

## Five-year results for use of single-flanged tympanostomy tubes in children

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### Abstract

**Aims:** To assess the five-year outcome of the use of single-flanged tympanostomy tubes in children, including the time to extrusion, rate of retained tubes and rate of persistent perforation.

**Materials and methods:** The medical records relating to 640 single-flanged tympanostomy tubes intended for short-term use in paediatric patients were retrospectively reviewed.

**Results and analysis:** We found that 36.4 per cent of the tubes had extruded within 12 months and 71.0 per cent within 24 months. Results showed that 14.1 per cent of the tubes had been removed because of prolonged retention, with a mean time to removal of 38.9 months. The time to extrusion was longer and the rate of retained tubes was higher than those reported for several other short-term tubes. We found that 4.5 per cent of tube insertions had resulted in a persistent perforation, a higher percentage than previously reported for other tubes intended for short-term use. Within five years of tube insertion, 70.5 per cent of the tympanic membranes had normalised.

**Key words:** Otitis Media With Effusion; Middle Ear Ventilation; Complications; Tympanic Membrane Perforation

### Introduction

Otitis media is one of the most frequent diseases of childhood. It affects a majority of children in the first years of life, and more than 70 per cent of children experience at least one episode of otitis media. Most cases of acute otitis media can be treated with antibiotics, and chronic otitis media with effusion may resolve spontaneously. Even so, a large number of children ultimately require tympanostomy tube placement to alleviate recurrent episodes of acute otitis media and chronic otitis media with effusion as well as chronic retractions.

The concept of tympanostomy tubes has a long history. In the mid-nineteenth century, experiments were already being conducted to find a way to prolong myringotomy patency. Amongst the most renowned of these investigators was the physician Politzer, who introduced a hard rubber eyelet middle-ear ventilation tube in the 1860s. However, this method was abandoned due to the high incidence of suppuration.<sup>1</sup>

In 1954, Armstrong reintroduced the tympanostomy tube when he reported the use of vinyl plastic tubes to ventilate the middle ear.<sup>2</sup> Since then, many different designs of tympanostomy tubes have been developed. Ideally, a tympanostomy tube would be

easy to insert and allow sufficient ventilation of the middle ear to alleviate otitis media. Furthermore, the ideal tympanostomy tube would not result in any episodes of otorrhoea and would extrude after a predictable period of time. Finally, it would not render any harm to the tympanic membrane, so as not to interfere with the spontaneous healing of the perforation.

The designs of the different kinds of tympanostomy tubes vary regarding size, material and coating and whether the tube is single- or double-flanged (although the original Armstrong tube had no flanges). A distinction is often made between short-term and long-term tubes. However, it must be noted that, despite a review of the literature, we failed to find a commonly accepted definition distinguishing the short-term tube from the long-term tube. Generally, short-term tubes are intended for use over a shorter period of time and are used when spontaneous remission of otitis media can be expected over time. When this cannot be expected or if repetitive tympanostomy tube placement has been needed, a long-term tube may be used, such as a T-tube. The main drawback of long-term tubes is that they result in a much higher incidence of persistent perforation.<sup>3</sup>

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Part of the study was presented at the XXIX Congress of the Nordic Association of Otolaryngology, June 15–18, 2005, Reykjavik, Iceland.

Accepted for publication: 1 May 2007. First published online 1 August 2007.

Although tympanostomy tube insertion is one of the most common surgical procedures in children, there is a lack of follow-up studies of the different kinds of tympanostomy tubes, and the number of prospective studies is limited. The present report is one of the largest long-term follow-up studies of a specific type of tympanostomy tube – the straight, single-flanged tube (Atos Medical AB, Horby, Sweden). This tube is made of fluoroplastic, with the following dimensions: length 7.0 mm; inner diameter 1.1 mm; and outer diameter of the flange 2.7 mm. The tube is considered to be a short-term tube.

### Patients and methods

We retrospectively reviewed the medical records of all paediatric patients who had undergone surgery with short-term tympanostomy tube insertion at our department during the years 1998 and 1999. Only the straight, single-flanged tube had been used as a short-term tube in our department during that period of time. If a patient had had a second set of tubes inserted during the study period, that patient was only included once in the recorded data. However, it was noted that some patients had received new tubes during their follow-up time.

All children were operated on under general anaesthesia. The tubes were inserted in the anterosuperior or anteroinferior quadrant, according to the surgeon's preference.

