CLINICAL STUDY

Single Stage Tympanostomy Tube Insertion: Design Issues on a New Surgical Approach

F. Rimell, MD1,2; S. Cofer3; Timothy A. Lander, MD1; S.C. Levine, MD2; A.C. Meyer, MD1,2; J.D. Sidman, MD1; Robert J. Tibesar, MD1; D.W. Yoon, MD4

1Pediatric ENT and Facial Plastic Surgery, Children’s Hospitals and Clinics of Minnesota; 2Department of Otolaryngology, University of Minnesota; 3Mayo Clinic, Rochester, MN; 4Fairview Health Services, Minnesota

INTRODUCTION

Tympanostomy tube (TT) placement in adults and older children is routinely performed in an office setting with topical anesthetic, while pediatric patients require general anesthesia because of the potential for head motion. The ability to place TTs in pediatric patients under moderate sedation would benefit the patient by reducing the amount of anesthetic drugs required and benefit the health care system by allowing the procedure to be performed in a lower cost setting.

A surgical system that allows for the safe and effective placement of TTs in pediatric patients under moderate sedation must:

1. Minimize Pain by reducing the number of instrument passes down the ear canal and minimizing the manipulation of the tympanic membrane (TM)
   - allowing moderate sedation to be sufficient
   - reducing patient movement/response to the procedure

2. Manage Movement of the patient during TT insertion
   - allowing surgeon to stabilize surgical hand to the patient
   - placing the TT in a quick and controlled manner

3. Maintain Visualization of the TT to ensure correct positioning and prevent over-insertion
   - patient movement during actual TT insertion

In addition to the surgical system, a training protocol for the surgeon and support staff is critical to success.

METHODS AND MATERIALS

A tympanostomy tube system (TTS) and supporting techniques have been developed to meet the requirements of minimizing trauma and managing movement while maintaining the necessary TT visualization (Figs.1,2).

Minimize Trauma

- Reduce passes down the canal and TM manipulation using a One-Pass™ TTS design that creates the myringotomy and positions and deploys the TT across the TM (Figs.3,4)
- Minimize the use of suction (without negatively impacting visualization)
- Use a topical analgesic (phenol)

Manage Movement

- TTS handle design allows surgeon to stabilize the device to the patient's head to safely absorb head movement (Fig.3)
- The TT is contained in a cutting sheath during myringotomy incision, allowing quick and controllable positioning across the TM (Figs.4,5)
- A slightly larger spacing between the medial flange and lateral Vis-tab increases the target deployment zone
- Patient control (swaddling/gentle holding) and surgeon communication with the anesthetist and support staff during the procedure to minimize movement during actual TT insertion

Maintain Visualization

- The TT (Fig.2) includes a unique visualization tab (Vis-tab) that interfaces with a slot in the cutting sheath to allow for direct visual confirmation of tube location during placement
- Multiple orientations of the Vis-tab (+90/-90) are provided to address left/right ear anatomy differences and surgeon preference (Fig.1)
- The TTS handle allows for user adjustment/rotation to customize sight lines for each surgeon's technique

RESULTS

- 314 TTs were placed in 158 children at four institutions
- 159 TTs in 80 children used general anesthesia or deep sedation, and 155 TTs in 78 children used moderate sedation
- The moderate sedation regimen was per ASA definition but typically included nitrous oxide and midazolam

There were 17 adverse events in 16 patients, including 10 plugged tubes, 9 otitis media events, 3 extruded tubes, 1 tube which dislocated into the middle ear, and 1 event in which the patient's hearing loss had increased by > 15dB at the first follow-up visit. These adverse events are typical of tympanostomy procedures and within expected rates.

There were 15 moderate sedation cases that were converted to general anesthesia due to design challenges (causing 4 over-insertions), anatomical issues, patient movement, and one potential laryngospasm. A beveled medial flange tube with a Vis-tab proved effective for attenuating patient movement without TT over-insertion.

DISCUSSION

By minimizing the pain of tube placement while allowing the surgeon to manage patient movement, the surgical system developed addresses the limitations of the standard surgical tray and allows for TT placement in pediatric patients, under moderate sedation.

The critical elements to procedure success and repeatability were found to be maintaining adequate visualization of the TT and deploying the tube while the surgeon is stabilized to the patient's head. The major complication encountered was over-insertion due to issues with tubes deploying correctly. As a result, multiple tubes were evaluated and over-insertion was mitigated through the use of a beveled medial flange tube with a Vis-tab to provide visual depth of penetration.

Being a novel instrument, the TTS creates new challenges for the surgeon. For example, myringotomy creation with the TTS uses an axial piercing motion instead of the radial cutting force employed by a myringotomy knife. However, axial piercing did not contribute to early tube extrusion.

Although this early study presents data that includes the learning curve of the surgeon, the safety profile of the TTS was acceptable and within normal rates for tube insertion using a standard surgical tray. Ultimately, we believe that the TTS has the potential to result in fewer complications due to its design which allows less passes into the canal along with a consistent myringotomy incision. The use of moderate sedation should also reduce complications specific to general anesthesia. Additional experience with the TTS for this high volume procedure will provide an improved understanding of both the benefits and potential complications.

CONCLUSIONS

A surgical system has been developed that minimizes trauma and allows a surgeon to manage pediatric patient head movement during TT placement. Early results with the system show that TT placement in pediatric patients may be accomplished safely under moderate sedation. In addition, supporting training techniques and programs have been developed to promote the successful adoption of the system.

CONTACT

FRANKLIN L. RIMELL, MD
Pediatric ENT and Facial Plastic Surgery
Children’s Hospital and Clinics of Minnesota
Associate Professor

Department of Otolaryngology
University of Minnesota
Email: rimel002@umn.edu

ONE-PASS™ TECHNOLOGY

1. Stabilize hand to the patient (to manage any head movement)

2. Advance through the tympanic membrane (TM) to create myringotomy

3. Scroll-back (with thumb) Retract the sheath, deploying the tube across the TM

HUMMINGBIRD™ TTS

TYMPANOOSTOMY TUBE SYSTEM

Figure 1. TTS with ergonomic handle. Two preloaded tip assemblies with the Vis-tab oriented at +90 and -90 degrees are provided to maximize visualization based upon anatomy and surgeon preference.

Figure 2. Multiple short term grommet-style TT designs were evaluated.

Figure 3

Figure 4

Figure 5

One-Pass™ and Hummingbird™ are registered trademarks of Percutec Medical, Inc.