In-Vitro Testing of Tympanostomy Tube Occlusion

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Abstract

Objective: To develop an in-vitro ear chamber to assess the propensity of tympanostomy tubes (TTs) to occlude.

Methods: An ear model was designed to mimic middle ear air and mucus flow conditions in children with post-TT otorrhea. TTs that had previously been studied in vivo (Goode and Reuter Bobbin cellula baffles) were placed in the model chamber. Proximal, homogenized, human middle ear mucus and an analog, egg white, were delivered through the tubes. An air bolus was delivered every two minutes to simulate swallowing. Chamber pressure was monitored over 2.5 hours. Occlusion was determined by a pressure peak and visual confirmation.

Results: Obstruction was found in 60% of the Reuter Bobbin and 40% of the Goode TTs using the mucus analog (egg white). These in-vitro results are similar to those reported from previous in-vivo studies. No plugging was observed over 2.5 hours for either TT using the homogenized human ear mucus.

Conclusions: The in-vitro TT test system with egg white as a mucus analog simulates observations from clinical trials. This model system may allow for more rapid prototyping and evaluation of new TT designs by decreasing the development time, cost, isolating variables, and maintaining a constant testing environment.

Introduction

Tympanostomy tubes (TTs) are commonly placed to treat recurrent acute otitis media and chronic otitis media with effusion (Owings et al., 1998). TTs can be rendered non-functional by premature occlusion, requiring TT replacement. Prevention of TT occlusion has long been the focus of clinical research (Jamal et al., 1995). However, clinical trials are very expensive and time-consuming. This limits the development of TTs to treat these vulnerable patients. An in-vitro test system could potentially facilitate TT design development.

Materials and Methods

Mucus Analog Preparation: A human mucus analog consisting of chicken egg white (albumin) was used. Egg white was chosen due to its very sticky (viscous), non-homogenized viscosity nature (~450cp non-homogenized) (Min et al., 2005) along with its ability to form a solid crust-like material after drying, similar to human mucus (Wiedenhof et al., 1980). The egg white was homogenized using a thin blade and had a physical consistency of 388 ± 5.4cp, similar to homogenized human mucus (402 ± 9.1cp).

Air Delivery: Air flow was modeled to occur as a bolus, such as may occur with swallowing, nose-blowing, and sneezing. Boluses of air were delivered every other minute, corresponding to normal human swallowing (Lear et al., 1964). Air was delivered at a volume twice that of hourly mucus flow. Air pressure was determined by titration in pilot experiments (~110 mm H2O ±20 mm H2O). Pressure proximal to the TT was measured. Upon obstruction, proximal pressure equaled the input pressure.

Results

Six of 10 of the Reuter Bobbin TTs formed an occlusion (60%) within two and a half hours while 4 out of 10 of the Goode tubes formed an occlusion (40%) using egg white. These in-vitro results were similar to those reported from previous clinical studies (Weigel et al. 1989). In contrast, 100% non-homogenized pooled human ear mucus resulted in universal tube occlusion, across all tube types. While, testing with homogenized and diluted human mucus yielded no occlusion formation in any TTs over the 2.5 hour test periods.

Conclusions

Our in-vitro TT testing chamber and the use of egg white as a mucus analog can reproduce occlusion rates similar to those found in clinical studies. These observations suggest that in vitro TT testing may facilitate comparison of TT designs, thereby expediting the clinical assessment and employment of better TT products.