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A New Ventilation Tube for Long-Term Middle Ear Ventilation

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Objectives: **The treatment of secretory otitis media often requires repeated tubulation of the tympanic membrane as the standard ventilation tubes are extruded before the disease of the middle ear has remitted. The T-tube and its modification have been developed to remain longer in situ, often requiring surgical removal. The rates of subsequent persisting tympanic membrane perforations and granulations around the tube have been unacceptably high. In the search for a long-term ventilation tube with fewer complications, the Duravent tube (Smith and Nephew) has been developed. The aim of the study was to estimate duration in situ and observe complications in using the Duravent tube compared with standard tubes and T- tubes.** ***Study Design:*** **Retrospective study.** ***Methods:*** **In all, 51 patients have been treated with the Duravent tube over a 2-year period. In all, 72 Duravent tubes have been inserted. All patients were subsequently invited for a follow-up examination at a median time of 28 months (range, 11–43 mo) after the tube insertion and were followed up for 5 years.** ***Results:*** **The duration in situ was optimal with a median duration of 17 months. The Duravent tube was extruded spontaneously in all but four cases in which surgical removal was necessary. The rate of persisting perforations of the tympanic membrane was low (4.2%) compared with 24% after the use of the T-tube. Likewise, the usual complications connected with long-term ventilation tubes were less frequent (14% compared with 35% when using the T-tube).** ***Conclusions:*** **In the present study, the Duravent tube has proved superior to other known long-term ventilation tubes. The problem of granulations, otorrhoea, and tube occlusion was significantly less than reported in other studies using the T-tube.** ***Key Words:*** **Long-term middle ear ventilation, ventilation tubes, grommet, tympanic membrane perforation, secretory otitis media.**

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INTRODUCTION

Tympanostomy tubes or grommets have been used successfully in the treatment of secretory otitis media for more than 40 years. Most widely, the standard grommet (e.g., Armstrong or Shepard) is used. Side effects such as granulation formation, otorrhoea, tympanosclerosis, and persisting perforation after extrusion have been observed.[1] Too-early extrusion of the tube has been a problem, which often resulted in the need for several repeat tubulation procedures. In the early 1970s, a long-term grommet was developed to solve this problem.[2] However, its use has been complicated by the need for surgical removal in up to 90% of the cases.[1] In the search for a grommet with better "retain ability" than the standard grommet and lower rate of persisting perforations after extrusion, the Duravent tube (DT) (Smith and Nephew) has been developed (Fig. 1). The aim of the present study was to estimate the duration in situ and observe complications in using the DT compared with standard tubes and T-tubes.

MATERIALS AND METHODS

In all, 51 patients (26 male and 25 female patients) with ages ranging from 5 months to 67 years (median age, 6 y) have been treated with DT over a 2-year period. In 21 patients, bilateral tubulation has been performed. A total of 72 Duravent tubes have been inserted. All patients were subsequently invited for a follow-up examination at a median time of 28 months (range, 11–43 mo) after the tube insertion and were followed up for 5 years. The evaluation included information on age, sex, date of insertion, number of previous myringotomies and ventilation tube insertions, otorrhea, duration in situ of the tube, and otomicroscopic examination. Whether the tube was in situ and functional or had been extruded spontaneously was noted, and the drum was examined for tympanosclerosis, granulation, and persisting perforation. A perforation is said to be chronic when it persists for at least 6 months after tube removal, although some perorations heal spontaneously even after a year.[3]

RESULTS

In all, 94% of the inserted tubes (68 of 72 tubes) could be followed up. Seventy-eight percent (56 of 72) of the treated ears had a history of earlier grommet insertion varying from one to six times. In 10 ears, the insertion of DT tube was performed in connection with a tympanoplastic operation.

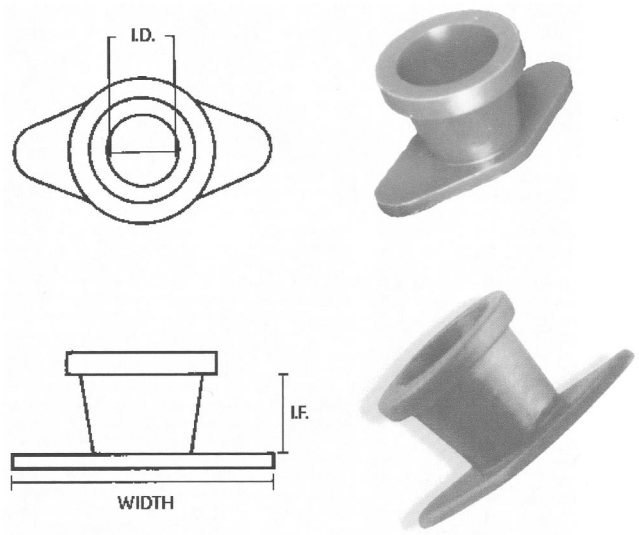

Fig. 1. The Duravent tube is made of compressible silicone. It has a greater inner diameter (ID) compared with other tubes. ID = 1.27 mm; inner flange (IF) = 1.37 mm; width = 4.5 mm.

Duration In Situ

The duration in situ of the DT is defined as the time elapsed from insertion of the tube until the first follow-up examination that showed extrusion of the tube.[4] Duration in situ is shown in Figure 2. Median duration in situ in the present study was 17 months (range, 1.5–36 mo). After 3 years, only three Duravent tubes (4%) were still in situ. Four Duravent tubes had been removed surgically, one after 21 months, one after 24 months, and two after 36 months (i.e., more than 90% of the tubes were spontaneously extruded during the observation period).