In our department, patients were monitored on a regular basis as long as the tubes were retained, and thereafter until the tympanic membrane appeared to have normalised. Thus, it was possible from the patients' records to retrospectively track the data needed for the study. Background data such as the child's age at surgery, sex and diagnosis were obtained from the medical record, as well as complicating factors such as immunodeficiency or craniofacial anomalies, including cleft palate. Data were collected concerning operative findings and, if noted in the chart, the quadrant into which the tube had been inserted. Previous, concomitant or later adenoidectomy was also noted.

The time until the tube was last recorded in place in the tympanic membrane and the time until the tube was no longer in place were noted. The time to extrusion was defined as the interval between the insertion of the tube and the first time the tympanic membrane was seen without any part of the flange of the tube medial to the tympanic membrane.

If the tube had been operatively removed, the reason for this removal and the time to removal was noted, as well as the time until the tympanic membrane and middle ear normalised. If not normalised within five years, the state of the tympanic membrane and the middle ear at that time was noted as well. We also recorded whether middle-ear surgery had been performed for tympanic membrane perforation or cholesteatoma.

A small minority of patients was lost to follow up during the study period.

Statistical analyses of the collected data were performed using the Statistical Package for the Social

Sciences version 12.0 software (SPSS Inc, Chicago, Illinois, USA).

### Results

A total of 640 tympanostomy tubes were inserted in 348 patients, of whom 57.2 per cent were boys and 42.8 per cent girls. The tube insertions were performed for three main diagnoses; otitis media with effusion (75.4 per cent), recurrent acute otitis media (20.2 per cent) and retraction pathology (4.4 per cent). There was no gender difference between the different diagnoses at insertion of the tympanostomy tube. Five patients had Down's syndrome, three patients had craniofacial anomalies and one patient had an immunodeficiency.

The mean age at tube insertion was 5.5 years (median 5, range 1 to 17). Patients' mean age at tube insertion was 6.1 years (median 6, range 1 to 14) for patients diagnosed with otitis media with effusion, 2.4 years (median 2, range 1 to 7) for patients diagnosed with recurrent acute otitis media and 9.8 years (median 10, range 3 to 17) for patients diagnosed retraction pathology (see Table I).

The mean age of patients who had not had a previous tube was 4.3 years (median 4, range 1 to 14). The mean age of patients with otitis media with effusion was 5.1 years (median 5, range 1 to 14), that for patients with recurrent acute otitis media was 2.3 years (median 2, range 1 to 7) and that for patients with retraction pathology was 9.2 years (median 10, range 3 to 12).

#### *Tubes spontaneously extruded*

Of the 640 inserted tubes, 582 (90.9 per cent) were followed until extrusion or removal. Of these, 459 (78.9 per cent) had extruded spontaneously; the mean time to extrusion was 19.6 months. Of the spontaneously extruded tubes, 167 (36.4 per cent) had extruded within 12 months and 326 (71.0 per cent) within 24 months.

Two hundred and fifty of the tubes had been inserted in the anterosuperior quadrant and 47 in the anteroinferior quadrant. For the remaining tubes, the location of tube placement was only partly specified (e.g. 'anteriorly') or not noted at all. The location of tube insertion did not affect time to extrusion ( $p=0.477$ ; chi-square test comparing the anterosuperior and anteroinferior quadrants).

TABLE I

AGE AT TUBE INSERTION, BY DIAGNOSIS

| Diagnosis            | Age at tube insertion<br>(mean; years) |                |
|----------------------|--|----------------|
|                      | 1st insertion                          | All insertions |
| Chronic OME          | 5.1                                    | 6.1            |
| Recurrent AOM        | 2.3                                    | 2.4            |
| Retraction pathology | 9.2                                    | 9.8            |
| All diagnoses        | 4.3                                    | 5.8            |

OME = otitis media with effusion; AOM = acute otitis media

### Surgically removed tubes

Eighty-two tubes (14.1 per cent) were removed because of prolonged retention. The mean time to removal was 38.9 months (median 38, range 17–60). Twenty-six tubes (4.5 per cent) were removed because of local infection with suppuration which could not be cured by local or systemic antibiotics and thus warranted the removal of the foreign body. Fifteen tubes (2.6 per cent) were removed due to other causes (e.g. non-functioning tube or discomfort) (see Table II).

### Five-year follow up

Of the 402 tympanic membranes that had not had a previous tube, 313 (77.9 per cent) later proved not to need a second tube. In 64 (15.9 per cent) of the cases, a repeat tube insertion was performed, and in 25 (6.2 per cent) two or more new tube insertions were performed during the following five years. The need for repeated tube insertion was not affected by the presence or absence of adenoidectomy concomitant with the first tube insertion.

