

+ Evidence in focus

Publication summary: Lustig LR, et al. *Laryngoscope* (2020)*

Tula® System shown to be safe and effective for in-office ear tube placement in children

+ Plus points

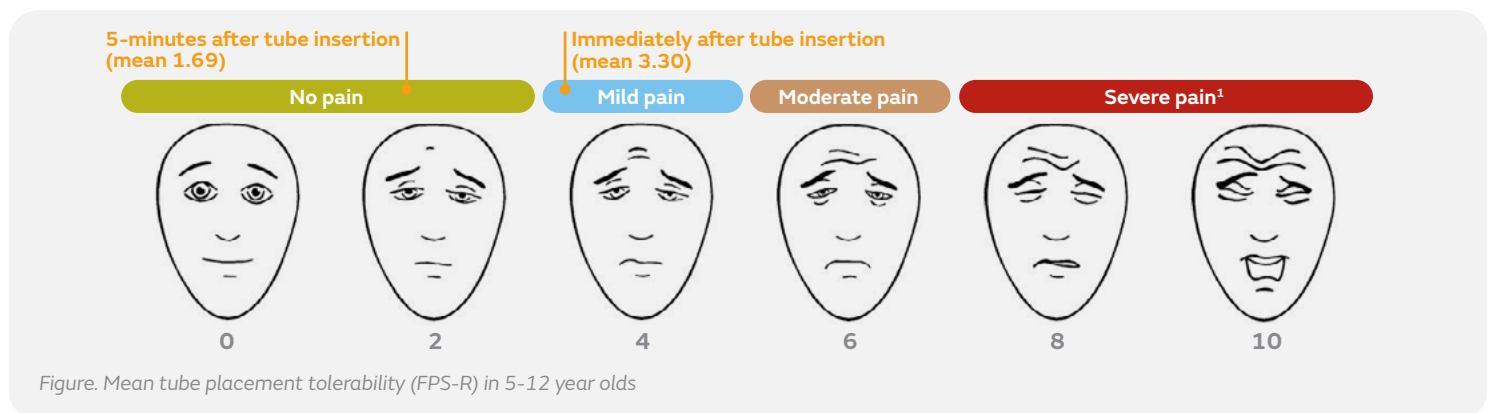


Overview

- Prospective, multicenter study evaluating the safety and effectiveness of in-office ear tube placement with the Tula System in children aged 6 months to 12 years
- Children were enrolled into one of three successive cohorts:
 - Operating room lead-in (n=68)
 - Office lead-in (n=47)
 - Pivotal (n=222)
- Effectiveness was assessed in the pivotal cohort, with co-primary endpoints of:
 - Procedural success: proportion of children with successful tube insertion in all indicated ears in one procedure
 - Tube placement tolerability: mean self-reported pain score on the Faces Pain Scale-Revised (FPS-R) in 5-12 year olds

Results

- Procedural success rates with the Tula System were:
 - 86% in children <5 years (103/120)
 - 89% in children 5-12 years (91/102)
- Pain was mild and transient on average in 5-12 year olds (Figure)
- At 3 weeks, 94% of ear tubes were functionally patent
- Only 7.6% of patients were suctioned in-office; high patency rates were maintained regardless of whether suction was performed
- 95% of parents completing a 3-week follow-up survey (n=202) agreed (13%) or strongly agreed (82%) that they were very satisfied with the Tula Procedure
- Zero serious device-, procedure- or drug-related adverse events



Conclusions

Using the Tula System, ear tubes were successfully and safely placed in pediatric patients aged 6 months to 12 years in an office setting without requiring the use of sedation, anxiolytics, or mechanical restraints such as papoose boards.

Citation

*Lustig LR, Ingram A, Vidrine M, et al. In-office tympanostomy tube placement in children using iontophoresis and automated tube delivery. *Laryngoscope*. 2020;130(Suppl 4):S1-9. Available at: [Laryngoscope](https://pubs.laryngoscope.com)

Reference: 1. Tsze DS, Hirschfeld G, Dayan PS, et al. Defining no pain, mild, moderate, and severe pain based on the Faces Pain Scale-Revised and Color Analog Scale in children with acute pain. *Pediatric Emer Care*. 2016;34(8):537-544.

About Tula®

The Tula System is intended to create a myringotomy and insert a tympanostomy tube using the Tula Tube Delivery System in pediatric (aged 6 months and older) and adult patients indicated to receive tympanostomy tubes. The Tula System is used to deliver a tympanostomy tube under local anesthesia induced using the Tula Iontophoresis System and TYMBION, a combination of an amide local anesthetic and an alpha- and beta-adrenergic agonist. Contraindications include certain abnormal ear anatomy, sensitivity/allergy to lidocaine or other local anesthetics, and reliance on electrically sensitive medical implants such as a pacemaker. Risks may include, but are not limited to, inadequate local anesthesia, dizziness, and common tympanostomy procedure risks. For full prescribing information including procedural success rates, contraindications, warnings and precautions, see the Tula IFU (IFU0007011) and TYMBION Drug Package Insert (IFU0007010) at www.tulatubes.com/IFU. Rx only.