Tympanostomy Tube Innovation: Advances in Device Material, Design, and Office-Based Technology

Rachel L. Whelan, MD¹, and Raymond C. Maguire, DO¹

Abstract

Objectives: With tympanostomy tube insertion remaining the most common procedure performed in children to date, growing interests in minimizing both procedural costs and anesthetic exposure in the pediatric population have inspired innovation with respect to tympanostomy tubes. As such, we aim to discuss the current state of tympanostomy tube innovation including insertion devices, tube material, and design. Methods: Computerized literature review. Results: (1) Numerous single-use devices consisting of a myringotomy knife and preloaded tympanostomy tube offer potential advantages of decreasing or eliminating operating room time and may be performed under moderate instead of a general anesthetic. (2) Innovation with respect to tympanostomy tube material and design may offer enhanced ototopical drug delivery, decreased rates of tube occlusion, and/or the ability to dissolve “on-command” with application of a novel ototopical material. (3) These technologies currently remain in various phases of preclinical and clinical testing. Conclusions: While clinical testing for a number of new technologies is preliminary and ongoing, tympanostomy tube-related innovations hold exciting promise to supplement or potentially replace the present-day armamentarium of tympanostomy tube design and insertion moving forward.

Keywords
tympanostomy innovation, tympanostomy design, tympanostomy update

Introduction

With national cost estimates for the treatment of otitis media with effusion ranging between US$2 and US$3.5 billion annually, tympanostomy tube (TT) placement remains the most common procedure performed in children in the United States.¹ Furthermore, in December 2016, the Food and Drug Administration (FDA) issued a drug safety communication regarding general anesthesia and sedation in children aged 3 years or younger. These recommendations included limiting the use of a single general anesthetic longer than 3 hours or multiple general anesthetics based upon data suggesting these exposures may affect long-term brain development in young children.²

With these factors in mind, TT innovation with the goals of decreasing cost and minimizing anesthetic exposure has come to the forefront in recent years. As such, the following chapter will discuss the current state of innovation with respect to TT insertion and subsequent management, including TT insertion devices, tube material, and design.

Innovation in TT Insertion Devices and Office-Based Technique

In recent years, the advent of a single-pass TT delivery system combining a myringotomy knife with a preloaded TT has been developed by a number of companies. These technologies are currently undergoing various stages of clinical trial testing with the goals of decreasing or eliminating operating room time and associated resources as well as anesthetic exposure. The current leading devices are described below.
The Hummingbird TTS (TT system; Preceptis Medical) offers a single-pass delivery system consisting of a cutting sheath used to perform a myringotomy and a preloaded TT that is released upon activation of a control button. A phase II prospective study on 128 children (253 TTs) over 4 US centers demonstrated an 88.3% success rate in performing the procedure under moderate sedation defined as a combination of oral midazolam, nitrous oxide, and oxygen via face mask. Median time for myringotomy and tube placement was 22 seconds per ear (range: 5-176 seconds). A total of 15 cases (11.7%) were converted to general anesthesia to complete TT placement due to excessive patient movement (n = 10) or difficult anatomy/lack of adequate visualization (n = 5). Postoperatively, there were 31 plugged tubes in 24 patients (12.3%) and 8 tubes extruded by first follow-up (3.2%), with authors concluding rates comparable to traditional postoperative complication profile. Additional phase II clinical trial testing is ongoing.

Solo TTD (TT device; AventaMed Ltd) similarly consists of a single-use, disposable device combining a myringotomy knife, a preloaded TT, and a control button. With this device, a myringotomy is performed using the myringotomy knife. Activation of the control button simultaneously retracts the knife and deploys the preloaded TT. The action of knife retraction propels the TT, which is collapsed at the tip of the device, into an open position. A “back stop” just proximal to the device tip acts as a safety feature to minimize the risk of inadvertent overinsertion into the middle ear space. A pilot feasibility study by Lawrence et al in 3D printed models as well as cadaveric heads demonstrated 26 of 26 attempted insertions to be successful without any instances of middle ear overinsertion. Three surgeons encompassing skill levels from junior trainee to attending surgeon participated in the study, reporting intuitive device design and relative ease of use. This system is currently marketed in Europe, with plans to seek FDA approval for US utilization.

The Tula device (Tusker Medical, Inc) features a single-use device with automated tube placement. After placing the blunt device tip on the surface of the tympanic membrane, button activation simultaneously extends a myringotomy blade, creates an incision, places a preloaded Paparella-style silicone tube, and retracts all sharp edges for safe removal from the ear canal in less than 0.5 seconds. Tula system was tested in conjunction with an iontophoresis system of local anesthetic drug delivery to the ear canal and tympanic membrane in a single-arm prospective trial over 9 US sites. Of 70 patients (127 ears) aged 6 months to 22 years (mean age: 7 years), 63 patients (90%) successfully received tubes in all indicated ears during their in-office visit with favorable caregiver satisfaction scores. These results were encouraging regarding the safety and feasibility of TT placement in awake, unrestrained pediatric patients in the office setting. Of note, Tusker Medical, Inc was recently acquired by Smith+Nephew with single device price estimates quoted at US$1200.

In addition to TT insertion devices, there is further innovation with respect to addressing tympanic membrane perforation. Aimed to provide an in-office, minimally invasive alternative to traditional tympanoplasty for the management of tympanic membrane perforation, TymCure (CTZ Medical) is a single-use instrument designed to be inserted through an existing perforation, spun to freshen the edges circumferentially, and deploy a biocompatible scaffolding material medial and lateral to the tympanic membrane to encourage ingrowth of tympanic membrane epithelialization. Device design and testing remain in the preclinical phases.

