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The mini-grommet and tympanosclerosis: results at two years

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Abstract
One hundred and sixteen children with otitis media with effusion (OME) underwent surgery with grommet insertion. A conventional Shah grommet was used in one ear, and a Mini-Shah grommet in the other. Final review of the subjects two years after surgery revealed a significantly lesser degree of tympanosclerosis in the ear into which the Mini-Shah grommet had been inserted. This benefit might have resulted from the lesser mass of the mini-tube or its shorter duration in situ.

Key words: Otitis media with effusion; Grommet insertion.

Introduction

Otitis media with effusion occurs in between 50 and 70 per cent of children under the age of seven years. While it may be expected to resolve in up to 80 per cent of cases, the majority of the remainder will require surgery with insertion of ventilation tubes, and many will undergo surgery on more than one occasion. However, tympanostomy tubes are not without complications themselves. Infection is seen in up to 28 per cent of children with large bore ventilation tubes (Brockbank *et al.*, 1988), although to a lesser degree with the smaller grommet. Residual perforation has also been seen in between 6–24 per cent of cases with large bore ventilation tubes (e.g. Goode's or Per-Lee tubes) (Brockbank *et al.*, 1988; Per-Lee J. H., 1981), and while being less commonly associated with the smaller grommet, residual perforations do still occur. Atrophy of the tympanic membrane at the site of grommet insertion is commonly seen and tympanosclerosis varying from minimal chalky patches to extensive plaques involving almost the whole tympanic membrane may occur. This may be a progressive process with tympanosclerosis developing even years after the original surgery (Mawson *et al.*, 1972). In addition there is evidence to suggest that grommets do not prevent the ill-effects of negative middle ear pressure (Skinner *et al.*, 1988; Padgham *et al.*, 1989). While there is an increasing trend towards treating OME conservatively, grommet insertion is still widely performed and indeed is the most common operation in children in the UK.

Tympanosclerosis as a complication of grommet insertion is limited to the tympanic membrane and has been shown to have little effect upon hearing (Tos and Stangerup, 1989). Its relevance therefore might be questioned. However, grommets, although first developed by Politzer in 1883, and introduced into surgical practice by Armstrong in 1954, were not widely used until the mid-1960s. This makes the oldest age group in which grommets have been used in any significant numbers only 30–40 years old. Tympanosclerosis has been shown to be a progressive disease, and while it does not appear to affect hearing there is no evidence of its effect in a more elderly population. Finally, a tympanosclerotic ear drum is aesthetically unpleasing, representing a pathological process, and, as Hippocrates said, 'First do no harm . . . '.

Method

One hundred and sixteen children between the ages of three and seven years with otitis media with effusion were entered into the study. Otitis media with effusion was diagnosed by:

a. Otoscopy: by one of two clinicians.
b. Audiometry: a pure tone audiogram with an average loss of more than 20 dB.
c. Tympanometry: type B curves.

Only those subjects in which myringotomy confirmed the presence of glue remained in the study. Subjects in which there was:

a. A previous history of ear surgery.
b. Atrophy or tympanosclerosis of the tympanic membrane.

were excluded from the study.

The subjects were randomly allocated to receive a Mini-Shah grommet or a conventional Shah grommet in one ear and the alternate grommet in the opposite ear. Under general anaesthetic an anterosuperior myringotomy was performed and glue aspirated by means of a Zoellner sucker with an 18 gauge fine end. The grommets were inserted and the point rotated so that the flange pointed medially towards the malleus handle. Sofradex drops were instilled and continued for three days postoperatively. The subjects were reviewed by a single examiner at six weeks, 6, 9, 12 and 24 months. The site and

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TABLE I
BLIND COMPARISON OF DEGREE OF TYMPANOSCLEROSIS AT TWO YEARS

Shah > Mini Shah	18
Shah = Mini Shah	12
Shah < Mini Shah	3

N = 33

patency of the grommets were recorded and the degree of tympanosclerosis graded on a scale of 0–4 (Slack *et al.*, 1984), depending upon the number of quadrants of the tympanic membrane involved by tympanosclerosis. Audiometry was performed if the subject was old enough to produce consistent results.

