



ORIGINAL RESEARCH

In-office insertion tympanostomy tubes in children using single-pass device

Theodore O. Truitt MD¹  | James R. Kosko MD² | Grace L. Nimmons MD³ | Jay Raisen MD⁴  | Sandra M. Skovlund MD⁴ | Frank Rimell MD⁵ | Shelagh A. Cofer MD⁶

¹St. Cloud ENT, St. Cloud, Minnesota, USA

²Children's Ear, Nose, Throat & Allergy (CENTA), Orlando, Florida, USA

³Health Partners Park Nicollet, St. Louis Park, Minnesota, USA

⁴Prairie SEA (Sinus, Ear, Allergy), Bismarck, North Dakota, USA

⁵Cedars-Sinai Medical Center, Los Angeles, California, USA

⁶Mayo Clinic, Rochester, Minnesota, USA

Correspondence

Theodore O. Truitt, MD, St. Cloud ENT, 1528 Northway Drive, Saint Cloud, MN 56303, USA.
Email: ttruitt@stcloudent.com

Funding information

Preceptis Medical

Abstract

Objectives: Insertion of tympanostomy tubes (TT) is generally accomplished in children in the operating room under general anesthesia. We report on 229 children treated in-office with a novel device.

Methods: Investigators participated in an IRB-approved, prospective, single arm, multisite investigation of in-office TT placement in awake children. Topical anesthetic was applied, and protective restraint was used. TT placement was performed with a single-pass TT insertion device. Safety was assessed by monitoring procedural events.

Results: Four hundred and forty-four ears were treated in 229 children at 10 sites. Children were in age groups 6-24 months (n = 211, mean = 13 months) and 5-12 years (n = 18, mean = 8.3 years). Two hundred and fifteen children received bilateral TT placement, and 14 received unilateral placement. Overall, 226/229 (98.7%) children had successful TT placement in the office (209/211 in 6-24 months and 17/18 in 5-12 years). Three children were rescheduled for the operating room due to anatomical challenges or patient movement. Median procedure time for bilateral cases in both age groups was 4:53. Two minor adverse events (AEs) were reported in one patient. Per independent assessment of 30 procedure videos by clinicians, TT placement was tolerated acceptably by all children.

Conclusion: In-office TT placement in awake young children using topical anesthetic, enabled by a single pass delivery device, was safe, successful and well tolerated. The American Academy of Otolaryngology (AAO) recently released a Position Statement supporting in-office TT placement in appropriate children. These results affirm an in-office alternative for clinicians and parents who have concerns with the risk, inconvenience and cost of surgery in an operating room under general anesthesia.

Oral presentation: Triological Society Combined Sections Meeting, January 23-25, 2020, Coronado, CA.

This is an open access article under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited, the use is non-commercial and no modifications or adaptations are made.

© 2021 The Authors. *Laryngoscope Investigative Otolaryngology* published by Wiley Periodicals LLC, on behalf of The Triological Society.

Level of Evidence: 2c.

Clinical Trials Registration Number: NCT03544138.

KEYWORDS

children, office, otitis media, tympanostomy tubes

1 | INTRODUCTION

Tympanostomy tube (TT) placement is the most common pediatric surgical procedure performed in the United States under general anesthesia (GA), with over 700 000 procedures performed annually.¹ Tube procedures under GA carry an inherent risk to children from acute anesthetic complications (including laryngospasm or emergence delirium).²⁻⁴ Additionally, there may be potential long-term adverse behavioral or developmental outcomes when young children who receive repeat tubes receive subsequent multiple exposures of GA.⁵ Otitis media and subsequent TT placement also involves a socioeconomic burden for parents. For example, once the consulting otolaryngologist recommends TT placement, there might be a second visit back to the primary physician for a preoperative exam and then a third visit back to a hospital or surgery center for TT placement under GA while complying with fasting requirements for the child. The preoperative visits, fasting requirements, and requirement for an operating room (OR) procedure add a significant burden of inconvenience and cost to parents. These factors, along with the risk of GA, have resulted in parents and pediatricians seeking alternatives when possible.⁶

