majority of OME cases in children recover autonomously during a three-month period; nonetheless, roughly 35% of children will have more than one episode of OME, and 5% to 10% of cases continue for over one year<sup>(4)</sup>. Grommets, also known as

ventilation or tympanostomy tubes, are 2 mm in diameter and constructed of inert plastic. They can be employed in patients of various ages, although the bulk of the time they are used in children. When exudate of the middle ear happens three or more times in a six-month period, grommets are frequently recommended<sup>(5)</sup>. A grommet's goal is to make ventilation of the middle ear rather than draining it. Grommets therefore mimic the role of the glue ear's closed eustachian tube and increase hearing<sup>(6)</sup>.

The grommet sometimes protrudes into the ear canal and becomes entangled in wax. The return of glue ear or middle ear infection can take place in 15% of cases. When the grommets are extruded, additional sets of grommets may be required till children develop without Eustachian tube difficulties<sup>(7)</sup>. Except for those intended for long-term placement, the tubes tend to move naturally. OME is more likely to return if a tube is removed too soon, but problems are more likely if it is left in too long<sup>(8,9)</sup>.

The recurrence rate of otitis media with exudate is high after myringotomy with tympanostomy tube insertion, ranging from 19.9 to 53.2%. The duration of tympanostomy tube extrusion is an essential factor in determining the frequency of recurrences of OME, with a longer extrusion period being associated with a lower recurrence rate. Several factors have been described in studies to influence tympanostomy tube extrusion. From these factors are; sex and age of patient, tube shape, size, and concurrent surgery, added to that size of adenoid, characters of effusions, postoperative reoccurrence of infections, and findings of tympanometry<sup>(10)</sup>. Within 6-24 months, tympanostomy tubes normally extrude from

the tympanic membrane, with no need for intervention or extraction. In a study<sup>(10)</sup> the average time of extrusion was 13.966.5 months. Multiple studies have identified early tympanostomy tube extrusion as a risk factor for recurrence<sup>(10)</sup>. Shepard ventilation tube had an average normal extrusion time of 10.39 -11.72 months. They may occasionally protrude earlier, as early as a few weeks following surgery. If the grommets extrude too soon and otitis media persists, another surgery for reinserting the grommets could be required. In some circumstances, another reason of hearing issues in the child's middle ear or somewhere may exist, and grommets may not result in hearing recovery. Once the grommet is removed, the glue ear or ear infections may reoccur in later years. The risk is estimated to be 5-10%<sup>(7)</sup>. Microscopic inspection of the projected tube revealed that all samples were made up of a cellular fibre material that was arranged in circular patterns parallel to the tube surface and frequently linked with tiny clusters of CD45+ inflammatory cells. The presence of squamous epithelium was confirmed by Scanning Electron Microscope (SEM), which displayed attached groups or layers of plate-like structures. Tube extrusion is thought to occur as an outcome of the proliferation of squamous epithelium, desquamation, differentiation, and medial emigration<sup>(11)</sup>. There is at present no agreement on the ideal period of retention, even though avoiding the introduction of another set of tubes is a goal of any tympanostomy<sup>(12)</sup>. The purpose of this study was to determine the effect of early grommet tube extrusion on children's eustachian tubes and whether additional intervention is required.

**SUBJECTS AND METHODS**

This retrospective cohort study included a total of 191 pediatric patients (aged 3 to 14 years old) who suffered from bilateral otitis media with effusion (OME), not responding to medicinal treatment, and undergone myringotomy with Shepard grommet tubes insertion. It was performed at Department of Otorhinolaryngology, Faculty of Medicine, Benha University, Benha, Egypt, during the period of January 2020 and August 2023.

**Exclusion criteria:** Patients with head and neck malformations, long-term suppurative otitis media, unilateral grommet tube insertion, or previous grommet tube insertion were excluded from this study.

The detection of OME relied on both the clinical and the tympanometry findings. The cases suffering from chronic OME over than 3 months with loss of hearing had undergone myringotomy with the placement of Shepard grommet tubes. Under general anesthesia, all patients had tubes inserted. Myringotomy was performed in ear drum anterior-inferior quadrant, then middle ear fluid was aspirated, and a tube was inserted. Adenoidectomy was carried out at the time of tube installation in 101 (52.9%) patients who had hyponasality and mouth breathing were identified to have hypertrophic adenoids on X-ray. After the grommet

tubes were extruded, patients were monitored for 6 months. The functionality of the Eustachian tube was evaluated before surgery and twice a month afterward. Before and after grommet extrusions, Eustachian tube assessment tests were performed. The final status of the Eustachian tube function tests were performed after 6 months.