At two years blind assessment of the tympanic membrane was possible in 62 cases, in contrast to one year, when the presence of grommets prevented this. A single examiner was asked to make a forced choice as to which ear had the greater degree of tympanosclerosis. In addition, the degree of tympanosclerosis for each tympanic membrane was also individually graded.

Results

Of the 116 children entered into the study, 105 were reviewed at one year, and 92 at two years, although only 91 attended all five review appointments. The remaining 24 patients did not attend for review, despite several postal reminders. The results in relation to extrusion rates, recurrence of otitis media with effusion and tympanosclerosis formation at one year have been published (Hampal *et al.*, 1991). They show the Mini-Shah grommet to be extruded more quickly than the Shah grommet and to be associated with a greater recurrence rate of OME. However, they also showed the degree of tympanosclerosis to be less in the ear into which the Mini-Shah grommet had been inserted. At two years, 92 children were reviewed. Fourteen had undergone surgery for recurrent OME (although none had undergone surgery at one year). In a further 16 the presence of a Shah grommet either in the tympanic membrane or external canal prevented blind assessment of the tympanic membrane. The Mini-Shah grommet had extruded in all subjects. In the 62 subjects where blind assessment was performed, tympanosclerosis was seen in 33 subjects. It was judged to be greater in the ear that had received the Shah grommet in 18 cases, greater in the ear that had received the Mini-Shah grommet in three cases, and equal in 12 cases (Table I).

In 78 cases (92 less the 14 who had undergone recurrent surgery) tympanosclerosis was graded on a scale of 0–4 as described previously. The incidence and degree of tympanosclerosis is shown in Table II. There is a statistically significant difference in the degree of tympanosclerosis between the two groups. The difference is more apparent in the Grade III and IV groups. Results at one year also show a significant difference in the degree of tympanosclerosis if the grommet is retained for longer than nine months. Audiometry was possible in 69 of 78 children. A mean threshold was recorded by averaging 0.5, 1 and 2 kHz. The results are shown in Table III and there is clearly no significant difference between the two groups.

TABLE II
TYMPANOSCLEROSIS AT TWO YEARS

	Ears showing tympanosclerosis at 2 years n = 78	
Grade	Mini Shah Grommet	Shah Grommet
1	4	8
2	12	4
3	3	21
4	0	5
Total	19	38 $P<0.001$

Discussion

The exact pathogenesis of tympanosclerosis is not clear. In the early 1970s it was suggested that tympanosclerosis was secondary to the middle ear disease itself (McKinnon, 1971). Elner *et al.* (1971) found that there was increased mobility of the tympanic membrane when Eustachian tube function was only slightly reduced and postulated that the increased negative pressure associated with middle ear disease led to stretched and torn fibres in the more mobile tympanic membrane and thus to tympanosclerosis by healing. However, it later became clear that ears into which a grommet had been inserted were more likely to develop tympanosclerosis. Tos *et al.* (1983) have suggested that an inflamed tympanic membrane is protected against tympanosclerosis by slight movement of the tympanic membrane caused by Eustachian tube function. These slight movements are prevented by grommet insertion, which thus predispose the tympanic membrane to tympanosclerosis. Lesser *et al.* (1988) demonstrated that the site of maximal incidence of tympanosclerosis correlated with the site of maximal shear stress caused by the mass of the grommet. He postulated that the mass of the grommet causes disruption of the fine cross fibrils between the outer radial and inner circular layers of the lamina propria of the tympanic membrane, eventually with impaired healing leading to tympanosclerosis formation. Intratympanic haemorrhage has also been implicated. Parker *et al.* (1990) demonstrated a greater degree of tympanosclerosis in ears in which there had been both evidence of intratympanic haemorrhage and a grommet in situ for longer than six months. This also suggests that grommet survival has a role to play. Our study has confirmed this with even the Mini-Shah grommet being associated with a greater degree of tympanosclerosis when retained for longer than nine months. It has also been suggested that aspiration of middle ear effusions might increase the degree of tympanosclerosis seen following grommet insertion. However, a recent report suggests that tympanosclerosis does not correlate with glue aspiration itself, but that glue aspiration does lead to increased surgical trauma with more bleeding at the site of the grommet, which in its own right may lead to a greater degree of tympanosclerosis.