It would be desirable to move a common, simple, quick procedure such as pediatric TT placement from an operating theater to the physician's office in the spirit of improved safety, decreased recovery time and decreased cost. TTs are routinely performed under local anesthesia in adults and cooperative older children. Within the ENT specialty, there has been a significant progression of procedures traditionally done under GA toward the clinic, including the treatment of sinusitis with balloon sinuplasty. Children frequently have procedures such as foreign body removal, frenulectomy, flexible laryngoscopy, and nasal cautery in the office. In-office pediatric TT placement would give parents an alternative to treat their children with otitis media and Eustachian tube dysfunction.

2 | MATERIALS AND METHODS

The objective of this prospective, multicenter, nonrandomized study was to assess in-office pediatric TT placement with the Hummingbird Tympanostomy Tube System (H-TTS, manufactured by Preceptis Medical, Maple Grove, MN) and topical anesthesia of the surgeon's choice. The H-TTS was previously cleared by the FDA for TT placement in awake children using conscious sedation (results published by Cofer et al in *Otolaryngology Head and Neck Surgery*),⁷ and the TT used in the H-TTS is also cleared by the FDA. This study is a

multicenter trial conducted at 10 clinical sites: five tertiary care pediatric facilities (Mayo Clinic, Rochester, MN; Park Nicollet, St. Louis Park, MN; Health Partners, St. Paul, MN; Cedars Sinai, Los Angeles, CA; Primary Children's Hospital, University of Utah, Salt Lake City, UT), two pediatric clinics (CENTA, Orlando, FL; Pediatric Otolaryngology Associates, Jacksonville, FL), and three general otolaryngology clinics (SCENT, St. Cloud, MN; Prairie SEA, Bismarck, ND; Altru, Grand Forks, MN).

After IRB approval of the protocol was obtained at each site, patients were enrolled and informed consent was obtained from the caregiver/parent. All parents of ear tube candidates were offered the option of TT placement in a surgical facility under GA or, if they met study criteria, as proposed in the current office study. Parents were also notified that any TT procedure that could not be completed in the office could be rescheduled for placement in the OR using GA. Per site criteria, an assent form was additionally obtained from older children. At any point during the process, including at any point during the office procedure, parents could change their mind and move the procedure to the OR.

Inclusion criteria were children ≥ 6 months and < 2 years or between 5 years and 12 years of age scheduled for TT placement. These age groups were selected since the younger children could undergo protective immobilization during the procedure, while the older group were considered able to understand the procedure, receive communication from the otolaryngologist, staff and parent, and restraint was optional.

Exclusion criteria included: any condition that, in the opinion of the investigator, may place the subject at greater risk (eg, child with a bleeding disorder or developmental delay); anatomy precluding adequate visualization and access to the tympanic membrane; and previous tube placement in the 6-24 month age group. Parents were offered to be present during the procedure at the surgeon's discretion. If parents were not present for the procedure, the surgeon described how the child would be restrained.

All procedures were performed in an otolaryngology office with equipment set up including an operating microscope, ear speculum, cerumen curette, Frazier suction, and the TT insertion device. Protective restraint was achieved either with a sheet/blanket and swaddle technique and/or a medical grade immobilization board. The patient's head was stabilized by a nurse assistant trained in office procedures.

Topical anesthesia of the surgeon's choice was applied to the TM to numb the incision site. No children received sedation. However, at the parent's discretion, preprocedural ibuprofen or acetaminophen was given to children just prior to the office appointment.

2.1 | Instrumentation

The H-TTS consists of a disposable surgical tool designed to deliver a preloaded TT into the tympanic membrane. The H-TTS integrates the multiple surgical instruments necessary for the surgical procedure into a one-pass device, which reduces potential trauma and procedural time for the patient. The TT used with the H-TTS is a slightly modified version of a standard, grommet style tube, with an inside diameter of 1.0 mm (Figure 1).