We were able to follow 82.7 per cent (529 tubes) of the initial 640 tubes until the tympanic membrane had normalised, or for five years after tube insertion. Three hundred and seventy-three (70.5 per cent) of these 529 tympanic membranes had normalised within five years of surgery.

At the five-year end-point, 118 (22.3 per cent) ears still showed signs of eustachian tube dysfunction or had a tube in situ. Twenty-four tympanic membranes (4.5 per cent) had a persistent perforation or had undergone surgery for a persistent perforation. Nine tympanic membranes (1.7 per cent) were partially atrophic but showed no signs of retraction and the middle ear was free from fluid. The remainder (five ears) had undergone mastoidectomy after the tube had extruded, because of cholesteatoma (two cases), mastoiditis (one), chronic suppurative otitis (one) and epidural empyema with sinus thrombosis (one) (see Table III).

When comparing the subgroup of the tympanic membranes that had not had a previous tube with the entire group of studied tympanic membranes, only minor differences were noted: a slightly higher rate of normalised tympanic membranes (74.2 per cent), and a slightly lower rate of tympanic membranes with a persistent perforation or which had undergone surgery for a persistent perforation (3.6 per cent).

TABLE II

TUBE EXTRUSION AND REMOVAL\*

| Reason for removal    | Tubes |      |
|-----------------------|-------|------|
|                       | n     | %    |
| Spontaneous extrusion | 459   | 78.9 |
| Excessive retention   | 82    | 14.1 |
| Infection             | 26    | 4.5  |
| Other causes          | 15    | 2.6  |

\*582 tubes, constituting a follow-up rate of 90.9%.

TABLE III

STATE OF TYMPANIC MEMBRANES 5 YEARS POST-OPERATIVELY\*

| State of TM  | TM  |      |
|--|-----|------|
|  | n   | %    |
| Normalised within 5 years  | 373 | 70.5 |
| Signs of eustachian tube dysfunction or tube in situ               | 118 | 22.3 |
| Persistent perforation (or operated on for persistent perforation) | 24  | 4.5  |
| Atrophic tympanic membrane (no eustachian tube dysfunction)        | 9   | 1.7  |
| Surgery for cholesteatoma  | 2   |      |
| Surgery for mastoiditis  | 1   |      |
| Surgery for chronic suppurative otitis                             | 1   |      |
| Surgery for epidural empyema with sinus thrombosis                 | 1   |      |

\*529 tympanic membranes, constituting a follow-up rate of 82.7%. TM = tympanic membrane

### Discussion

The effect of ventilation tube treatment for hearing loss associated with otitis media with effusion in children has been extensively studied, and in 2005 was summarised by Lous *et al.* in a Cochrane review.<sup>4</sup> Ventilation tube treatment for recurrent acute otitis media has also been thoroughly investigated.<sup>5–7</sup>

Even though the insertion of transmyringal ventilation tubes is one of the most common surgical procedures, there is no consensus on what kind of tube is best. There are numerous designs of transmyringal ventilation tubes, varying in shape, size and material, but there are only a few reports that have randomised the use of different kinds of tubes. Weigel *et al.*<sup>8</sup> conducted a randomised study comparing three short-term tubes (Armstrong bevelled tube, Shepard grommet and Reuter Bobbin tube) with the long-term Goode T-tube. The groups were small but the authors could still show significant differences in the results of the different kinds of tubes, mainly regarding tube obstruction and otorrhoea. Gibb and MacKenzie also showed significant differences in results for eight different tubes, in a prospective and generally (but not completely) randomised study.<sup>9</sup> Apart from the few prospective, randomised studies, knowledge of outcomes for various types of tubes derives from comparisons between different studies of specific tubes. Thus far, the largest study of a specific kind of tube was a long-term follow up of the Armstrong bevelled grommet, which included 1096 tubes.<sup>10</sup> We present a retrospective study of 640 single-flanged tympanostomy tubes, with a follow-up rate of 90.9 per cent until extrusion or removal. We were able to follow 82.7 per cent of all ears until normalisation or until five years had elapsed post-operatively.

We found differences in patients' ages at surgery, associated with differences in diagnosis, as expected. This finding reflects the varying natural courses of the different diseases; recurrent acute otitis media is a disease of the youngest paediatric group, while otitis media with effusion with clinically significant hearing loss affects the pre-school group to a greater extent. The age difference between the

group with otitis media with effusion and the group with recurrent acute otitis media was reduced when age at first tube insertion was compared, since the likelihood of undergoing more than one tube insertion procedure is greater in patients with otitis media with effusion, compared with patients with recurrent acute otitis media.

