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The mini-grommet and tympanosclerosis

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Abstract
One hundred and sixteen children with otitis media with effusion underwent myringotomy and insertion of a conventional pattern of Shah grommet in one ear and the much smaller Mini Shah grommet in the other. Close observation post-operatively determined the comparative rate of extrusion, recurrence of effusion, and of onset and degree of tympanosclerosis. At one year review, the Mini Shah shows a significantly earlier extrusion and a greater tendency to recurrence of otitis media with effusion. However, this is compensated by a decreased incidence of tympanosclerosis and reduced severity in those affected. This tends to support the view that shear forces produced by heavier patterns of ventilation tube promote tympanosclerosis.

Introduction

Surgical management of otitis media with effusion has been criticized as 'a modern epidemic', prevalent in the higher socio-economic groups (Black, 1984). The insertion of a tympanostomy tube or grommet is increasingly recognized as conferring no long-term benefit to hearing or protection against attic retraction (Skinner *et al.*, 1988) but rather as promoting progressive tympanosclerosis and atrophy (Slack *et al.*, 1984). Such concerns have led to studies on the benefits of adenoidectomy (Maw and Herod, 1986), although no correlation is proven between adenoid mass and the presence of effusion (Hibbert and Stell, 1982) and it has been recommended that 'the operation could be virtually abandoned with no ill effects' (Stell, 1981).

An alternative approach is to seek a design of grommet which avoids the development of tympanosclerosis and a reduction in mass has been suggested (Slack *et al.*, 1984; Lesser *et al.*, 1988). This study aims to:

a. Determine the extrusion rate of the Mini Shah grommet compared with the conventional Shah pattern (Fig. 1).
b. Match this with the consequent recurrence rate of otitis media with effusion for the two designs.
c. Balance this against any comparative advantage for incidence and severity of tympanosclerosis.

Method

One hundred and sixteen children with ages ranging from 3 to 7 years were studied. All had otitis media with effusion (OME) as determined by otoscopy, tympanometry and audiology. Only children satisfying the following criteria were admitted to the trial:

a. No previous history of ear surgery.
b. No previous changes in the tympanic membrane such as tympanosclerosis or atrophy.
c. A positive finding of a bilateral middle ear effusion at myringotomy.

Immediately prior to surgery, patients were assigned to insertion of an Exmoor Shah (AG/T5WW) grommet in one ear and a Mini Shah (AG/T5(P)) grommet in the other ear, sides being chosen on a random basis. The surgery was undertaken by two of the authors (LMF and BUK). The tympanic membrane was carefully examined under the operating microscope and fluid aspirated through a radial incision high in the anterosuperior quadrant. The size of myringotomy was determined by the size of grommet chosen, to allow a snug fit and, after insertion, the grommet was rotated to point the inner projection towards the malleus handle (Gibb, 1980). Sofradex drops were then instilled and the child discharged with the instruction to continue application twice daily for three days. Swimming was allowed, but diving and entry of soapy water discouraged.

Each subject was reviewed by a single examiner (LMF) at six weeks, six, nine and twelve months after

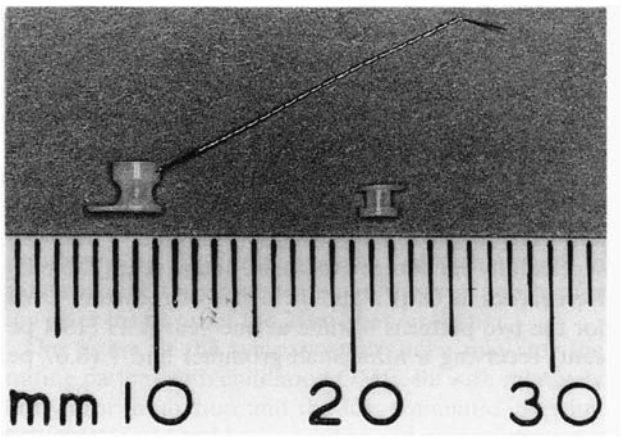

Fig. 1
Grommets: left = Shah Grommet, Right = Mini Shah Grommet.

