# Medium-term middle ear ventilation with selfmanufactured polyethylene T-tubes for the treatment of children with middle ear effusion

Y. TALMON, M.D., H. GADBAN, M.D., A. SAMET, M.D., P. GILBEY, M.D., V. LETICHEVSKY, M.D.

#### Abstract

We present the results of the insertion of self-made polyethylene T-tubes for a period of 15–24 months for the treatment of chronic middle-ear effusion. We compare the outcome of our patients to the reported outcome of patients treated with other commonly used ventilation tubes for either shorter or longer periods of time.

In a retrospective review of 603 T-tubes inserted in 306 children up to the age of 12 years, charts were reviewed for age, sex, surgical procedure performed, duration of ventilation and complications.

In all cases the indication for surgery was chronic middle-ear effusion. The tubes were electively removed by the authors after 15–24 months of ventilation. Spontaneous extrusion was considered a complication. The mean period of ventilation was 20 months. Post-operative otorrhoea was experienced in 6.6 per cent of ears; 4.8 per cent of tubes extruded spontaneously, whereas 3.15 per cent had to be removed earlier than originally planned; 4.9 per cent of ears were re-ventilated at a later date, and 1.49 per cent of ears developed a persistent perforation.

We demonstrate that the outcome of patients treated with our self-manufactured tubes for a period of 15–24 months is, in many respects, better or at least comparable to the reported outcome of patients treated with other commonly used ventilation tubes for either shorter or longer periods of time, and that the many complications associated with the conventional T-tube can be reduced.

We suggest that our favourable outcome may be due to the duration of ventilation, which was controlled to be shorter than the conventional long-term T-tubes and longer than that of grommets.

Key words: Otitis Media with Effusion, Surgical Procedures, Operative

## Introduction

In 1952, Armstrong was the first to use plastic tubes to ventilate the middle ear.<sup>1</sup> Since then the insertion of tympanostomy tubes has become one of the most commonly performed operative procedures. The indications for this operation are well established.<sup>2</sup>

Many types of ventilation tubes are available commercially. Complication rates of various tubes have been reported.<sup>3–7</sup> Common complications include post-operative otorrhoea, tube self-extrusion, persistent perforation, and the need for removal due to tube blockage, persistent otorrhoea, or the peri-tubal development of granulation tissue unresponsive to medical treatment.

We have developed a cheap, versatile, easy to insert, easy to remove and easy to manufacture Ttube, which has been in use at our institute since 1980.

The duration of ventilation is controlled to be between 15–24 months, and spontaneous extrusion is considered a complication in any case. After several years of positive experience, we sought to compare the outcome of our patients to the reported outcome of patients treated with commonly used ventilation tubes for either shorter or longer periods of time.

#### Materials and methods

A retrospective review was conducted of all tympanostomy tube insertion cases performed in children up to the age of 12 years at the author's institute during a six-year period (1988–1993). Patients were identified from hospital records. Cases of tympanostomy tube insertion performed in conjunction with other otolaryngological procedures such as adenoidectomy or adenotonsillectomy were included in the study. Hospital records and patient charts were reviewed for the following data: patient age, patient sex, surgical procedure performed, duration of ventilation, and complications. In all cases the indication for surgery was chronic middle-ear effusion.

From the Department of Otolaryngology – Head and Neck Surgery, The Western Galilee Hospital, Nahariya, Israel. Accepted for publication: 18 April 2001.

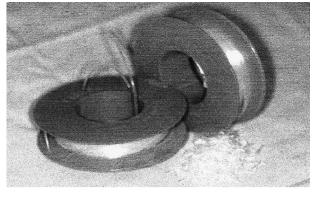


Fig. 1

Rolls of high-grade polyethylene tubing (I.D. 1.14 mm, O.D. 1.57 mm). Lengths of tubing are cut from these rolls in order to create the T-tubes.