#### *Time to extrusion*

We found a mean time to extrusion of 19.6 months. By comparison, Lindstrom *et al.* reported a mean time to extrusion of 16.5 months for Armstrong grommets.<sup>10</sup>

When comparing different studies' results regarding time to extrusion, it is crucial to define how the time to extrusion has been measured. Apparently, the exact date on which the tube leaves the tympanic membrane cannot be registered. Instead, the extrusion must be assumed to have occurred in the interval between the last time the tube was otoscopically observed in situ and the first time it was observed not to be in place. Regrettably, most authors do not describe how the time to extrusion is calculated. In the present report, the time to extrusion was defined as the interval between the insertion of the tube and the first time the tympanic membrane was seen without any part of the flange of the tube medial to the tympanic membrane.

Another way of describing the time to extrusion is to note the percentage of tubes which have extruded after a specific period of time. We found that 36.4 per cent of tubes had extruded after 12 months and 71.0 per cent after 24 months. Todd reported an audit of 186 ears in which 91.4 per cent of Shepard tubes had extruded after 12 months.<sup>11</sup> Gibb *et al.* reported equivalent results for Shepard tubes. The same authors also reported that approximately 45 per cent of Bobbin tubes and 55 per cent of Shah tubes had extruded after 12 months, and that 100 per cent of those tubes had extruded within 24 months. The tube used in the present study could best be compared to the collar button tube, which has an extrusion rate of 30 per cent after 12 months and 80 per cent after 24 months.<sup>9</sup> For long-term tubes, extrusion rates after 24 months have been reported to be 20–35 per cent.<sup>8,12,13</sup>

#### *Retained tubes*

Some authors have found that removal of the tympanostomy tube reduces the risk of persistent perforation, but this has been disputed by others. There is thus no consensus on how to treat tubes that are retained for an extended period of time. Likewise, there is no definition of the point at which tube retention is considered excessive.<sup>14–17</sup>

In the present study, we found that 14.1 per cent of tubes were removed because of excessive retention. Generally, we had used a three-year limit, beyond which a persistently retained tube was removed. Subsequently, our mean time to removal was 38.9 months, which is longer than that reported by many other studies. Despite this, our removal rate was markedly higher than that reported for other types

of short-term tubes. Other authors have reported that only 1.3 per cent of Armstrong bevelled grommets required operative removal for retention.<sup>10</sup>

However, the retention rate amongst our patients was much lower than that found for long-term tubes such as the T-tube.<sup>12,18,19</sup>

The mechanisms behind tube extrusion have not yet been clarified. Factors possibly affecting time to extrusion are: choice of quadrant for tube insertion, tube material, diameter of flanges, presence of an outer flange and frequency of otorrhoea.

#### *Quadrant of tube insertion*

It has been argued that the quadrant chosen for tube insertion affects the time to extrusion. The postulate has been that a tube placed in the anterosuperior quadrant will stay longer due to the pattern of epithelial migration.<sup>20</sup> What is rarely discussed is the fact that the epithelium constitutes just one of several layers of the tympanic membrane. To our knowledge, a similar migration pattern has not been documented for the lamina propria, which contains the strength and weight-bearing collagen fibres of the tympanic membrane.

The present study revealed no difference in time to extrusion when comparing tubes inserted in the anterosuperior and anteroinferior quadrants. The results are equivalent to those from previous clinical studies with randomised research protocols, which also showed no difference in time to extrusion when comparing quadrant of tube insertion.<sup>21,22</sup>

#### *Tube material and flange diameter*

Different materials may lead to various degrees of foreign body reactions. In the present study, the tube material was fluoroplastic, which is commonly used in tympanostomy tubes. Regrettably, the tube material is seldom specified in reports, making it difficult to compare the results of different studies. The flange diameter is also infrequently reported. Intuitively, one may suspect that the diameter of the inner flange would play a major role; the bigger the flange, the harder it must be for the ear to expel the tube.

The present study has many similarities with the aforementioned study of the Armstrong bevelled grommet by Lindstrom *et al.*: the same tube material, and the same diameter of the tube and the inner flange (according to our correspondence with these authors). The Armstrong tube was retained in only 1.3 per cent of Lindstrom and colleagues' cases, as compared with 14 per cent in our study.<sup>10</sup> The differences between the two kinds of tubes were, firstly, the presence of an outer flange and, secondly, the inner flange being bevelled in the Armstrong tube.