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TABLE I
EXTRUSIONS OF GROMMETS: CUMULATIVE TOTAL

Time (Wks)	Mini Shah Grommet	Shah Grommet
6	2 (2.2%)	1 (1.1%)
12	8 (8.8%)	1 (1.1%)
24	30 (32.9%)	1 (1.1%)
36	73 (80.2%)	8 (8.8%)
52	85 (93.4%)	27 (29.7%)

A 1 year $p<0.001$ N = 91.

surgery. Note was made of the status of the grommet, especially its patency and retention in the tympanic membrane. Audiometry appropriate to age was performed at the first and last of these visits. Should a grommet be blocked or extruded, clinical, tympanometric and audiological evidence of recurrent OME was sought. The presence and extent of any tympanosclerosis was recorded. For this purpose, the tympanic membrane was divided into four quadrants (anterosuperior and inferior and posterosuperior and inferior) and extent accordingly graded on a scale of 0–4, as described by Slack *et al.* (1984).

Unfortunately there were inconsistent attenders, but 91 children attended for the planned five review appointments. Diligent clerical and secretarial work encouraged a further 14 defaulters to return for the final one year follow-up. No child underwent further surgery during review. The presence of at least one grommet *in situ* prevented blind assessment by the observer.

Results

116 children were admitted to the study after satisfying the entrance criteria; 15 of these underwent adenoidectomy ± tonsillectomy as well as grommet insertion. Of the total, 25 (21.5 per cent) were lost to follow-up during the review period. Fourteen of these were successfully encouraged to at least attend for the final one year check, while the remaining 11 persisted in defaulting. A complete follow-up on 91 is therefore available, with one-year data on 105. At one year 6 (5.7 per cent) of Mini Shah and 74 (70.48 per cent) of Shah grommets were still *in situ*.

Extrusion Rates for the Exmoor Shah and Mini Shah grommets are presented in Table I. The data is drawn from the 91 regular attenders. The one-year results show a significant difference ($p<0.001$) in extrusion rate between the two grommet types. For the remaining absentees there is insufficient data to determine the timing of the extrusion. The one-year results for grommet retention, recurrence of SOM and tympanosclerosis are derived from the reliable attenders plus the 14 who were successfully encouraged to attend at one year (Table II).

Recurrence of OME. The incidence of recurrent OME for the two patterns of tube at one year is 19 (18.1 per cent) receiving a Mini Shah grommet and 7 (6.67 per cent) receiving a conventional Shah grommet. Statistical analysis by comparison of the percentages shows a significant difference in the recurrence of OME ($p<0.05$).

Tympanosclerosis. The incidence and severity of tympanosclerosis at one year is presented in Table III. There is a highly significant difference in the incidence of tympanosclerosis between the two groups ($p<0.01$). The difference in severity of tympanosclerosis is significant in the grades 3 and 4 ($p<0.05$), while no difference is statistically apparent in grades 1 and 2 ($p>0.5$). In order to ascertain whether grommet 'survival' influences tympanosclerosis, ears that had undergone insertion of Mini Shah grommets were further analysed at the 9 month follow-up (Table IV). There is a significant difference in the incidence of tympanosclerosis between those ears in which the Mini Shah grommet had extruded prior to 6 months and in those with grommets still *in situ* at nine months ($p<0.05$).

Audiometry. Of 105 children seen at one year, 64 were sufficiently mature to provide reliable pure tone audiometry. The mean threshold, averaging 0.5, 1 and 2 kHz, for the Shah grommet was 17.53 (SD 3.29) dB, range 10–21.7 dB, and 18.4 (SD 3.70) dB, range 10–30 dB for the Mini Shah. On statistical analysis by comparison of means there was no significant difference ($p = 0.34$).

Discussion

This study demonstrated the anticipated earlier extrusion of Mini Shah grommet compared with the much larger Shah grommet. A consequent increase in the recurrence rate of OME might be acceptable if associated with a lower incidence of complications such as tympanosclerosis.

The literature on tympanostomy tubes has tended to dwell on designs allowing longer periods of intubation. Gibb and Mackenzie (1985) compared extrusion rates of eight types of grommets and found that most Shepard and Exmoor tubes were expelled within six to nine months. The Shah tube tended to extrude between nine to fifteen months and the longest retained pattern proved to be the Sheehy collar button, *in situ* 15 to 24 months. The authors concluded that such factors as site of insertion, the condition of the tympanic membrane and the experience of the surgeon did not influence extrusion rate, but that the shape and design of the grommet did.