Our tubes are made from high-grade polyethylene tubing, with an inner diameter of 1.14 mm and an outer diameter of 1.57 mm (Portex, Hythe, Kent, England). Lengths of polyethylene tubing, 2–3 cm long, are cut from a roll of tubing (Figure 1). Flanges are created by the partial longitudinal splitting of the tube (Figure 2). The flanges are folded back (Figure 3), warmed over an open flame and then pressed against a hard metal surface until the final angle is reached. Some experience is required in order to reach a ninety-degree angle. In order to create the final shape of the tube, a small triangle of polyethylene is cut from each side of the base of the flanges (Figure 4). The tube is sterilized by ethylene oxide gas, and trimmed to the appropriate size in the operating theatre before insertion. The length of the shaft is between 0.7-1.0 cm, and the flanges are between 0.2-0.4 cm, depending on the age of the child. The tube is inserted under general anaesthesia. After removal of cerumen and disinfection with 0.5 per cent iodine solution, an incision is made in the tympanic membrane. Despite previous studies describing the advantages of an anterosuperior incision,<sup>8</sup> we prefer an incision in the posteroinferior quadrant. Fluid is aspirated from the middle ear. The tube is inserted using a tube inserter (Smith and Nephew Richards, Memphis, TN, USA). The inser-

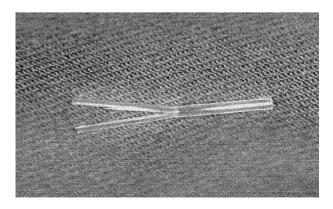


FIG. 2 The partial longitudinal splitting of the tube using scissors creates flanges.

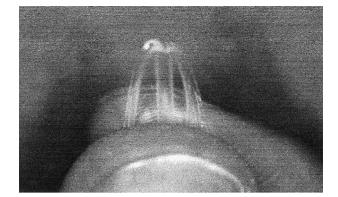


FIG 3

The flanges are folded back, warmed over an open flame, and pressure is applied against a hard surface.

tion procedure is not difficult to perform, as the tube is sufficiently rigid and is expelled easily out of the inserter. No peri-operative or post-operative topical or systemic antibiotic treatment was given to any of the patients.

When removed at the appropriate time, the removal is atraumatic as the flanges fold while the tube is pulled out. This procedure is performed in the out-patient clinic, and does not require any anaesthesia.

# Results

During the six-year study period, 680 tympanostomy tubes were inserted in the ears of 345 children. Seventy-seven tubes inserted in the ears of 39 children were lost to follow up for various reasons, and the remaining 603 tubes in the ears of 306 children were followed for at least one year after tube removal/extrusion. One hundred and ninetynine of the patients (65 per cent) were male, and 107 (35 per cent) were female. Two hundred and five (67 per cent) of the operations were performed in conjunction with adenoidectomy, 59 (19.3 per cent) in conjunction with adenotonsillectomy, and 42 (13.7 per cent) as the only procedure performed (Figure 5). The ages of the patients ranged from one year to 12 years. Most were between two to seven years old

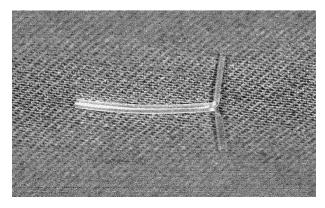


FIG. 4

In order to create the final shape of the tube, a small triangle of polyethylene is cut from each side of the base of the flanges.

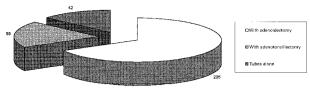


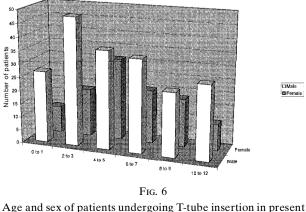
Fig. 5

T-tube insertion in 306 patients in present study – as the only operative procuedure and in conjunction with other procedures.

(Figure 6). The indication for tube insertion was chronic middle-ear effusion. The diagnosis was confirmed by audiometry and tympanometry. In all cases, fluid was found in the middle-ear cavity.