2.2 | Training

Prior to enrolling children in the study, surgeons were trained with the H-TTS device on a simulated head/tympanic membrane model and performed at least six in vivo TT placements (three patients or six ears) with the H-TTS device under GA. Further, clinical staff and study coordinators trained on the study protocol and the logistics of in-office pediatric TT placement.

2.3 | Study design

Success of the procedure was defined as completion in the office without having to schedule TT placement for the OR. The efficacy endpoint for the study was successful delivery of the TT across the tympanic membrane by the H-TTS. The safety endpoint was the rate of procedural adverse events. Patients were followed through the first postprocedural follow-up visit at 3-10 weeks.

Data procured included the procedure time (including wax removal and defined as speculum into the first ear until speculum out

of the second ear), number of surgical passes with the H-TTS, additional instruments besides the H-TTS used to place the TT, and an assessment of time to patient recovery by the staff (defined as calm and/or absence of inappropriate crying by the patient after procedure completion). A parent survey was completed immediately after the procedure.

Additionally, a committee of three clinicians (a neurologist, a pediatrician, and a pediatric intensivist) independently reviewed videos in children 6-24 months old from 30 consecutive procedures (where video consent was obtained). The video recordings were performed by staff and started on patient arrival in the procedure room and continued until at least 3 minutes after procedure completion. Each clinician recorded whether, in their opinion as a practicing clinician, the child tolerated the procedure acceptably (yes or no).

2.4 | Compliance to federal regulation

The study, including the responsibilities of the investigators and sponsor, was carried out in compliance with all federal regulation for clinical studies, including 21 CFR Part 50 (Protection of Human Subjects), 21 CFR Part 54 (Financial Disclosure by Clinical Investigators), and 21 CFR Part 56 (Institutional Review Boards). Further, per federal regulation, the study was registered on ClinTrials.gov.

3 | RESULTS

Two hundred and twenty-nine children (444 ears) were treated at 10 sites by 13 investigators. Two hundred and eleven children (420 ears) were in the age group 6-24 months (mean = 13 months; Mdn = 12 months), and 18 children (24 ears) were in the 5-12 year group (mean = 8.3 years; Mdn = 8.1 years). The topical anesthetic received for most ears was phenol (423/444 ears, 95.3%), either from a large stock container and surgeon-selected applicator or a single-use kit. In two ears, 4% lidocaine with H₂O₂ was used, and topical anesthetic was not used in 19 ears per the prerogative of the surgeon. In 66.8% of the cases (153/229), a parent(s) was verified as present in the procedure room. Demographics are in Table 1.

Overall, 226 out of 229 children had TT placement completed in the office with the H-TTS (98.7%). In the 6-24 month group, 209/211 (99.1%) children had TT placement completed in the office; in the 5-12 year group, 17/18 (94.4%) children had TT placement completed in the office. Placement of the TT across the TM with only the HTTS was successful in 431/444 ears (97.1%). Median bilateral procedure time for the 6-24 month group (n = 208) was 4:53 (range: 2:00-15:54); the median bilateral procedure time for the 5-12 year group (n = 6) was 4:30 (range: 3:00-14:01). In cases where placement of the TT across the TM was completed only by the H-TTS, it required one surgical pass in 84.4% of the ears and two surgical passes in 98.2% of the ears. See Tables 2-5.

The H-TTS did not independently deliver the TT into the TM in a total of 13 ears (12 ears in the 6-24 month group and 1 ear in the

