Impact of Tympanostomy Tube Design on Rate of Occlusion

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ABSTRACT

Objective: Tympanostomy tubes (TTs) are commonly rendered non-functional by mucus plug formation. This may be affected by TT dimensions and shape. The purpose of this study was to determine if TT internal lumen diameter (ID), shaft length (SL), and shape affects the rate of TT occlusion.

Methods: TTs of differing SL (12mm v. 1mm), ID (0.76mm v. 1.27mm), and shape (straight v. funnel) were placed in a validated TT testing chamber which simulated in vivo air and mucus flow conditions, using egg white as a mucus analog. Occlusion was determined by a characteristic pressure peak and visual verification. Rate and frequency of occlusion were compared.

Results: Occlusions were observed in 10 of 20 short SL TTs and 6 of 20 long SL TTs. Time to occlusion was not different between straight and funnel shape TTs (p = 0.1094). Occlusions developed in 7 of 20 straight shaped TTs and 5 of 20 funnel shaped TTs. Time to occlusion was not different between straight and funnel shaped TTs (p = 0.0127). Occlusions developed in 14 of 20 small ID and 8 of 20 large ID TTs. ID impacted time to occlusion (p = 0.0127). Occlusions developed in 7 of 20 straight shaped TTs and 5 of 20 funnel shaped TTs. Time to occlusion was not different between straight and funnel shaped TTs (p = 0.0127).

Conclusions: TT shape, but not TT SL or ID, significantly affected the rate of TT occlusion. Larger diameter TTs are more prone to TT occlusion in this in vitro model. Larger diameter TTs should be considered when avoidance of TT occlusion is critical.

INTRODUCTION

Tympanostomy tubes (TTs) frequently occlude, rendering them non-functional. Hearing loss and other problems resulting from recurrent otitis media may ultimately require TT replacement, which is associated with potential morbidity, expense, and inconvenience. Thus, the rate of TT occlusion would ideally be minimized.

Previous research has shown that TT dimensions, both internal diameter (ID) and shaft length (SL), affect the rate of clearing established TT plugs. To our knowledge, no prior study has examined the effect of TT shape and size on TT plug formation. The purpose of this study was to use a recently developed and validated model to examine the effect of SL, ID, and shape (straight v. funnel) on the development of TT occlusion.

MATERIALS AND METHODS

Study Design: TTs of different SL, ID, and shape were tested using the method and model described by Sherman and colleagues. In brief, this involved delivery of both air and a mucus analog, chicken egg white, through TTs secured in a latex diaphragm. Egg white was used rather than human mucus as it has been shown to yield results more consistent with clinical trials. Pressure proximal to the TT was measured. A gradual increase in pressure represented progressive occlusion of the TT. When a complete obstruction developed, the pressure reached the air delivery pressure. As the total time studied was an arbitrary parameter, the time to TT occlusion was the primary outcome measure.

Tympanostomy Tubes: All tubes used in this study were donated by MiddleTec ENT (Jacksonville, FL).

Methods:

- Tubes used in SL comparison: Goode.T tubes (silicone, ID = 1.14 natural SL=12mm v. trimmed with razor to a 1mm SL).
- Tubes used in ID comparison: Moretz TTs (titanium, SL = 1.0mm) with ID = 1.27 mm v. ID = 0.76 mm.
- Tubes used in barrel shape comparison: Sheehy collar button (fluoroplastic, ID = 1.27, SL = 2.02, straight) v. Baxter Beveled Bobbin (fluoroplastic, ID = 1.27, SL = 2.02, funnel).

Statistical Analysis: Twenty tubes were used for each group. Survival fractions were calculated using the Kaplan-Meier Method. The uncertainty of the fractional survival was reported as 95% confidence intervals (CIs) and shown as error bars. Survival curves were compared using the log-rank (Mantel-Cox) test. Analysis was performed using a commercially available statistical analysis program (GraphPad Prism Software, La Jolla, CA).

RESULTS

Occlusions were observed in 10 of 20 short SL TTs and 6 of 20 long SL TTs. Time to occlusion was not different between long and short SL (p = 0.3017). Occlusions were observed in 14 of 20 small ID TTs and 8 of 20 large ID TTs. Time to occlusion was greatest (better) in large ID TTs (p = 0.0227). Occlusions were observed in 7 of 20 straight shaped TTs and 5 of 20 funnel shaped TTs. Time to occlusion was not different between straight and funnel shaped TTs (p = 0.1094).

CONCLUSIONS

Our observations suggest that TT ID, unlike TT SL or barrel shape, is a significant factor in the development of TT occlusion. Clinicians should consider the use of TTs with a larger ID (avoidance of occlusion) critical. As use of large bore TTs is associated with complications, future research should focus alternative strategies, such as alternative TT compositions or surface preparations to minimize the risk of TT occlusion.