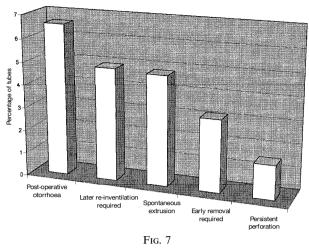
The average functional period of the tubes was 20 months, and ranged from four to 37 months. Only 12 patients (3.48 per cent) failed to return for follow-up as requested after 24 months. In these cases tubes remained in the ear for up to 37 months. There was a higher rate of persistent perforation in these patients, two ears out of 24 (8.3 per cent as opposed to 1.49 per cent overall). Spontaneous self-extrusion was considered a complication in all cases.

The most frequent complication noted was otorrhoea, which developed in 40 ears (6.6 per cent). Most cases responded well to topical and/or systemic antibiotic treatment, but 10 tubes (1.65 per cent) continued to drain chronically despite therapy and had to be removed. Nine additional tubes were removed: seven (1.16 per cent) due to chronic occlusion, and two (0.33 per cent) due to peri-tubal granulation tissue formation. Altogether 19 tubes (3.15 per cent) were removed earlier than planned, between four to 16 months from the time of insertion. Twenty-nine tubes (4.8 per cent) extruded spontaneously. Nine ears (1.49 per cent) developed persistent perforations for more than one year after tube extrusion/removal. If one disregards patients who failed to return for follow-up at 24 months, the rate of persistent perforation drops to 1.05 per cent. Thirty ears (4.9 per cent) were re-ventilated subsequently due to the re-accumulation of effusion in the middle ear (Figure 7).



Age and sex of patients undergoing T-tube insertion in present study.

https://doi.org/10.1258/0022215011908937 Published online by Cambridge University Press



Complications of T-tube insertion in present study.

### Discussion

In this study we have assessed the outcome of the insertion of self-made T-tubes for the treatment of chronic OME, and compared it to the reported outcome of the insertion of other tubes for either shorter or longer periods of time. The duration of ventilation in our study was 15–24 months. Our T-tubes are made from polyethylene tubing, and we have described the method of manufacture.

The controlled mean duration of middle-ear ventilation in our study was 20 months. The spontaneous extrusion time for ventilation tubes such as Shepard or Shah grommets or Donaldson tubes is six–15 months,  $^{3,5,6,9,10}$  whereas the spontaneous extrusion time for ventilation tubes such as the Goode T-tube or the Shah permavent tube is 24–52.5 months.  $^{4,5,7,11,12}$  We emphasize that the reported ventilation times in other studies relate to spontaneous extrusion, whereas in our study, the authors removed the majority of the tubes at a predetermined time. They were removed 15–24 months after insertion and during the period of spring or early summer. This is designed to allow the children to enjoy water sports during the long summer season.

Lacking a clear cut definition of short- and longterm periods of ventilation, and based on the above reported data, we have defined short-term ventilation as less than 15 months and long-term ventilation as over 24 months. We define a functional period of 15-24 months as medium-term ventilation. Abdulla et al. have reported their experience with the medium-term trimmed Permavent tube, and shown a probable significant decrease in the re-insertion rate compared to short-term grommets.<sup>3</sup> Table I shows reported duration of ventilation for various tubes in comparison to the present study. In most cases, we prefer medium-term duration of ventilation, and like to keep the tubes in place for as long as two years. We endeavour to be capable of controlling the time of extrusion of the tubes, and therefore regard self-extrusion as a complication in any case.

		(CONTROLLED	REMOVAL)	
	Authors	Year	Mean functional period	Tube type
Long-term tubes	Rothera and Grant <sup>11</sup>	1985	30 Months	Goode
	Wielinga and Smyth <sup>12</sup>	1990	52.5 Months	Goode
	Prichard <i>et al.</i> <sup>7</sup>	1992	24 Months	Goode
	Bulkley <i>et al.</i> <sup>4</sup>	1991	30 Months	Goode
	Hern <i>et al.</i> <sup>5</sup>	1995	41 Months	Shah permavent
Short-term tubes	Hampal <i>et al.</i> <sup>9</sup>	1991	6 to 9 Months	Shepard
	Hussain <sup>10</sup>	1995	9 to 15 Months	Shah grommets
	Abdulla <i>et al.</i> <sup>3</sup>	1994	12.5 Months	Shah grommets
Mid-term tubes	Levine <i>et al.</i> <sup>6</sup> Abdulla <i>et al.</i> <sup>3</sup> Present study	1994 1994 1994 1999	15 Months No final data 20 Months	Donaldson Trimmed permavent Polyethylene T-Tube

