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Main Articles

Tympanosclerosis and mini grommets: the relevance of grommet design

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Abstract
Fifty children with otitis media with effusion undergoing grommet insertion had into one ear a Mini-titanium grommet inserted and into the other ear a Mini-teflon grommet. Post-operative follow-up until after extrusion of the grommets demonstrated only a small difference between the extrusion times of the two grommets (a significant difference of 41 days) and no difference in the degree of tympanosclerosis seen with each grommet. We propose that the mass of a grommet appears to play less of a role than has previously been suggested in the pathogenesis of tympanosclerosis following grommet insertion and that duration of intubation may be the most significant factor.

Key words: Otitis media with effusion; Middle ear ventilation; Tympanosclerosis

Introduction

The use of grommets in the treatment of otitis media with effusion (OME) is associated with a number of long term complications, such as infection, residual perforation, atrophic changes of the tympanic membrane and tympanosclerosis (Skinner *et al.*, 1988).

Although tympanosclerosis is seen as a complication of OME alone, it is more common following grommet insertion (Tos *et al.*, 1983; Slack *et al.*, 1984). There is no evidence to associate tympanosclerosis, when confined to the tympanic membrane, with either hearing loss or significant complications (Tos and Stangerup, 1989). It does however represent a pathological process and as such should be avoided.

The exact pathogenesis of tympanosclerosis is uncertain but various theories involve the mass of the grommet (Lesser *et al.*, 1988), the duration of intubation (Parker *et al.*, 1990), intratympanic bleeding (Parker *et al.*, 1990) and the loss of the protective effect of tympanic membrane movement (Elner *et al.*, 1971). We have previously shown that the Mini-Shah grommet is associated with a significantly lesser degree of tympanosclerosis than the conventional Shah grommet at both one and two years after insertion (Hampal *et al.*, 1991; Dingle *et al.*, 1993). It was however also associated with a greater recurrence rate of OME presumably as a result of its shorter retention time.

Mini-grommets are now made from both teflon and titanium. Manufacturers claim a longer period of retention for grommets fashioned from titanium. The aim of this study was to determine whether the duration of intubation is indeed different between these two grommets and which grommet is associated with the greater degree of tympanosclerosis. By the varying masses and extrusion rates of the grommets in our original and subsequent studies it may become clearer which are the risk factors in the formation of tympanosclerosis.

Method

Ethical committee approval for the following study was sought and obtained. Fifty children with bilateral OME undergoing surgery were admitted for insertion of grommets. Excluded from the study were patients with:

(a) Previous ear surgery
(b) Tympanosclerosis
(c) Atrophy of the tympanic membrane

Patients undergoing concurrent surgery such as tonsillectomy or adenoidectomy were not excluded from the study.

Subjects were randomly allocated to receive a 'Tiny Tytan' (Registered Trade mark, Xomed

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Treace) titanium grommet into one ear and a teflon grommet from the same manufacturers and of identical dimensions but different mass into the other ear. In this way each patient acted as their own control.

Under general anaesthesia an antero-superior myringotomy was performed, the middle ear effusion aspirated by suction, and the grommet inserted. Sofradex eardrops were inserted to prevent both occlusion of the grommet by blood clot, and post-operative infection (Robson *et al.*, 1992).

Patients were reviewed six weeks following surgery by a single examiner (observer 1) and then at three-monthly intervals until both grommets had extruded. The site and patency of the grommets were recorded and the degree of tympanosclerosis graded on a scale of 0–4 depending upon the number of quadrants involved by the process (Slack *et al.*, 1984).

After extrusion of both grommets the patients were examined by a single impartial examiner (observer 2) thus giving a 'blind' assessment of the degree of tympanosclerosis for each grommet.

Results

Forty-seven children were reviewed until after extrusion of both grommets. The remaining three defaulted despite several postal reminders. One patient defaulted further review by the impartial examiner despite several postal reminders. Assessment of the degree of tympanosclerosis was possible in all but one patient in whom intractable otitis externa made visualization of the tympanic membrane impossible.

The results are considered as paired data. The extrusion times for each grommet and degrees of tympanosclerosis as assessed by observer 1 are shown in Tables I & II. The data for observer 2 is not tabled but differs by not more than 1 grade in only a few cases. The extrusion time was taken as the time of the visit at which the grommet was noted to have extruded (and so was invariably an overestimate). In three cases there had been an unusually long interval from the previous clinic appointment and in these cases an extrusion time was imputed which was one month longer than the mid-point of the interval. Although this is an arbitrary choice, it does not affect the comparison as in each case both grommets had extruded during the long interval concerned.

The mean times to extrusion were: (a) 11.8 months for the Mini teflon grommet; (b) 10.5 months for the Mini titanium grommet.