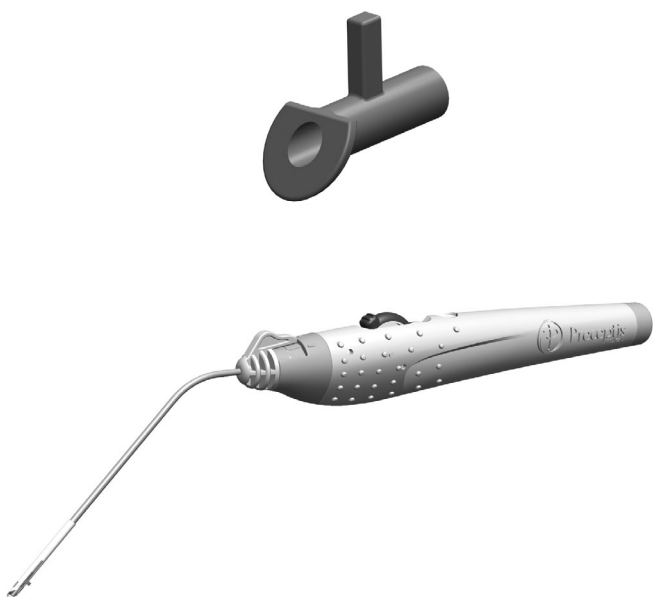


FIGURE 1 Tympanostomy tube used with the Hummingbird Tympanostomy Tube System

TABLE 1 Demographics

Demographics	6-24 month group (n = 211)	5-12 year old group (n = 18)	Entire cohort (n = 229)
Mean age	13 months	8.3 years	-
Procedure indications			
Unilateral	2	12	14
Bilateral	209	6	215
Total number of ears treated	420	24	444

TABLE 2 Successful office placement

Success	6-24 month group (n = 211 patients)	5-12 year old group (n = 18 patients)	Entire cohort (n = 229 patients)
Tubes placed in office	99.1% (209/211)	94.4% (17/18)	98.7% (226/229)

TABLE 3 Hummingbird Tympanostomy Tube System (H-TTS) delivery success

Efficacy	6-24 month group (n = 420 ears)	5-12 year old group (n = 24 ears)	Entire cohort (n = 444 ears)
H-TTS delivery success	97.1% (408/420)	95.8% (23/24)	97.1% (431/444)

TABLE 4 Procedure time

Procedure times	6-24 month (n = 210 ^a)	6-24 month bilateral (n = 208 ^a)	6-24 month unilateral (n = 2)	5-12 year old (n = 18)	5-12 year old bilateral (n = 6)	5-12 year old unilateral (n = 12)	Bilateral (n = 214 ^a)	Unilateral (n = 14)
Mean	5:28	5:28	5:30	2:59	6:18	1:49	5:30	2:21
Median	4:57	4:53	5:30	2:20	4:30	1:38	4:53	1:54
Range	2:00, 15:54	2:00, 15:54	5:00, 6:00	0:54, 14:01	3:00, 14:01	0:54, 3:08	2:00, 15:54	0:54, 6:00

^aProcedure time not recorded for 1 bilateral case in 6-24 month group.

5-12 year group). In 8 of these 13 ears, alligator forceps were used in addition to the H-TTS to complete TT placement. The other five ears (three patients, two in 6-24 month, and one in 5-12 year) were rescheduled for the OR. In these three patients rescheduled for the OR, one patient was due to excess movement; one patient was due to a thick crust over the TM which could not easily be removed and prevented adequate topical anesthetic application; and one was due to severe retraction of the TM.

There were two procedural adverse events reported in a total of 444 ears (2/444, 0.45%), both in the same patient in the 6-24 month group. The adverse events included acute tube extrusion on the left side and tube dislocation into the middle ear on the right. The surgeon attributed the cause to excess patient movement per the use of a floating staff nurse who was not trained on the procedure and did not have experience in pediatric office procedures. The patient was subsequently scheduled for the OR, with the tube being retrieved and the patient receiving bilateral TTs.

Patient recovery was assessed by the otolaryngologist and staff, and recovery was defined as the child being calm and/or no inappropriate crying. Overall, 94.3% of the children were assessed as having

recovered once back with the parents, and 98.7% were considered recovered prior to leaving the clinic. In the 6-24 month group, 98.6% (208/211) of the children were considered recovered before leaving the clinic; in the 5-12 year group, 100% (18/18) children were considered recovered before leaving the clinic. For three patients in the 6-24 month group, it was unknown if the child was calm before leaving the clinic. See Table 6.