 TABLE I

 MEAN FUNCTIONAL PERIOD OF T-TUBES AS REPORTED IN THE MEDICAL LITERATURE (SPONTANEOUS EXTRUSION) AND IN THE PRESENT STUDY (CONTROLLED REMOVAL)

One of the main reasons for choosing T-tubes is the possibility of trimming them as we like, leaving long flanges to prevent spontaneous extrusion, thus minimizing the need for re-insertion of tubes at a later date.

Another advantage is the fact that we can perform tube removal at our convenience, atraumatically, without the need for general anaesthesia, and thus avoiding the high incidence of complications associated with long-term tube placement. It has been shown that the incidence of residual perforation can be reduced if the tube is electively removed at an appropriate time.<sup>5</sup> Long-term tubes have shown to be associated with higher complication rates.<sup>7</sup> Otorrhoea is the most common complication of middleear ventilation with tympanostomy tubes. Previous reports indicate an otorrhoea rate of 3.4 per cent to 68.6 per cent,<sup>7,13</sup> with rates of 21 to 70.4 per cent for Goode's T-tubes,<sup>5,7,14</sup> and 18.5 per cent for Shah permavent tubes.<sup>5</sup> Long-term tubes are generally associated with a higher incidence of otorrhoea. Our overall otorrhoea rate was only 6.6 per cent.

The development of persistent perforation is a less common complication, ranging from zero to five per cent for short-term ventilation tubes and 15 to 47.5 per cent for long-term ventilation tubes.<sup>4,5,7,14</sup> The rate of persistent perforation in this study was 1.49 per cent. These perforation rates are difficult to compare due to the fact that the term 'persistent perforation' is not specifically defined in most cases. We define a persistent perforation as a perforation still existing for over one year after tube removal/ extrusion. Many of the perforations are probably not a significant problem. Most are self-limiting, and over half of the cases resolve without intervention.<sup>6</sup> Table II demonstrates the gradual resolution of perforations over time in this study. All in all, our perforation rate was regarded to be low in comparison with the conventional ventilation tubes.

Re-ventilation by a repeated T-tube insertion was required in 4.9 per cent of our cases. This compares with a reported incidence of five to 20 per cent for the conventional T-tubes.<sup>4,12,16</sup>

All in all, the outcome of children treated with our self-manufactured polyethylene T-tubes for periods of 15-24 months is favourable in comparison to the conventional grommet or the long-staying tube (Table III). However, we recognize that the comparison of restrospective studies is problematic due to the greater number of variables involved. The site of the myringotomy incision, additional surgical procedures performed in conjunction with tube insertion, the indications for surgery, demographic characteristics of patients and climate are only some of the variables that could affect the outcome and make an exact comparison between studies impossible. It is necessary to conduct prospective randomized studies on both tube design and the duration of ventilation, and some such studies are currently underway.

# Conclusions

We have shown that the outcome of children treated with our ventilation tubes for periods of 15–24 months was favourable in comparison to the reported outcome of children treated with the conventional grommet or the long-staying ventilation tube.

It was felt that the lower complication rate in our study (post-operative otorrhoea, persistent perforation and later re-ventilation) might be due to the controlled duration of ventilation of between 15–24 months.