The included subjects were divided into two groups; **Group (A)** included 318 ears with standard extrusion time of grommets (6 to 12 months), **Group (B)** included 64 ears with early extrusion time (before 3 months from grommet tube insertion). Both groups were followed for 6 months after extrusion of the grommet's tubes.

**Ethical approval:**

**Benha Faculty of Medicine's Ethical Committee (REC-FOMBU) in Egypt authorized the study protocol with the approval number RC-32-9-2023. The study protocol conformed to the Helsinki Declaration, the ethical norm of the World Medical Association for human testing. Written informed consent of all the participants' parents was obtained.**

**Statistical analysis**

To document the information, an "investigation report form" was used. The data was then tabulated, categorized, and analyzed using SPSS version 26 (Statistical Package for the Social Sciences). For the dataset, descriptive metrics such as average and standard deviation, median, quantity, and percentage were calculated.

**RESULTS**

Early extrusion is regarded if it occurs before the age of three months. In our study, the standard extrusion time was 6 to 12 months.

**Patients' Characteristics:**

The average age at the period of tube introduction was (5.3 years) years for group A and 5.1 years for group B, without any statistical difference in age and sex distribution between the groups. Adenoidectomy was performed in 101 (52.9%) patients, without any statistical difference in the distribution of patients undergoing adenoidectomy across both groups, as indicated in **Table 1**.

**Table (1):** Characteristics of Patients

	<b>Group A: (318 ears)</b>	<b>Group B: (64 ears)</b>
<b>Gender (male: female)</b>	16:10	18:13
<b>Mean age at intubation (years)</b>	5.3 years	5.1 years
<b>Patients with adenoidectomy</b>	84 (52.8 %)	17 (53.1%)

The Eustachian tubes of both groups expressed malfunction 3 months before intervention. A number of 10 eustachian tubes showed type A tympanogram, 213 expressed type B tympanogram, and 159 showed type C tympanogram. All the cases were negative for Inflation and deflation (Table 2).

**Table (2):** Results of Eustachian tube tests 3 months before intervention.

No. of eustachian tubes	Tympanogram types	Inflation and deflation	Mean acoustic reflex threshold in dB			
			500Hz	1000Hz	2000Hz	4000Hz
10	A	-ve	NR*	NR	NR	NR
123	B	-ve	NR	NR	NR	NR
90	B	-ve	95	100	100	110
75	C	-ve	NR	NR	NR	NR
84	C	-ve	90	85	95	95

NR\*: Not recorded

The results of ET tests after 6 months of Grommets extrusion in group A proved that 312 cases showed type A tympanogram from them 270 showed positive inflation and deflation tests and the remaining 24 were negative for these tests. Moreover, 6 cases recorded type B tympanogram with negative inflation and deflation tests (Table 3).

**Table (3):** Results of Eustachian tube tests 6 months after grommets extrusion in group (A).

No.	Tympanogram types	Inflation and deflation	Mean acoustic reflex threshold in dB			
			500Hz	1000Hz	2000Hz	4000Hz
270	A	+ve	90	90	98	95
42	A	-ve	NR	NR	100	110
6	B	-ve	NR	NR	NR	NR

The cases listed in group B after 6 months of Grommets extrusion were divided into; 55 cases with type A tympanogram (43 and 12 were positive and negative inflation and deflation tests, respectively), 7 cases were type B tympanogram with negative inflation and deflation tests, and 3 cases were type C tympanogram with negative inflation and deflation tests (Table 4).

**Table (4):** Results of Eustachian tube tests 6 months after grommets extrusion in group (B).

No.	Tympanogram types	Inflation and Deflation	Mean acoustic reflex threshold in dB			
			500Hz	1000Hz	2000Hz	4000Hz
42	A	+ve	90	90	98	95
13	A	-ve	85	95	95	100
7	B	-ve	NR	NR	NR	NR
3	C	-ve	115	NR	NR	NR

The group A has 318 ears with ET dysfunction before intervention, 270 ears gave normal ET after intervention and 48 ears showed dysfunction after intervention with cure rate of 84.9%. While the group B has 64 ears with ET dysfunction before treatment, 54 ears with normal ET after intervention and 10 ears with ET dysfunction after intervention with cure rate of 84.4%. No statistical difference was found between both groups (Table 5).