The force produced by the insertion of the grommet through the tympanic membrane may also lead to disruption of the structure of the tympanic membrane. Repeated insertion of polyethylene tubes into rat tympanic membranes has been shown to produce severe struc-

TABLE III
AUDIOMETRIC RESULTS AT TWO YEARS

	Mean	Standard Deviation	Range
Shah	17.2 db	6.1 db	5–30 db
Mini Shah	17.1 db	5.3 db	5–28 db

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tural changes in the connective tissue layer only weeks after tube insertion (Soderberg *et al.*, 1986). The mini-grommet is easier to insert, with less distortion of the tympanic membrane, which may partly account for the lesser degree of associated tympanosclerosis. In addition they are easier to insert through the narrow canals of very small children, leading to less canal trauma.

Our study was designed to determine whether the smaller, lighter Mini-Shah grommet was associated with a lesser degree of tympanosclerosis than the conventional Shah grommet. Our assessment of the size of the tympanosclerotic patches may be criticised as visual assessment of the tympanic membrane has been shown to be inaccurate (Hampal, Personal Communication). However, we found that judging the degree of tympanosclerosis by quadrants was more consistent and reproducible than a measurement of percentage involvement of the tympanic membrane. In addition, in the ears in which blind assessment was performed a simple choice was made between the ears as to which had the greater degree of tympanosclerosis. All ears were examined by conventional otoscopy with its inherent shortcomings rather than microscopy, which proved impracticable in this age group.

It might be expected that the mini-grommet would block more readily than the conventional grommet (Reid *et al.*, 1988). This was not apparently the case in our study. The main factor in tube blockage appears to be the consistency of the middle ear effusion (Dawes *et al.*, 1991) and it is conceivable that adequate aspiration of the middle ear effusions prevented early blockage of the mini-grommet.

Audiometric assessment of children after grommet extrusion has shown no significant difference between hearing in the ears receiving the Mini-Shah or the Shah grommet and previous studies have indeed also shown no significant difference in hearing between tympanosclerotic and normal ear drums. However, there are no studies looking at the long term effect of tympanosclerosis upon hearing and before it can be said to have no effect on hearing in a more elderly population longer term follow-up is required.

Summary

The Mini-Shah grommet has a mass of 3.5 mgs compared to that of 13 mgs for the conventional Shah grommet (Manufacturer's data: Exmoor). Our study has shown that this smaller lighter grommet is associated with a lesser degree of tympanosclerosis. It is, however, also associated with a faster extrusion rate and greater recurrence rate of OME. This preponderance of recurrent OME in the ear with the Mini-Shah grommet may at least partly be accounted for by the greater length of time elapsed since the grommet extrusion. While the smaller lighter grommet may well be associated with a less altered and scarred ear drum, a compromise with regard to hearing is required as some children will suffer with recurrent OME.

We are at present comparing the extrusion rates and degree of tympanosclerosis for the mini-titanium grommet and the mini-teflon grommet. The mini-titanium grommet is expected to be retained longer, and to be associated with a lesser recurrence of OME. However, the price we may have to pay is a greater degree of tympanosclerosis due to increased grommet survival. A mini-T-tube has also been designed which may confer long term benefit to hearing without the even greater complications associated with T-tubes. There is an increasing trend toward micro-surgery in the ear, and the ideal ventilation tube, associated with a minimum of side-effects, yet conferring long term benefit to hearing, has yet to be found.

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