

## **Factors affecting the extrusion rates of ventilation tubes<sup>1</sup>**

**I J Mackenzie** FRCS(ED) FDS

*Department of Otolaryngology, Royal Infirmary, Edinburgh EH3 9EN*

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**Summary:** A survey in which 939 ventilation tubes of 8 different patterns were inserted and reviewed (up to a maximum of 2½ years) is analysed. Various factors determining the rate of extrusion are discussed. The Sheehy Collar Button tube remained functional for a longer period than any of the other tubes included in the survey.

### **Introduction**

Judging by the number of different ventilation tubes that are available today, it might be concluded that a generally satisfactory tube has not yet been designed. It is usually stated that ventilation tubes in current use tend to remain in place on average for 6 to 7 months before being spontaneously extruded, but their tenure is highly variable, sometimes days, sometimes years (Paradise 1977). A comparative study of extrusion rates and the factors affecting them was therefore designed.

### **Methods**

A prospective study was carried out following the insertion of 939 ventilation tubes at Ninewells Hospital, Dundee, over a period of 15 months from November 1978 to February 1980 for serous otitis media. The survey included 609 patients, 355 male and 254 female, whose ages ranged from 9 months to 77 years (average 10.8 years).

The Exmoor ventilation tube is designed like a grommet used in the engineering industry; other types of ventilation tubes in use are also colloquially called grommets, although this is not strictly accurate because of their design. All patients admitted for insertion of grommets were included in the survey except those who were admitted for insertion of Per-Lee tubes. It has been well established that the Per-Lee tube stays in for many years and is ideal for those ears requiring long-term ventilation (Holt & Harner 1980).

The types of grommet inserted were those that were thought to be easily available. The study started with 10 different types but supplies of 2 became difficult and these were therefore removed from the study. The types (Pappas 1974, Shah 1971) and numbers of each grommet inserted were Exmoor 142, Shepard 137, Bobbin 132, Arrow 58, Shah 131, Armstrong 138, Collar Button 141 and Paparella 60. The sister in charge of the operating theatre was given a list of the order in which the grommets were to be presented. This was a straightforward rotation and if the operator, for whatever reason, felt that he was unable to insert the grommet offered, that ear was withdrawn from the study. This happened on 23 occasions which, in view of the large number of grommets inserted, made no statistical difference to the results.

The patients were examined the following day at Ninewells or Bridge of Earn Hospital and then at 3-monthly intervals at Ninewells or at a peripheral clinic. They were seen until the grommet had been extruded. It had been hoped that audiometric and tympanometric assessment could be made at each of these appointments, but unfortunately this was not possible in all cases, particularly in the peripheral clinics.

The notes have been reviewed up to 2 years 3 months after the insertion of the grommets,

<sup>1</sup>Based on paper read to Section of Otolaryngology, 4 March 1983. Accepted 2 May 1984

but because of industrial action in 1982 this process was delayed. During the period of survey 19 patients were lost to follow up and 2 patients died, a patient loss rate of 3.4%.

At operation a proforma was completed which included details about the operator, the patient and the procedure. The age and sex of the patient and whether any other operations were carried out at the same time (e.g. adenoidectomy) were recorded. The quality of the tympanic membrane, the type and position of the myringotomy incision, the quality of the middle ear fluid present, the difficulty of insertion, and the presence of blood, were factors considered most likely to affect the extrusion rate. The operator was given a choice of options for each of the factors described above, and indicated the most appropriate with a tick. The proforma sheets were kept in the notes, and at outpatient follow up details of whether the grommet was patent, blocked or extruded were added.

When the sheets had been completed up to a 2 year 3 months follow up, the data were transcribed onto the University of Dundee computer, which carried out most of the statistical analysis.

## Results

Comparison of the extrusion rates for the various grommets showed that grommet design was important. The Shepard and Exmoor grommets were extruded very quickly, all having been extruded by 15 months and over 50% by 6 months. The difference in material of polypropylene and teflon in these two grommets seemed to make no difference to their performance.

The Bobbin and Shah grommets were all extruded by 18 months but over 50% were still *in situ* at one year; the Shah was considered the easier grommet of the two to insert.

The Arrow grommet had a high initial extrusion with nearly 80% extruded at one year, but those that were in at one year remained *in situ* for a further year. The Paparella grommet had a slow extrusion rate with over 50% of the grommets in place at 15 months, the rest being extruded by 2 years 3 months.

The Collar Button and Armstrong had the slowest extrusion rates, very few having been extruded at 6 months and nearly half still being in place at 18 months. At 2 years nearly 20% of the Collar Buttons and slightly fewer Armstrong grommets were still in place. On reviewing the notes, a large number of Collar Button grommets are still in place at 3 years. Of the two, it was generally accepted that the Collar Button was easier to insert.

There was no significant difference between consultants and junior staff in the extrusion rates of the simple grommets, but for those ventilation tubes where insertion is accepted as being more difficult, the extrusion rates were significantly faster ( $P = < 0.01$ ) in the junior staff group. Figures for the Arrow grommet were of particular note: by the end of the first year only one of the 46 inserted by junior staff was *in situ*, compared with 11 of 12 inserted by consultants. It is of interest that the consultants had said these grommets were difficult to insert, whereas only 50% of those inserted by junior staff were thought to be difficult. During the period of observation 5 Arrow grommets were found to have been inserted back to front. A similar though less dramatic pattern was experienced with the flanged Armstrong tubes.

Of 26 grommets that at operation were noted to be a loose fit, only 4 were in place at one year.

Audiometric assessment was most successful at the first 3-monthly appointment and 370 of 475 patients (78%) had normal hearing, but unfortunately not everyone was tested. An effort was made to correlate the improved hearing or lack of it with the different types of grommet, but no difference was found with respect to type of grommet or quadrant of insertion.

At the first 3-monthly appointment 787 (83%) grommets were patent. Over the next 18 months, 190 (73%) of 260 grommets reported as blocked at one visit had extruded by the next visit.

The complication rate was small, with 5 infected ears of which only 2 required the removal of the grommet; and in the long term 2 patients were left with perforations and 4

patients were noted to have tympanosclerosis, but this is a poor figure as the patients were not followed up after the extrusion of the grommet.

### **Discussion**

There were two factors which we wrongly anticipated would be relevant: first, the material of manufacture which was shown to make no difference, and secondly the quadrant of insertion. Theoretical reasons have been given that grommets stay in longer in the anterior superior quadrant, but with over 150 grommets being inserted in each quadrant, except the posterior superior quadrant, no significant difference could be found in the extrusion rate.

It may be suggested at this stage that when a grommet was reported as blocked an epithelial regeneration had taken place beneath it, although apparently with an auriscope it appeared still to be *in situ*.

Surprisingly, therefore, only 3 factors seemed to make any difference to the actual extrusion rate of grommets: the shape of the grommet, the experience of the operator, and whether the grommet was a loose fit at insertion.

Of the difference in extrusion rates, that between the Exmoor and the Sheehy Collar Button was the greatest. They are, however, both easy to insert and have a similar appearance; the internal diameter and width of the Collar Button is approximately 1 mm greater than the Exmoor but the Exmoor grommet is 1 mm longer. It had been expected that the flanged grommets of Armstrong and Shah would have stayed in the longest.

The results of this study give the surgeon the choice of either a short-stay grommet of Exmoor/Shepard design, which should last one winter, or, if a grommet is required to last two winters, then the Sheehy Collar Button will be the most useful.

*Acknowledgments:* I would like to thank the staff of the ENT Unit at Ninewells Hospital, and Mr A G Gibb for his help and for allowing me to continue the study after my move to Edinburgh.

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