 TABLE II

 The gradual resolution of tympanic membrane perforations in present study

Time from removal/extrusion	1 month		3 months		6 months		1 year	
	No.	%	No.	%	No.	%	No.	%
No residual perforation	531	88.06	573	95.03	582	96.052	594	98.51
Residual perforation	72	11.94	30	4.97	21	3.48	9	1.49

https://doi.org/10.1258/0022215011908937 Published online by Cambridge University Press

			MEDICINE EITERITORE
	Present study %	Other authors%	
Post-operative otorrhoea	6.6	Prichard <i>et al.</i> <sup>7</sup>	54.9
1		Hern <i>et al.</i> <sup>5</sup>	18.5
		Von Schoenberg <i>et al.</i> <sup>14</sup>	70.4
		Gates <i>et al.</i> <sup>13</sup>	3.4
Later reventilation required	4.9	Hawthorne and Parker <sup>16</sup>	5
		Wielinga and Smyth <sup>12</sup>	20
		Bulkley et al. <sup>4</sup>	15.4
Persistent perforation	1.49	Von Schoenberg <i>et al.</i> <sup>14</sup>	47.5
1		Prichard <i>et al.</i> <sup>7</sup>	21.1
		Hern <i>et al.</i> <sup>5</sup>	18.2
		Levine <i>et al.</i> <sup>6</sup>	5
		Solomon <i>et al.</i> <sup>15</sup>	10.3

 TABLE III

 THE INCIDENCE OF COMPLICATIONS OF T-TUBE INSERTION IN THIS STUDY AND IN THE MEDICAL LITERATURE

#### References

- 1 Armstrong BW. A new treatment for chronic secretory otitis media. Arch Otol Head Neck Surg 1954;59:653-4
- 2 Handler SD. Current indications for tympanostomy tubes. *Am J Otolaryngol* 1994;**15**:103–8
- 3 Abdulla VA, Pringle MB, Shah NS. Use of the trimmed Shah permavent tube in the management of glue ear. J Laryngol Otol 1994;108:303-6
- 4 Bulkley WJ, King Bowes A, Marlowe JF. Complications following ventilation of the middle ear using Goode Ttubes. Arch Otolaryngol Head Neck Surg 1991;117:895–8
- 5 Hern JD, Hasnie A, Shah NS. A long term review of the Shah permavent tube. J Laryngol Otol 1995;109:277–80
- 6 Levine S, Daly K, Giebink GS. Tympanic membrane perforations and tympanostomy tubes. Ann Otol Rhinol Laryngol 1994;103:27-30
- 7 Prichard AJN, Marshall J, Skinner DW, Narula AA. Long term results of Goode's tympanostomy tubes in children. *Int J Pediatr Otorhinolaryngol* 1992;**24**:227–33
- 8 Armstrong BW. Prolonged middle ear ventilation: the right tube in the right place. Ann Otol Rhinol Laryngol 1983;92:582-6
- 9 Hampal S, Flood LM, Kumar BU. The mini-grommet and tympanosclerosis. J Laryngol Otol 1991;105:161-4
- 10 Hussain SS. Extrusion rate of Shah and Shepard ventilation tubes in children. *Ear Nose Throat J* 1995;105:161-4
- 11 Rothera MP, Grant HR. Long-term ventilation of the middle ear using the Goode T-tube. J Laryngol Otol 1985;99:335-7

- 12 Wielinga EWJ, Smyth GDL. Comparison of the Goode Ttube with the Armstrong tube in children with chronic otitis media with effusion. J Laryngol Otol 190;**104**:608–10
- 13 Gates GA, Avery C, Prihoda JJ, Holt GR. Posttympanostomy otorrhea. *Laryngoscope* 1986;**96**:630–4
- 14 Von Schoenberg M, Wengraf CL, Gleeson M. Results of middle ear ventilation with Goode's tubes. *Clin Otolar*yngol 1989;14:503–8
- 15 Solomon PR, Lax MJ, Smitheringale AJ. Tympanic membrane perforation following ventilation tube removal in a pediatric setting: A historical study. J Otolaryngol 1993;22:48–9
- 16 Hawthorne MR, Parker AJ. Perforations of the tympanic membrane following the use of Goode-type 'long-term' tympanostomy tubes. J Laryngol Otol 1988;102:997–9

Address for correspondence:

Y. Talmon, M.D., The Department of Otolaryngology – Head and Neck Surgery, The Western Galilee Hospital, Nahariya, Israel.

Fax: (972) 49850671

Dr Y. Talmon takes responsibility for the integrity of the content of the paper.

Competing interests: None declared