Large bore tympanostomy tubes are better retained, but associated with significant complication rates. Brockbank *et al.* (1988) noted otorrhoea in 28 per cent and persistent perforation in 6 per cent of ears treated with the Goode T-tube and so concluded that it should be reserved for refractory cases of OME or patients with cleft palate. The Per-Lee tube can be retained for periods in excess of 10 years (Gibb, 1986), but removal because of blockage or infection carries a high risk of

TABLE II
SUMMARY OF RESULTS AT 1 YEAR

Grommet	Grommets *in situ* $N = 105$	Recurrent SOM $N = 105$	Tympanosclerosis $N = 105$
Mini Shah	6 (5.7%)	19 (18.10%)	24 (22.86%)
Shah	74 (70.45%)	7 (6.67%)	42 (40.00%)

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TABLE III
TYMPANOSCLEROSIS AT 1 YEAR AND TEST OF SIGNIFICANCE BY COMPARISON OF PERCENTAGES

Grade	Mini Shah Grommet	Shah Grommet	P value
1	5	7	p>0.5
2	10	12	p>0.5
3	9	19	p<0.05
4	0	4	p<0.05
Total	24	42	p<0.01

$N = 105$.

residual perforation. A 24.8 per cent permanent defect in the tympanic membrane resulted from removal or extrusion in Per-Lee's own study (1981). In severe cases of refractory Eustachian tube dysfunction, the ventilation allowed by the perforation may make it acceptable, but such devices seem unsuitable for routine use.

The ideal period of intubation for the majority of children with OME remains to be determined. Maw and Herod (1986) found that grommet insertion with adenoidectomy and possibly tonsillectomy gave some hearing improvement in operated ears at six months, but that the gain was lost by twelve months. There is evidence that even short periods of per-tympanic ventilation can produce long term remissions of OME. Ruckley and Blair (1988) found that a thermal perforation of the membrane would persist for an average of 26 days, but in a three month follow-up only 19 per cent of patients suffered recurrence of OME. This compares with a spontaneous remission rate of only 27 per cent over a three month period without surgery (Tos *et al.*, 1982).

Tympanosclerosis is the most significant complication associated with grommet insertion and is manifested as the appearance of white, thickened plaques in the tympanic membrane and middle ear. Scanning electron microscopy demonstrates a latticework of collagen fibres housing spherical masses of calcium phosphate (McKee and Kerr, 1989) within the lamina propria. The incidence of tympanosclerosis is increased by grommet insertion and development is a progressive phenomenon, persisting long after extubation. Slack *et al.* (1984) recorded tympanosclerosis in 40 per cent of ears intubated with Shepard grommets after one year. In an animal model (the rat), Soderberg *et al.* (1986) demonstrated that repeated insertion of a polyethylene tympanostomy tube produced 'severe' structural changes in the lamina propria with increased connective tissue fibrosis within weeks of surgery. Lesser *et al.* (1988) studied the location of tympanosclerosis in tympanic membranes 15 years after grommet insertion and found the antero-inferior and postero-inferior quadrants, mid-way between annulus and umbo, to be most affected. Slack *et al.* (1984) found that at 15 months post-operatively, of those patients with tympanosclerosis nearly 75 per cent showed it in these sites. The authors of both studies suggested that the mass of a grommet might affect the microstructure of the tympanic membrane. In an elegant study, Lesser *et al.* (1988) correlated the site of maximal incidence of tympanosclerosis with the sites of shear stress which might be produced by the mass of a grommet. They suggested that disruption of fine cross fibrils would allow the outer radial layer and the inner circular layer of the tympanic membrane to shear from one another and that this effect might be avoided by the use of a lighter grommet. They recorded that 'the lightest grommet in common use is 12.35 mg and others are ten times this weight'. This compares with the 3.5 mg weight of the Mini Shah and 13 mg of the regular Shah grommet (manufacturers data—Exmoor).