Parent satisfaction surveys with a 5-point Likert scale were requested following the procedure, and 204 of 229 possible surveys were returned. Parents strongly agreed or agreed in 95.1% of the surveys that it was important to have an alternative to GA for their child's ear tube procedure; they strongly agreed or agreed 85.8% of the time that reduced cost and increased efficiency from an office tube procedure were important to them; and they strongly agreed or agreed in 97.5% of surveys that they would recommend this procedure to other parents. See Figure 2.

Thirty consecutive procedure videos in which the parent provided video consent were assessed independently by a committee of three clinicians to assess how the child tolerated the procedure. In all 30 patients (90 evaluations), the independent

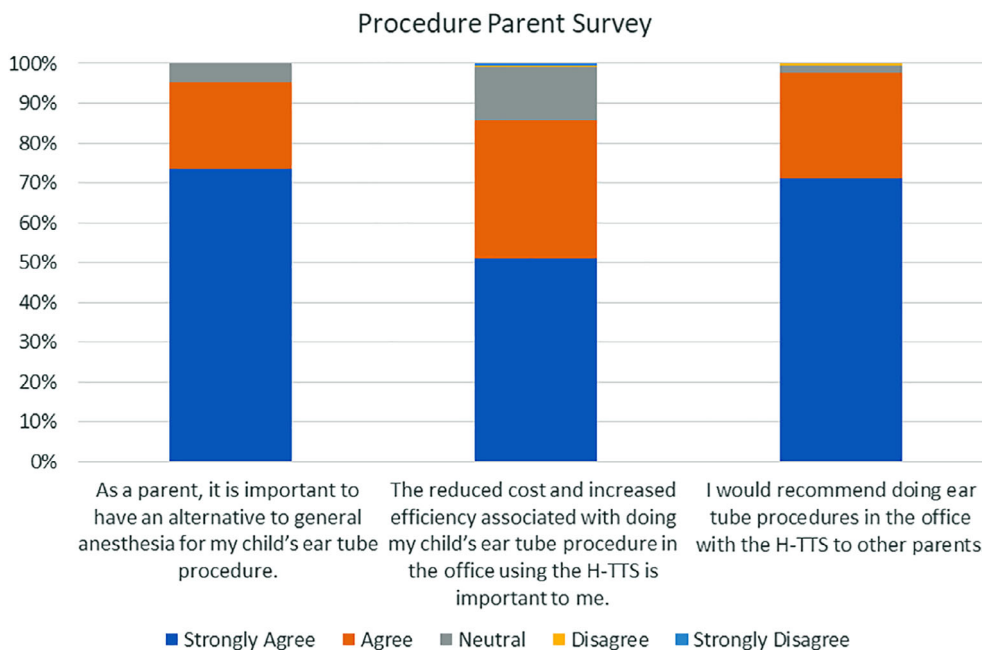
TABLE 5 Surgical passes

Number of passes	6-24 month group (% completed) n = 418 ears (2 ears not attempted due to unsuccessful procedure on other ear)	5-12 year old group (%) n = 24 ears	Entire cohort n = 442 ears (2 ears not attempted due to unsuccessful procedure on other ear)
One pass	84.0%	91.7%	84.4%
Two passes	98.1%	100%	98.2%
>2 passes	100%	N/A	100.0%

TABLE 6 Patient recovery

Patient recovery	6-24 month group (n = 211)	5-12 year old group (n = 18)	Entire cohort (n = 229)
Once back with parent	94.3% (199/211)	94.4% (17/18)	94.3% (216/229)
Prior to leaving clinic	4.3% (9/211)	5.6% (1/18)	4.4% (10/229)
Unknown if child calm prior to leaving clinic	1.4% (3/211)	-	1.3% (3/229)

FIGURE 2 Results from parent satisfaction survey



clinical reviewers deemed that the child tolerated the procedure acceptably.

A total of 197/229 follow-ups have been completed. Of these, 163 follow-up visits were completed in the 3-10 week timeframe. The early extrusion and plugging rates at 3-10 weeks were 2.4% and 8.1%, respectively.