Persisting Tympanic Membrane Perforation After Tube Extrusion

Six patients presented with a drum perforation. In these patients the tubes had been in situ for a median period of 25 months. The relative risk for having a perforation when the tube was in situ for longer than 25 months was 5.16 (Fig. 3 and Table I). By September 2000, none of the patients had residual tympanic perforation. We did not find any correlation between the risk of perforation and the number of previous tubulation procedures.

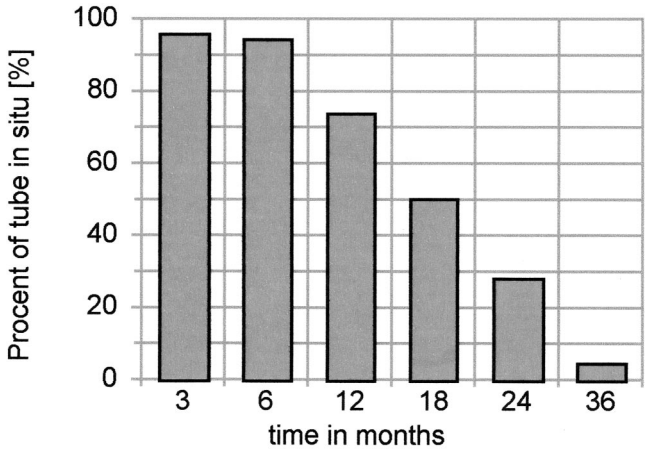

Fig. 2. Duration in situ for the Duravent tube.

Tympanosclerosis

Pronounced tympanosclerosis was found in 36% of the cases, slight tympanosclerosis in 28%, and no tympanosclerosis in 36%. No correlation was found between the degree of tympanosclerosis and the duration in situ of the tube. All cases with pronounced tympanosclerosis had a history of repeated tubulation (three to six times).

Granulations Surrounding Tube, Tube Occlusion, and Otorrhea

Fourteen percent of the Duravent tubes (nine patients) had granulations surrounding the tube with intermittent otorrhoea. The lumen of the tube was found open in 96% of the Duravent tubes.

DISCUSSION

The mean duration in situ for the standard ventilation tube (e.g., Armstrong or Shepard) is 7 months.[5] According to Goode,[5] a ventilation tube is characterized as a long-term ventilation tube if it has a duration in situ of more than 1 year. Consequently, the DT can be described as such showing a median duration in situ of 17 months. The DT is superior to the T-tube by having a natural extrusion rate of more than 90% as opposed to the T-tube, which has to be removed surgically in almost 90% of the cases.[1] The removal should be performed, at the latest, after 3 years because the rate of permanent tympanic membrane perforations increases significantly after this period. Even the modified Goode T-tube has a much lower rate of natural extrusion (approximately 65%).[6] The natural duration in situ of 7 months for the standard tube mentioned earlier is often too short, demanding repeated tubulation procedures. The median duration in situ of 17 months for the DT tube must be regarded as being close to optimal treating time for most cases of secretory otitis media.[7] The perforation rate of 4.2% after DT extrusion in the present study is acceptable. The perforation rates after standard tube extrusion are 0.5% to 2%[5]; after modified Goode T-tube, 9.6%[6]; and after ordinary T-tube, 24%.[8] According to Strachan et al.,[8] the rate of tympanosclerosis after tubulation with a standard tube or T-tube is

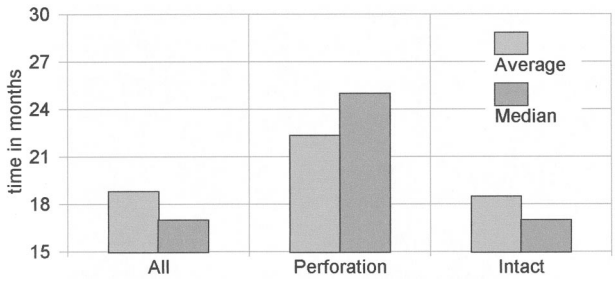

Fig. 3. Duration in situ for the tube considering the tympanic membrane.

TABLE I.
Tympanic Membrane Perforation Related to Length of Tubulation.

	Tympanic Membrane Perforation Related to Length of Tubulation		
Tubulation	Perforation	No Perforation	Total
>20 mo	4	15	19
<20 mo	2	47	49
	6	62	68

Relative risk = 5.16; odds ratio = 25.07.

approximately 30%. The rate of tympanosclerosis of 64% in the present study is probably explained by the fact that the study was carried out at the otolaryngology department of the hospital, a secondary care unit, 69% of the cases having had tubulation one to six times before insertion of the DT. This is in good accordance with a recent report indicating that tympanosclerosis of tympanic membrane might be the result of prolonged increased oxygen in the middle ear.[9] The silicone material of the DT seems sufficiently inert. Only 14% of the cases showed granulations around the tube with intermittent otorrhoea, as opposed to 35% having otorrhoea in connection with using the T-tube.[8] When the costs and risks have to be held at the lowest possible level, it is important to avoid surgical intervention for removal of the inserted tube. Goode[5] suggested that the T-tubes should be removed surgically after an 18-month period. The Duravent tubes in the present study stayed in situ only until the disease of the middle ear was resolved (i.e., a median period of 17 months).

CONCLUSION

In the present study, the DT has proved superior to other known long-term ventilation tubes. It had a median duration in situ of 17 months. The natural extrusion rate was more than 90% within the observation period. The serious complication of persisting tympanic membrane perforation in 24% of the cases treated with T-tube was reduced to 4.2% when the DT was used. The problem of granulations, otorrhoea, and tube occlusion was significantly less than reported in other studies using the T-tube.

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