If, in addition to the extrusion times, the right-left differences were analysed (two groups of 25 and 22 children), any anatomical asymmetry and the handedness of the operator inserting the grommet is taken into account. This leads to a slight alteration in the mean difference to 1.34 months, with 95 per cent confidence interval 0.19 to 2.48 (or 41 days, 95 per cent confidence interval six to 75 days).

For these figures $t = 2.36$, and $p = 0.023$. This is confirmed by the corresponding non-parametric Mann-Whitney test, which gives $p = 0.0255$.

Analysis of the results of individual grades of tympanosclerosis is impractical due to the small group sizes and the results are best considered by observing which ear was considered to have the greater degree of tympanosclerosis. For observer 1, 33 ears were considered to have the same degree of

TABLE I

Study no	Extrusion time R	Extrusion time L	Tympanosclerosis R	Tympanosclerosis L
1	18	18	3	3
2	17	12	0	0
3	8	8	0	0
4	16	6	0	0
5	9	12	0	0
6	DNA	DNA		
7	16	12	0	0
8	6	11	0	0
9	10	5	0	0
10	14	5	3	1
11	8–16	8–16	0	0
12	12	10	1	2
13	9	16	0	0
14	7–17	7–17	0	0
15	12	12	2	3
16	9	5	0	0
17	7	7	0	0
18	5	5	0	0
19	12	12	0	0
20	8	8	0	0
21	18	18	4	3
22	15	9	2	0
23	9	3	0	0
24	DNA	DNA		

Group 1: Extrusion times and degrees of tympanosclerosis
Right ear; Mini titanium grommet
Left ear; Mini teflon grommet

TABLE II

Study no	Extrusion time R	Extrusion time L	Tympanosclerosis R	Tympanosclerosis L
1	12	12	4	4
2	12	12	2	3
3	12	12	2	2
4	16	16	0	0
5	11	11	1	0
6		unrecordable		
7	14	14	0	1
8	12	12	0	0
9	12	12	0	0
10	3	15	0	0
11	15	18	2	1
12	10	10	2	1
13	9	3	0	0
14	14	14	0	0
15	12	16	0	0
16	21	18	0	0
17	6	12	4	4
18	12	12	2	0
19	9	9	0	0
20	9	9	2	4
21	6	9	0	0
22	8	15	0	0
23	12	9	3	4
24	9	9	0	1
25	6	6	0	0
26	6–12	6–12	0	0

Group 2: Extrusion times and degrees of tympanosclerosis
Right ear; Mini teflon grommet
Left ear; Mini titanium grommet

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tympanosclerosis. In eight the titanium grommet had more tympanosclerosis and in six the teflon grommet had more tympanosclerosis. Thus if a clear choice as to which ear had more tympanosclerosis had to be made observer 1 would say the titanium one in (8 + 33/2)/47 i.e. 52.1 per cent and (6 + 33/2)/47 i.e. 47.9 per cent. The difference between these is estimated as (8–5)/47 i.e. 4.3 per cent with 95 per cent confidence interval −12.1 per cent to +20.6 per cent (Newcombe 1992). This is compatible with zero difference and is not statistically significant.

For observer 2 (the impartial examiner) the difference is between (7 + 34/2)/46 and (5 + 34/2)/46, or 52.2 per cent and 47.8 per cent the difference is estimated as (7–5)/46 i.e. 4.3 per cent with confidence limits of −11.3 per cent to +20.0 per cent. Again this is compatible with zero difference and is not statistically significant.

The relationship between extrusion time and tympanosclerosis can also be examined. For each examiner the mean and SD extrusion times are produced, which are compared between tympanosclerosis grades by one-way analysis of variance (ANOVA). In addition correlations are computed by Spearman rank type. There is an association between grommet survival and degree of tympanosclerosis, with longer survival being associated with a greater degree of tympanosclerosis, however the association does not reach statistical significance.

Discussion

Tympanosclerosis is the pathologic development of white plaques, showing various degrees of mineralization with calcium phosphate in the middle ear (McKee and Kerr, 1989). Its appearance in the lamina propria of the tympanic membrane is a recognized complication of OME especially if associated with grommet insertion (Tos *et al.*, 1983; Slack *et al.*, 1984). Tos and Stangerup (1989) after a follow up of seven years, found tympanosclerosis in 59 per cent of ears which had undergone grommet insertion compared with only 13 per cent in the opposite ear, which had only undergone myringotomy.

The mechanism of damage is uncertain and has been the subject of much research. Aspiration of middle ear effusion does not in itself cause tympanosclerosis of the tympanic membrane (Dawes *et al.*, 1991) although intratympanic bleeding at myringotomy does seem a factor if followed by prolonged grommet survival (Parker *et al.*, 1990). Lesser (Lesser *et al.*, 1988) demonstrated that sites of shear stress in the tympanic membrane correlated with the areas likely to develop tympanosclerosis and suggested that a grommet of reduced mass might be beneficial. This was confirmed by our subsequent studies of mini-grommets (Hampal *et al.*, 1991; Dingle *et al.*, 1993). Unfortunately mini-grommets are less well retained than conventional tubes and a reduced tympanosclerosis rate was offset by earlier extrusion of the grommet and earlier recurrence of OME.