**Table (5):** The cure rate after 6 months following grommets extrusions in both groups.

Group number	Number of ears with E.T dysfunction before intervention	Number of ears with normal E.T after intervention	Number ears with E.T dysfunction after intervention	Cure rate in group
A	318	270	48	84.9%
B	64	54	10	84.4 %

## DISCUSSION

Alterations in traditional assumptions about the first signs of middle ear disorders rely on the obstruction of the Eustachian tube resulting in decreased ventilation of the middle ear space, leading to the creation of increased negative pressure in the middle ear and, eventually, the onset of middle ear illnesses. The pressure measurements of middle ear in cases suffering from ear diseases showed that the voluntary activity of sniffing generates an extremely negative intratympanic pressure. Eustachian tube closure failure characterizes this sort of Eustachian tube malfunction. Chronic barotrauma from sniffing or reverse Valsalva maneuver seems to be a key warning sign for recurring effusions of the middle ear and persistent middle ear sickness, such as sticky otitis<sup>(13)</sup>.

As a result, the main cause of middle ear disease and its sequences is an anomaly or dysfunction of the Eustachian tube. Before contemplating therapies, NICE suggested that bilateral otitis media with effusion (OME) and loss of hearing can be confirmed during a 3-month period<sup>(5)</sup>. This calls to avert surgery in children who have OME for a short period of time. This statement is based on the fact that most OME are self-limited, which has previously been confirmed in cohort investigations and randomized trials control groups<sup>(14, 15)</sup>.

The most prevalent consequence of ventilation tube implantation is otorrhea. A large cohort study of 1,184 children with ventilation tubes found that 52% of children had  $\geq 1$  episode of otorrhea following tympanostomy tube installation<sup>(16)</sup>. Other risks include persistent tympanic membrane puncture, tympanosclerosis, and retained tubes. Cholesteatoma development is the most significant consequence<sup>(17)</sup>.

**Song et al.**<sup>(18)</sup> performed a research on 82 pediatric patients (177 ears) with ventilation tubes inserted. The time it took for the tube to extrude was found to be strongly connected with the parameters of the presence of a middle ear discharge and a record of earlier ventilation tube insertion. The ventilation tube extrusion time was found to be unrelated to gender, age, size of adenoid, post myringotomy fluid of middle ear, existence of bleeding, connected adenoidectomy, and tympanic membrane status, tympanometry, or air bone gap audiometry. The insertion of ventilation tubes helps in the enhancement of patients' sense of hearing and their general level of life. Nevertheless, the chance of a recurrence is high after breathing tube placement remains high. In a retrospective analysis (10) of 258 ears that had ventilation tubes inserted, the rate of recurrence was 29%, which is within the range of documented rates in the medical literature<sup>(19,20, 21)</sup>.

In our research, the rate of recurrence was only about 15% higher in both categories. This was due to a higher number of patients undergoing adenoidectomy.

**Alaraifi et al.**<sup>(10)</sup> indicated a greater recurrence of ears with early ventilation tube extrusion. The recurrence rate of ears that had TT for over a year was

around half that of ears that got TT for less than a year. This result was similar to earlier researches which found greater recurrence when the period of extrusion was lower than one year<sup>(3,22)</sup>. These rates are greater than the recurrence rates found in our study. Our recurrence rates coincide with **Bonding and Tos** results<sup>(7)</sup>. **Le et al.**<sup>(23)</sup> discovered a trend for surgically treated ears to have greater otitis and worse hearing after tube extrusion in a prospective controlled evaluation of the efficacy and sequelae of ventilation tubes. This corresponds to our findings.

## CONCLUSION

Early extrusion for grommets tube has the same fate as those with standard extrusion time. No further treatment in early extrusion time grommets until 6 months with treatment and follow up is elapsed.

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**Conflict of Interest:** Nil.