TABLE IV
TYMPANOSCLEROSIS: ROLE OF GROMMET SURVIVAL

Grade of tympanosclerosis	Grommets extruded by 6 months $N = 30$	Grommets *in situ* at 9 months $n = 18$
0	26	10
1	2	3
2	1	2
3	1	1
4	0	2
Total	4	8 p<0.05

The most recent study, from a unit which has contributed significantly to the understanding of the pathogenesis of tympanosclerosis, examines the role of intratympanic haemorrhage (Parker *et al.*, 1990). If there was no immediate intratympanic haemorrhage, only 18.5 per cent of ears developed tympanosclerosis six months after grommet insertion. This compares with 49.2 per cent of ears showing such changes if haemorrhage was observed. It was suggested that the duration of grommet intubation might contribute further in that ears without immediate evidence of post-insertion intramembranous haemorrhage and with the grommet extruded at six months did not develop tympanosclerosis. Mini grommets show a similar tendency to greater pathological changes in the few patients retaining the tube for more than nine months. The results of the study presented lend support to the argument that a smaller grommet may protect against tympanosclerosis whilst still palliating OME. This benefit may be due to the easier insertion through a smaller myringotomy or to the lesser mass of the tube once *in situ*. A subsequent study is planned to determine whether delayed damage is avoided. With both grommets extruded, truly 'blind' observations are possible. Only a minority of patients in this study underwent adenoidectomy and a further study is underway to determine the effect of such surgery in decreasing the recurrence rate of otitis media with effusion after insertion of the Mini Shah grommet.

The future of the tympanostomy tube may, for the routine patient with childhood OME, lie with relatively short term intubation and the less traumatic insertion and retention of truly micro-tubes rather than the comparatively bulky conventional grommet.

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References

Black, N. (1984) Surgery for glue ear—a modern epidemic. *Lancet,* **8381:** 835–837.

Brockbank, M. J., Jonathan, D. A., Grant, H. R., Wright, A. (1988) Goode T-tubes: do the benefits of their use outweigh their complications. *Clinical Otolaryngology,* **13:** 351–356.

Gibb, A. G. (1980) Long term assessment of ventilation tubes. *Journal of Laryngology and Otology,* **94:** 39–51.

Gibb, A. G., Mackenzie, I. J. (1985) The extrusion rate of grommets. *Archives of Otolaryngology,* **93:** 695–699.

Gibb, A. G. (1986) Long term tympanic ventilation by Per-Lee tube. *Journal of Laryngology and Otology,* **100:** 503–508.

Hibbert, J., Stell, P. M. (1982) The role of enlarged adenoids in aetiology of secretory otitis media. *Clinical Otolaryngology,* **7:** 253–6.

Lesser, T. H. J., Williams, K. R., Skinner, D. W. (1988) Tympanosclerosis, grommets and shear stresses. *Clinical Otolaryngology,* **13:** 375–380.

McKee, G. J., Kerr, A. G. (1989) Tympanosclerosis—a scanning electron microscopic study. *Clinical Otolaryngology,* **14:** 11–16.

Maw, R. A., Herod, F. (1986) Otoscopic, Impedance and Audiometric Findings in glue ear treated by adenoidectomy and tonsillectomy. *Lancet,* **1:** 1399–1402.

Parker, A. J., Maw, A. R., Powell, J. E. (1990) Intratympanic membrane bleeding after grommet insertion and tympanosclerosis. *Clinical Otolaryngology,* **15:** 203–207.

Per-Lee, J. H. (1981) Long term middle ear ventilation. *Laryngoscope,* **91:** 1063–1073.

Ruckley, R. W., Blair, R. L. (1988) Thermal myringotomy. *Journal of Laryngology and Otology,* **102:** 125–128.

Skinner, D. W., Lesser, T. H., Richards, S. H. (1988) A 15 year follow-up of a controlled trial of the use of grommets in glue ear. *Clinical Otolaryngology,* **13:** 341–346.

Slack, R. W., Maw, R. A., Capper, J. W., Kelly, S. (1984) Prospective study of tympanosclerosis developing after grommet insertion. *Journal of Laryngology and Otology,* **98:** 771–774.

Soderberg, O., Hellstrom, S., Stenfors, L. E. (1986) Structural changes in the tympanic membrane after repeated tympanostomy tube insertion. *Acta Otolaryngologica,* **102:** 382–390.

Stell, P. M. (1981) Adenoidectomy. *Clinical Otolaryngology,* **6:** 1–3.

Tos, M., Holm-Jensen, S., Sorensen, C. H., Morgensen, C. (1982) Spontaneous course and frequency of secretory otitis in 4-year-old children. *Archives of Otolaryngology, Head and Neck Surgery,* **108:** 4–10.

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