4 | DISCUSSION

The merits of TT placement in children have been well discussed and proven, and it has become the most common ambulatory surgery performed on children in the United States.¹ Although TT placement in adults and older children is routinely performed in the office, the present mode of TT placement for infants or young children is to undergo

the procedure under GA in an OR.^{8,9} The arguments for doing so primarily rest on the potential for the child to be uncooperative and that placement of a TT is too painful and stressful for an awake child and too difficult for a surgeon.

However, comparable in-office otolaryngic procedures (eg, foreign body removal from the nose and ears of a young child) are routinely performed in the office setting without GA. Further, GA for TT placement has a 9% incidence of minor complications and a 2% incidence of major adverse events.² Moreover, the recent Mayo Anesthesia Safety in Kids (MASK) study¹⁰ and the FDA Safety Alert⁵ on the use of GA in children under 3 years report that multiple exposures or long durations of GA in young children may predispose them to adverse behavioral or development outcomes. TT placement does not involve long durations of GA, but published rates of repeat TT placement (ie, multiple exposures of GA) range from 19.9% to 46.8%.^{11,12}

Additional surgeries (eg, adenoidectomy) can further increase the number of GA exposures in young children. It should be noted that patient age at subsequent tube placement and adenoidectomy may be greater than 3 years.

In response to parental concerns over GA, Rosenfeld performed and reported on a series of successful TT placements in the office in young children. These placements were performed without the use of local anesthesia, despite its analgesic appeal, due to concerns that it could prolong the procedure and further induce local pain. Rosenfeld concluded that office insertion of TT in young children is a feasible alternative to GA for caregivers and clinicians who are comfortable with this choice as determined via a shared decision-making process.⁶ In a subsequent editorial, Rosenfeld also cautioned that pediatric TT placement in the office with standard instruments depends highly on the skill and experience of the surgeon, including his or her ability to determine appropriate children and parents.¹³

This study attempts to expand on Rosenfeld's progress and performed pediatric in-office TT placement in young children using a commonly used local anesthetic to reduce the pain of the procedure and using a tube delivery system designed to both reduce the surgical trauma for the child and increase ease of use for the surgeon. Our data shows that bilateral in-office TT placement in children 6-24 months and 5-12 years old using local anesthesia, protective restraint and the H-TTS device can be achieved in under 5 minutes, with high tube placement success rate of 98.7% and a low AE rate (0.45%).

The cases that could not be completed were due to excess patient movement, a mucosal film over the TM which prevented topical application and severe eardrum retraction not appreciated prior to otomicroscopy (or inclusion).

In 66.8% of the procedures, a parent was present to help calm and distract their child and to assess how their child was tolerating the procedure. The assessment of patient recovery prior to leaving the clinic showed a small difference between the cases where the parent was present (100% were recovered before leaving the clinic) and where they were not present (95.7% were recovered). In any regard, most clinicians are likely to agree that parental presence is usually beneficial in reducing anxiety for the child. In Rosenfeld's reported in-office tube experience, a caregiver was always present during the procedure, per his preference.⁶ Therefore, it is reasonable to speculate that future pediatric in-office TT placement will likely have significant parental presence in the procedure. Overall, an overwhelming number of parents surveyed in this study would strongly recommend the procedure to other parents.

The early extrusion and plugging rates at 3-10 weeks were 2.4% and 8.1%, respectively. These rates are consistent with premature extrusion (4%) and occlusion (7%) pooled rates reported in UptoDate (meta-analysis of >60 randomized trials and 70 case series).¹⁴

There have been six previous significant publications on in-office TT placement in children without GA: two used standard surgical instruments; two used laser myringotomy; and two involved the same automated tube delivery system.^{6,15-19} For the automated system, Lustig recently reported (2020) in-office tube placement in children under 5 years old using iontophoresis, an automated tube delivery system, and the parents holding the child rather than papooseing or

swaddling. Tubes were placed successfully in 85.8% of children with a mean procedure time of 35-40 minutes (as publicly reported).²⁰

The limitations of this study include lack of randomization and potential bias by the health care providers in evaluating child recovery. Child tolerability of the in-office procedure was therefore also independently assessed by three clinicians who graded the child's response at each stage of the procedure and opined on whether they felt that the child successfully tolerated the procedure.