#### *Presence of an outer flange*

Hypothetically, one of the factors behind tube extrusion could be accumulation of epithelial debris under an outer flange.<sup>21</sup> This would lead to compression of the tympanic membrane tissues under the flange, which could in turn lead to a compromised blood

flow and local pressure necrosis around the tube, making it easier for the tube to leave the tympanic membrane. Obviously, this phenomenon cannot take place if there is no outer flange. To our knowledge, this hypothesis has not been tested clinically or in animal models.

### Otorrhoea

Inflammation induces increased desquamation of the epithelium, and otorrhoea could therefore theoretically be a co-factor in tube extrusion. The frequency of otorrhoea associated with tympanostomy tube was not investigated in this study. The reason for this was that our hospital serves a relatively sparsely populated area, with long travel distances. We know from experience that patients often consult their local general practitioner in cases of uncomplicated otorrhoea. Our retrospective review would therefore not be valid regarding the frequency of otorrhoea associated with the studied tubes.

### Persistent perforation

Previous studies have used different time intervals to define persistent perforation; from six weeks to more than five years.<sup>23</sup> In our study, we defined a persistent perforation as one that did not spontaneously close within 12 months of tube extrusion being recorded. No myringoplasty had been performed within this frame of time. Despite this 'hard' definition of persistent perforation, we found a high rate of such perforations (4.5 per cent). This rate is higher than that reported for many other short-term tubes. In a 2001 meta-analysis by Kay *et al.*, the rate of persistent perforation was found to be 2.2 per cent for short-term tubes.<sup>3</sup> It is possible that the need for repetitive tube insertions increases the risk of persistent perforation. However, when analysing the tympanic membranes in the present study which had only undergone one tube insertion procedure, the rate of persistent perforation was still as high as 3.6 per cent.

The longer the tube stays in place, the higher the risk of persistent perforation. For long-term tubes, Kay *et al.* found that 16.6 per cent of insertions resulted in persistent perforation.<sup>3</sup> We believe that the high rate of persistent perforation in the present study was a result of the longer times to spontaneous extrusion and the proportionally higher rate of tube removal.

It is routine practice in our department to 'freshen' the edges of the perforation with a sharp instrument when a tube is removed. Many other methods intended to enhance perforation closure have been described, such as paper patching, Silastic® sheeting, patching with absorbable agents and cauterisation with trichloroacetic acid. There is, however, only weak evidence that any one treatment is superior to others.<sup>24</sup> Possibly, another choice of treatment could have led to a lower incidence of persistent perforation in our patients. Nevertheless, in the cases of spontaneous extrusion, the rate of persistent perforation was 3.7 per cent, which is still higher than Kay and colleagues' reported rate (2.2 per cent) in the previously mentioned meta-analysis of short-term tubes.

- **This five-year follow-up study indicates that the use of single-flanged tympanostomy tubes results in longer times to extrusion and higher rates of retained tubes than has been reported for several other types of short-term tympanostomy tube**
- **Single-flanged tympanostomy tubes also result in higher rates of persistent perforation**
- **Tympanic membranes had normalised within five years in 70.5 per cent of cases following single-flanged tympanostomy tube insertion**

### Results five years post-operatively

In the present study, 22.1 per cent of ears undergoing their first tube insertion required at least one more tube insertion over the following five years. Luxford and Sheehy have reported a similar rate (21 per cent) in a large study including 2266 insertions of two different kinds of tubes.<sup>15</sup>

In the present study, the tympanic membrane had normalised within five years in 70.5 per cent of cases. This is almost equivalent to Valtonen and colleagues' findings; in a prospective study of 610 ears, they found normalised tympanic membranes in 67.3 per cent of ears five years post-operatively.<sup>25</sup> Their reported rates for retraction pathology and middle-ear fluid, five years post-operatively, are also similar to ours.

### Conclusion

This five-year follow-up study indicates that the use of single-flanged tympanostomy tubes results in longer times to extrusion and higher rates of tube retention than had been reported for several other types of short-term tympanostomy tubes. The study also indicates that single-flanged tympanostomy tubes result in higher rates of persistent perforations; however, prospective, randomised trials are needed to confirm these findings. Approximately 70 per cent of tympanic membranes had a normal appearance within five years of tube insertion.

### Acknowledgements

The authors wish to thank the Centre for Clinical Research, Västmanland county, for general support and advice (specifically, Mr T Wiklund and Mr A Tegelberg).

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Dr J Knutsson takes responsibility for the integrity of the content of the paper.

Competing interests: None declared

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