## REFERENCES

1. **Lous J, Burton M, Felding J et al. (2005):** Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children. *Cochrane Database Syst Rev.*, 25(1):CD001801. doi: 10.1002/14651858.CD001801.
2. **MacKeith S, Mulvaney C, Galbraith K et al. (2022):** Ventilation tubes (grommets) for otitis media with effusion (OME) in children. *Cochrane Database Syst Rev.*, 22(3): CD015215. doi: 10.1002/14651858.
3. **Abdel-NabyAwad G (2016):** Timing for removal of asymptomatic long-term ventilation tube in children. *Indian J Otolaryngol Head Neck Surg.*, 68:406-12.
4. **Rosenfeld R, Shin J, Schwartz S et al. (2016):** Clinical practice guideline: otitis media with effusion (update). *Otolaryngol Head Neck Surg.*, 154(1): 1-41.
5. **Paradise J, Feldman H, Campbell T et al. (2007):** Tympanostomy tubes and developmental outcomes at 9 to 11 years of age. *N Engl J Med.*, 356(3):248-61.
6. **Lu S, Xu J, Lu H et al. (2022):** Balloon eustachian tuboplasty and grommet insertion: a combined surgical treatment for chronic suppurative otitis media with eustachian tube dysfunction. *J Evid Based Complementary Altern Med.*, 22: 9516029. doi: 10.1155/2022/9516029
7. **Bonding P, Tos M (1985):** Grommets versus paracentesis in secretory otitis media. A prospective, controlled study. *The American Journal of Otolaryngology*, 6(6):455-60.
8. **Klingensmith M, Strauss M, Conner G (1985):** A comparison of retention and complication rates of large-bore (Paparella II) and small-bore middle ear ventilating tubes. *Otolaryngol Head Neck Surg.*, 93(3):322-30.
9. **Turner J (1967):** Myringostomy by use of a fixed prosthesis. *The Laryngoscope*, 77(4):524-33.
10. **Alaraifi A, Alkhaldi A, Ababtain I et al. (2022):** Predictors of tympanostomy tube extrusion time in otitis media with effusion. *Saudi Med J.*, 43(7):730-35.
11. **Sammons R, Burnett S, Pahor A et al. (2002):** Histochemical, immunohistological and scanning electron microscope analysis of tissue retained on

- spontaneously extruded ventilation tubes. *J Laryngol Otol.*, 116(5):333-9.
12. **Waldman E, Ingram A, Vidrine D *et al.* (2023):** Two-Year Outcomes After Pediatric In-Office Tympanostomy Using Lidocaine/Epinephrine Iontophoresis and an Automated Tube Delivery System. *Otolaryngol Head Neck Surg.*, 169(3):701-709.
  13. **Magnuson B, Falk B (1983):** Eustachian tube malfunction and middle ear disease in new perspective. *J Laryngol Otol.*, 12(3):187-93.
  14. **Rosenfeld R, Schwartz S, Pynnonen M *et al.* (2013):** Clinical practice guideline: tympanostomy tubes in children. *Otolaryngol Head Neck Surg.*, 149(1): 1-35.
  15. **Mandel E, Doyle W, Winther B *et al.* (2008):** The incidence, prevalence and burden of OM in unselected children aged 1–8 years followed by weekly otoscopy through the “common cold” season. *Int J Pediatr Otorhinolaryngol.*, 72(4):491-9.
  16. **van Dongen T, van der Heijden G, Freling H *et al.* (2013):** Parent-reported otorrhea in children with tympanostomy tubes: incidence and predictors. *PLoS One*, 8(7):e69062. doi: 10.1371/journal.pone.0069062.
  17. **Yaman H, Yilmaz S, Alkan N *et al.* (2010):** Shepard grommet tympanostomy tube complications in children with chronic otitis media with effusion. *Eur Arch Oto-Rhino-L.*, 267:1221-4.
  18. **Song C, Park M, Kim Y *et al.* (2010):** Factors affecting the extrusion rate of ventilation tubes. *Clin Exp Otorhinolaryngol.*, 3(2):70-75.
  19. **Alaraifi A, Alkhaldi A, Ababtain I *et al.* (2022):** Predictors of otitis media with effusion recurrence following myringotomy. *Indian J Otolaryngol Head Neck Surg.*, 74(3):4053-58.
  20. **Klopp-Dutote N, Kolski C, Strunski V *et al.* (2018):** Tympanostomy tubes for serous otitis media and risk of recurrences. *Int J Pediatr Otorhinolaryngol.*, 106:105-9.
  21. **Hao J, Chen M, Liu B *et al.* (2019):** Compare two surgical interventions for otitis media with effusion in young children. *Eur Arch Oto-Rhino-L.*, 276(8):2125-31.
  22. **Mandel E, Rockette H, Bluestone C *et al.* (1992):** Efficacy of myringotomy with and without tympanostomy tubes for chronic otitis media with effusion. *J Pediatr Infect Dis.*, 11(4):270-77.
  23. **Le C, Freeman D, Fireman B (1991):** Evaluation of ventilating tubes and myringotomy in the treatment of recurrent or persistent otitis media. *J Pediatr Infect Dis.*, 10(1):2-10.