It should be noted that the current mode of delivery for TT placement under GA in an OR routinely includes tolerability concerns for the child. It is well acknowledged that fasting (NPO) restrictions, separation of the child from their parent, the OR environment, and mask induction often cause anxiety and agitation for the young child.²⁰⁻²² Emergence delirium (ED) after GA is often severe enough to require physical restraint to prevent self-injury. Cravero reported that 57% of children experienced ED after TT placement using sevoflurane, with the ED being defined as a minimum of 3 minutes in which the child had to be physically restrained.⁴

Per the request of the FDA for a formal opinion on in-office tubes, the American Academy of Otolaryngology (AAO) issued a Position Statement in 2019 on in-office TT placement in pediatric patients while awake. The Position Statement included 19 citations and concluded, "although insertion of tympanostomy tubes in children is generally accomplished in the OR under GA, insertion in the clinic in appropriately selected patients using shared decision making between clinicians and families can be appropriate."²³

Although this study was not designed to evaluate the cost-savings of in-office TT placement vs in the OR under GA, it is well-recognized that the office is the lowest cost point-of-service for minor procedures due to elimination of a facility fee and perioperative anesthesia fees. Davidson reported that myringotomy tube insertion in the minor procedure room (ie, sedation unit) was less than half the cost of completing the procedure in the OR.²⁴ It follows that with the additional elimination of anesthetic fees, costs for in-office TT placement can be reasonably expected to be less than in a hospital minor procedure room.

In addition to cost-savings, the added convenience for the patient and parents is another advantage of office TT insertion. Patients do not need to abstain from oral intake before the procedure and do not have the extra time that is part of a day at a surgical facility. It was not part of our study protocol to perform the tube placement on the same day as the consultation. After enrollment, most families returned on another day to have the procedure. The authors feel that same day, office insertion of TTs in children would be a potential benefit to patients and their families.

The results of this study were submitted to FDA by the sponsor, and the H-TTS was subsequently cleared for commercialization by the FDA for in-office TT placement in children 6-24 months old.

5 | CONCLUSION

This study shows that in-office TT placement in young children is a safe and tolerable option for parents who desire an alternative to GA

for their children. TT placement was completed in the office in 98.7% of the cases with an AE rate of 0.45%, and the median procedure time for bilateral TT placement was under 5 minutes. Additionally, for parents an in-office approach provides increased convenience and reduces the burden of additional health care visits. Additional analysis of the cost savings for in-office TT placement in young children is needed.

ACKNOWLEDGMENT

The study was sponsored and funded by Preceptis Medical, Maple Grove, MN.

CONFLICT OF INTEREST

Theodore O. Truitt—Preceptis Medical (Consultant); Stryker ENT (Consultant). James R. Kosko—None. Grace L. Nimmons—None. Jay Raisen—Intersect ENT (Consulting Services). Sandra M. Skovlund—Skovlund Medical Products (Founder); Inspire Medical (Consultant). Frank Rimell—Preceptis Medical (Consultant and Medical Director). Shelagh A. Cofer—None.