Innovation in TT Material and Design

In addition to the costs and anesthetic risks associated with traditional TT insertion, postoperative complications including early extrusion/tube clogging, retained tubes and resultant perforation, and chronic otorrhea are reported to occur 1% to 3% of the time. As such, innovation with respect to TT material and design are aimed to minimize various aspects of the current postoperative complication profile.

In attempts to reduce the incidence of retained TTs, Brian Reilly and colleagues at Children’s National Hospital are engineering a biocompatible tube material that will dissolve “on-command” upon contact with a unique otophical compound. Biocompatibility in the rat model demonstrated no pathologic or reactive tissue surrounding tube placement. The tube material showed resistance to degradation with application of Ciprofloxacin and Ciprodex drops, while both ethanol and hydrogen peroxide successfully degraded the tubes over a period of 48 hours. Given potential ototoxicity associated with ethanol use, further efforts to achieve the ideal degradation agent are ongoing.

Currently under development through the Wyss Institute at Harvard University, PionEar liquid-infused TTs (PionEar) are designed with a champagne flute-like geometry to facilitate mucous egress and maximize ototopical drug delivery. This innovative device design aims to decrease bacterial biofilm development and selectively allow passage of antibiotic drops into the middle ear space. PionEar tubes remain in the preclinical phases of testing.

Current Limitations and Future Directions

In recent years, innovation with respect to TTs has been aimed at decreasing resource utilization, minimizing anesthetic exposure, and improving the current postoperative complication profile associated with traditional TT placement. While novel TT design and associated devices could have the potential to significantly decrease associated procedural costs and anesthetic exposure on a large scale, limitations associated with office-based procedures must be considered, particularly in the pediatric population.

Although several studies report success rates of up to 90% in children tolerating office-based TT placement when performed using a local anesthetic followed by traditional TT insertion, continued studies are needed to determine the feasibility, complication profile, and ideal setting for implementation of these innovations.
Conclusions

While clinical testing for a number of new technologies is preliminary and ongoing, TT-related innovations hold exciting promise to supplement or potentially replace the present-day armamentarium of TT design and insertion moving forward.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

ORCID iD

Raymond C. Maguire https://orcid.org/0000-0002-2276-0305

References

1. Gates GA. Cost-effectiveness considerations in otitis media treatment. Otolaryngol Head Neck Surg. 1996;114(4):525-530. doi:10.1016/S0194-5998(96)70243-7
2. FDA Drug Safety Communication: FDA review results in new warnings about using general anesthetics and sedation drugs in young children and pregnant women. 2017. https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-review-results-new-warnings-about-using-general-anesthetics-and. Accessed December 12, 2019.
3. Cofer S, Meyer A, Yoon D, et al. Tympanostomy tube placement in children using a single-pass tool with moderate sedation. Otolaryngol Head Neck Surg. 2017;157(3):533-535. doi:10.1177/0194599817707178
4. Lawrence R, McGowan P, Daniel M. An all-in-one tympanostomy tube insertion device: results of usability testing in fourteen cadaveric and twelve plastic model ears. Clin Otolaryngol. 2017;42(3):765-768. doi:10.1111/coa.12689
5. Zeiders JW, Syms CA, Mitskavich MT, et al. Tympanostomy tube placement in awake, unrestrained pediatric patients: a prospective, multicenter study. Int J Pediatr Otorhinolaryngol. 2015;79(12):2416-2423. doi:10.1016/j.ijporl.2015.11.003
6. TymCure. 2016. http://www.tymcure.com/. Accessed December 12, 2019.
7. O’Niel MB, Cassidy LD, Link TR, Kerschner JE. Tracking tympanostomy tube outcomes in pediatric patients with otitis media using an electronic database. Int J Pediatr Otorhinolaryngol. 2015;79(8):1275-1278. doi:10.1016/j.ijporl.2015.05.029
8. Wiedermann JP, Mai JP, Dumont M, Jenkins A, Cleary K, Reilly BK. “On-command” dissolvable tympanostomy tube in the chinchilla model: a proof of concept. Int J Pediatr Otorhinolaryngol. 2017;101:20-24. doi:10.1016/j.ijporl.2017.07.017
9. Mai JP, Dumont M, Rossi C, Cleary K, Wiedermann J, Reilly BK. Biocompatibility of “on-command” dissolvable tympanostomy tube in the rat model. Laryngoscope. 2017;127(4):956-961. doi:10.1002/lary.26355
10. Ear tubes may finally get an upgrade. Innovation. Smithsonian. 2018. https://www.smithsonianmag.com/innovation/ear-tubes-may-finally-get-upgrade-180970946/. Accessed December 12, 2019.
11. Syms CA, Grantham ML. Otologic iontophoresis: a no-papoose technique. Ann Otol Rhinol Laryngol. 2013;122(8):487-491. doi:10.1177/00034894132200802
12. Cohen LL, Martin SR, Ganwell KL, McCarty C, Shih SW. Behavioral techniques to optimize success of in-office pediatric tympanostomy tube placement without sedation. Int J Pediatr Otorhinolaryngol. 2015;79(12):2170-2173. doi:10.1016/j.ijporl.2015.09.041