Research has suggested that tympanosclerosis confined to the tympanic membrane has no significant adverse effect upon hearing (Tos and Stangerup, 1989; Dawes *et al.*, 1991; Dingle *et al.*, 1993) but only very long term studies would be totally reassuring. Any modification to grommet design which avoids tympanosclerosis but allows prolonged intubation seems desirable. Major enlargement of the inner flange and bore certainly allows longer retention but are associated with residual perforation, atrophy and otorrhoea as in the Per-Lee (1981), Paparella (Klingensmith *et al.*, 1985), or T-tube design (Brockbank *et al.*, 1988).

Abdullah (Abdullah *et al.*, 1994) has however modified the Shah permavent tube to produce a medium to long term grommet which is reliably retained for two years and exhibits less tympanosclerosis (11 per cent) than is seen with a conventional Shah grommet (47 per cent). They attribute this benefit to the use of a high grade silicone tube which is trimmed to allow easier insertion and to reduce the mass from 13 mg to eight mg.

Moore (1990) showed that even relatively minor modifications to grommet design can delay extrusion. In a comparison of Shepard and Sheehy tubes the latter was retained for twice as long. Although both are of very similar dimensions, the former has a curved, fluted shape whilst the latter has wider flanges at right angles to the lumen, the "collar button" design.

Research into differing materials of manufacture has been disappointing in prolonging retention. Gold plated grommets have proved to extrude more rapidly than teflon (Tami *et al.*, 1987). Titanium grommets have been promoted as light weight (half the weight of stainless steel), micropolished and tissue compatible (Xomed Treace, manufacturers data). Shone (Shone and Griffith, 1990) indeed demonstrated a better retention at six months but no significant difference after one year. There was a greater tendency to infection and granulation formation. We sought a gromet which combined the advantages of small size, collar button shape and a suitable material of manufacture. The Tiny Tytan seemed a good compromise.

The grommets studied were of identical dimensions but different mass. Both have a lumen diameter of 0.76 mm, an outer flange diameter of 1.5 mm, and an inter flange length of 2 mm. The titanium pattern weighs 6.5 mg and the teflon only 3.1 mg (manufacturers data). The various patterns of grommet used in this and our previous study are shown in Figure 1.

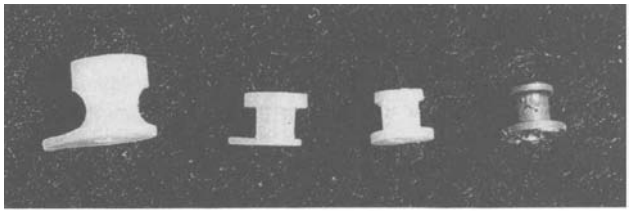

FIG. 1

Various patterns of grommet used in this and our previous study. From left to right: Shah, Mini-Shah, Mini-teflon, Mini-titanium.

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Our results, somewhat surprisingly, showed only a small difference in extrusion rates between the two grommets. Analysis of the paired data showed a statistically significant difference between the extrusion rates of the two grommets. Although the titanium grommet has a longer retention time, we feel that a significant difference of 41 days is unlikely to contribute greatly to the pathogenesis of tympanosclerosis.

We are thus left with grommets of virtually the same average retention time but different masses. There was no demonstrable difference in the degree of tympanosclerosis between the two grommets and thus neither mass nor material appears in this study to play a part in the formation of tympanosclerosis. This in fact contradicts our previous study (Dingle *et al.*, 1993) which suggested that the Mini-Shah grommet was associated with a significantly lesser degree of tympanosclerosis as a result of its considerably lesser mass (3.5 mg compared with 13 mg), and leads to the supposition that duration of intubation may be the most significant factor in the pathogenesis of tympanosclerosis.

While the results of the two studies cannot be statistically compared in view of the different study groups, a broad view shows the Mini-Shah grommet to be associated with a rapid extrusion time and the lowest incidence of tympanosclerosis and the conventional Shah to be associated with a long retention time and the highest incidence of tympanosclerosis. The extrusion times and rates of tympanosclerosis of the Mini teflon and Mini titanium grommets lie between the two.

We suggest that the rapid extrusion time of the Mini-Shah grommet may be due to the small inner flange diameter and collar design.

The exact pathogenesis of tympanosclerosis is still not clear however we believe that there is increasing evidence, as shown by this present and our previous studies that the formation of tympanosclerosis following grommet insertion may be predominantly related to the duration of intubation.

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