ORCID

Theodore O. Truitt  <https://orcid.org/0000-0001-9145-6043>

Jay Raisen  <https://orcid.org/0000-0002-8171-1933>

BIBLIOGRAPHY

- Cullen KA, Hall MJ, Golosinskiy A. Ambulatory surgery in the United States, 2006. *Natl Heal Stat Rep*. 2009;11:1-25.
- Hoffman KK, Thomson KG, Burke BL, Derkay CS. Anesthetic complications of tympanostomy tube placement in children. *Arch Otolaryngol Head Neck Surg*. 2002;128:1040-1043.
- Miller RD, Pardo M. *Basics of Anesthesia*. 6th ed. Philadelphia, PA: Elsevier; 2011.
- Cravero JP, Beach M, Dodge CP, Whalen K. Emergence characteristics of sevoflurane compared to halothane in pediatric patients undergoing bilateral pressure equalization tube insertion. *J Clin Anesth*. 2000;12(5):397-401.
- FDA Drug Safety Communication: FDA review results in new warnings about using general anesthetics and sedation drugs in young children and pregnant women. Published December 14, 2016.
- Rosenfeld RM, Sury K, Macarinas C. Office insertion of tympanostomy tubes without anesthesia in young children. *Otolaryngol Head Neck Surg*. 2015;153(6):1067-1070.
- 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.
- Rosenfeld RM, Shin JJ, Schwartz SR, et al. Clinical practice guideline: otitis media with effusion (update). *Otolaryngol Head Neck Surg*. 2016; 154(1 suppl):S1-S41.
- Lieberthal AS, Carroll AE, Chonmaitree T, et al. The diagnosis and management of acute otitis media. *Pediatrics*. 2013;131(3):e964-e999.
- Warner D, Zaccariello MJ, Katusic SK, et al. Neuropsychological and behavioral outcomes after exposure of young children to procedures requiring general anesthesia: the Mayo Anesthesia Safety in Kids (MASK) study. *Anesthesiology*. 2018;129(1):89-105.
- Boston MK, McCook J, Burke B, Derkay C. Incidence of and risk factors for additional Tympanostomy tube insertion in children. *Arch Otolaryngol Head Neck Surg*. 2003;129(3):293-296.
- O'Neil 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.
- Rosenfeld RM. Shared decision making and office insertion of tympanostomy tubes. *Otolaryngol Head Neck Surg*. 2016;154(5): 807-809.
- UptoDate. Wolters Kluwer; 2019.
- 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.
- Brodsky L, Brookhauser P, Chait D, et al. Office-based insertion of pressure equalization: tubes the role of laser assisted tympanic membrane fenestration. *Laryngoscope*. 1999;109(12):2009-2014.
- Summerfield MJ, White PS. Ventilation tube insertion using topical anesthesia in children. *J Laryngol Otol*. 1992;106(5):427-428.
- Friedman O, Deutsch ES, Reilly JS, Cook SP. The feasibility of office-based laser-assisted tympanic membrane fenestration with tympanostomy tube insertion: the DuPont Hospital experience. *Int J Pediatr Otorhinolaryngol*. 2002;62(1):31-35.
- Lustig LR, Ingram A, Vidrine DM, et al. In-office tympanostomy tube placement in children using Iontophoresis and automated tube delivery. *Laryngoscope*. 2020;130(suppl 4):S1-S9.
- Cohen B, Thevenin A, Mille-Zemmoura B, Moenne-Loccoz J, Remerand F, Laffon M. Anxiety during inhalation induction in paediatrics: sitting versus supine position, a randomized trial. *Anaesth Crit Care Pain Med*. 2018;37(5):435-438.
- Fortier MA, Del Rosario AM, Martin SR, Kain ZN. Perioperative anxiety in children. *Paediatr Anaesth*. 2010;20(4):318-322.
- Fortier MA, Kain ZN. Treating perioperative anxiety and pain in children: a tailored and innovative approach. *Paediatr Anaesth*. 2015;25(1):27-35.
- AAO-HNS Position Statement. In-Office Placement of Tubes in Pediatric Patients While Awake. <https://www.entnet.org/content/placement-tubes-pediatric-patients-while-awake>. Accessed September 24, 2020.
- Davidson J, Ioanidis K, Fantillo V, Paradis J, Strychowsky J. Cost and efficiency of myringotomy procedures in minor procedure rooms compared to operating rooms. *Laryngoscope*. 2020;130(1):242-246.

How to cite this article: Truitt TO, Kosko JR, Nimmons GL, et al. In-office insertion tympanostomy tubes in children using single-pass device. *Laryngoscope Investigative Otolaryngology*. 2021;6:325-331. <https://doi.org/10.1002/lio2.533>