**INTRODUCTION**

The method for placement of a tympanostomy tube (TT) through the tympanic membrane for ventilation of the middle ear has changed little since its inception. The procedure itself requires several invasive steps that include: cerumen removal, a myringotomy, possible suction, and finally, placement of the TT through the myringotomy.

Unnecessary trauma to the external auditory canal and manipulation of the TT within the myringotomy can create pain and discomfort, leading to movement and lack of cooperation by the patient. Therefore, the standard of care for pediatric patients is to perform the procedure under general anesthesia, which is intended to eliminate pain and the potential for head movement.

It was our intent to design a medical device which would allow the ENT surgeon to complete a myringotomy and deliver a standard grommet-style TT with a quick, single-pass through the tympanic membrane. This type of surgical instrument would not only decrease the time for the procedure, but minimize trauma and allow ease of TT placement in a young child.

**METHODS**

The prospective, treatment-only clinical study was performed at two tertiary care pediatric facilities and a community surgical center. Once the study was approved by the Institutional Review Boards at the University of Minnesota and the Children’s Hospital and Clinics of Minnesota, children that required TT placement for the treatment of otitis media or chronic eustachian tube dysfunction were screened for the study. After enrollment criteria were met and written consent obtained, a patient was considered enrolled.

A newly designed surgical instrument, the tympanostomy tube system (TTS) was used in all cases to allow single-pass placement of a TT. A grommet designed TT was delivered in all cases.

Anesthesia techniques varied from general anesthesia to moderate sedation with nitrous oxide (N₂O) and phenol as a topical anesthetic. In eleven (11) moderate sedation cases, oral Versed accompanied N₂O. Pre- and post-operative audiograms were performed, and patients were scheduled for follow-up visits between 3 weeks and 10 weeks post-procedure.

**RESULTS**

Two hundred-twenty (202) TT tube placements occurred in 101 pediatric patients. The mean age was 28 months. Forty-eight (48) of the 101 patients received moderate sedation. In twelve (12) of the moderate sedation cases, the patient was converted to general anesthesia due to surgical challenges. During the moderate sedation cases, the child was able to move, and some degree of head motion occurred during TT placement. This was managed by gently holding the child to stabilize the head. Time for insertion of the TTS only was measured in 135 ears. The mean was 14 seconds, median 12 seconds and range 4 – 180 seconds.

At the post-operative visit, nine (9) adverse events were reported eight (8) patients. Clogged tubes were identified in four (4) patients, including one in which the tube also extruded; two (2) patients had otitis media; one (1) had an ear infection; the tube had extruded in one (1) patient; and in another, the TT was discovered in the middle ear space and was retrieved during a later procedure (adenoid removal).

Additionally, in 9 delivery attempts, the TT was over-inserted medial to the tympanic membrane. In each of these cases, the TT was retrieved with alligator forceps and/or suction, and the TT re-positioned without incident.

Design changes during the clinical experience included using a stiffer material for the grommet style tube as well as increasing the length of the visualization tab to establish depth of insertion.

**DISCUSSION**

Currently, placement of a TT in an uncooperative child can be difficult without the use of general anesthesia. It requires a cooperative patient who can maintain good head control during the procedure, as it is very difficult to make a safe myringotomy or to appropriately place a TT if the head is moving. Even with good control and cooperation by the patient, there can be discomfort due to auditory canal trauma and the pushing motion on the tympanic membrane during TT delivery. The goal was to develop a device that would complete the myringotomy and deliver a grommet style TT with a single-pass, minimizing surgical trauma.

The purpose for developing such a device was to simplify placement of a TT in an uncooperative child, thereby providing an option for performing the procedure without the need for general anesthesia in a sedation unit or office setting.

The obvious concern for the ENT surgeon is the potential to deliver the TT into the middle ear space. The TTS has a motion of force that is radial to the tympanic membrane. This change in the motion of force can lead to over-insertion of the TT as demonstrated in this clinical experience. As a result, the TT manufacturing process was modified to use a stiffer silicone, which increased tactility, and a visualization tab was added to provide visual control over the depth of penetration. These changes mitigated the risk of TT over-insertion in the clinical experience.

By reducing the steps involved, as well as the trauma and pain associated with the delivery of a grommet-style TT through the tympanic membrane, we believe that the placement of a TT in an uncooperative child can occur with moderate sedation and local anesthesia in a sedation unit or office setting. Rosenfeld, et al, have already demonstrated that TT placement can be performed on a moving child using a papoose board without anesthesia. We have tried normal insertion techniques using a papoose board with N₂O sedation and found it difficult for both the surgeon and the child. We believe that having a TTS device as an option for routine tympanostomies to reduce the steps and potential trauma of TT insertion will make this process easier for both surgeon and patient.