# The emergence of in-office ventilation tubes for the treatment of otitis media in children

### BY NATHAN PAGE AND JOÃO PIMENTEL

In-office tympanostomy tube systems offer a quicker, anaesthesia-free alternative to traditional surgery for children, with promising outcomes and reduced costs.

ympanostomy tube or grommet insertion is the most common surgery performed on children worldwide. Whilst a relatively short and straightforward procedure, it is typically performed under general anaesthesia in young children who would otherwise struggle to keep still. In recent years, office-based alternatives to tympanostomy tube insertion have emerged which provide a quicker, single-step method using a handheld insertion device pre-loaded with the tube. The advantages of avoiding a general anaesthetic and the reduced cost are compelling, however, there remain valid reservations regarding the practicality of performing the procedure in young children and the longer-term outcomes. A recent study addressing the paucity of information on

longer-term data noted comparable long-term outcomes for in-office versus operating room-inserted tubes, including time to occlusion / intrusion. Interestingly, the study noted better outcomes for attending- versus resident-inserted tubes, suggesting this technique may have a steeper learning curve than the traditional OR insertion of tubes [1]. Here, we present two devices currently in use: the Hummingbird Tympanostomy Tube System and the Solo+ Device.

#### Reference

 Voigt A, Mooney S, Minkowitz M, et al. Outcomes of in-office versus operating room insertion of tympanostomy tubes in children. Int J Pediatr Otorhinolaryngol 2023;175:111772.



# Hummingbird

Myringotomy with tube placement is one of the most common surgical procedures performed on children in the United States and is usually performed under general anaesthesia. Concern about anaesthesia in young children has led to an increased interest among parents and physicians in performing procedures on awake patients. Myringotomy has long been performed safely on adults in the clinic setting, but there are additional challenges when working with paediatric patients. The Hummingbird Tympanostomy Tube System is designed and FDA-approved for myringotomy and tube placement in the office for children six months of age and older. The safety, success rate and tolerance of the Hummingbird procedure have been demonstrated in a peer reviewed publication [1]. At our institution, studies evaluating the cost-effectiveness and longevity of the tubes are ongoing. This article will discuss one surgeon's experience with the Hummingbird, including patient selection, preparation, the procedure itself and the parent / patient experience.



#### Patient selection

As with any awake in-office procedure, patient selection is key. I discuss the procedure with parents in detail to ensure they are comfortable with the plan, including restraining the child if appropriate. I look for non-verbal cues to indicate that parents may be unprepared for this part of the process. I answer parent questions and only offer the procedure if we agree that it is ideal for the child. We include older children in this discussion at a developmentally appropriate level.

# Procedure preparation

Preparing the child depends very much on their age. For the youngest patients, typically under two years old, the focus is on distraction and speed. Within our practice, we provide a child life specialist who plays music or videos, and we gently restrain the infant and move through the procedure as expeditiously as possible.

For older children, the child life specialist spends a longer time with them before the procedure. The child is reassured about the safety of the procedure and the presence of their parents; we are also clear and honest about the parts that may cause discomfort. Because the pain from the numbing medication is short-lived (typically seconds), we can often talk them through that without



the need for stabilisation. Communication with the child and the parents is one key to a positive experience.

# Ear tube placement with the Hummingbird

The procedure is quick, with bilateral ear tube placement typically completed in under five minutes. To help with this process, at least one medical assistant is present to steady the child's head, in addition to having a parent present in the room. Younger children are wrapped in a blanket to help avoid movement.

For OR-based ear tube procedures, middle ear fluid is usually suctioned prior to ear tube placement. Given that this can be loud and uncomfortable for an awake child, we avoid this if possible. In the initial clinical study performed at the Mayo Clinic, no issues were observed with blocked tubes or residual fluid despite rarely suctioning the ears [2].

Sometimes there is fluid under pressure, as in the case of acute otitis media. I have found that in these situations, suctioning some of the purulent fluid is required to verify the position of the tube.

#### Physician, patient and parent experience

Our experience so far has been very positive. Parents who have had children undergo tubes under anaesthesia as well as in the office have overwhelmingly been happy with their office tube experience. The reduced time involved, absence of post-anaesthesia recovery and avoidance of the fasting required to undergo anaesthesia

are some of the frequently cited factors that make office tube placement preferable. Cost is also considerably reduced compared to surgical tube placement in the operating room. From the physician's perspective, I appreciate the capability of performing this common procedure in the office without the risks and costs of anaesthesia. In my experience, the Hummingbird device facilitates safe and effective in-office tube placement in most children, and I am now offering it to all appropriate patients who are candidates for ear tube placement.

#### References

- Truitt TO, Kosko JR, Nimmons GL, et al. In-office insertion tympanostomy tubes in children using single-pass device. Laryngoscope Investig Otolaryngol 2021;6(2):325–31.
- Mayo Clinic. Hummingbird TTS Ear Tube Delivery Study; https://www.mayo.edu/ research/clinical-trials/cls-20169926 [Link last accessed December 2024].

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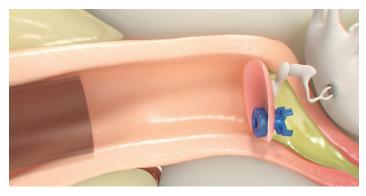
# Solo+™

## Streamlined procedure

The Solo+ device has helped revolutionise grommet placement by making the procedure significantly quicker. Traditional grommet insertion involves multiple steps: making an incision in the tympanic membrane, suctioning the effusion, and inserting the grommet. Solo+ is designed as an all-in-one device that combines these steps, which reduces the procedure time to just a few seconds – this is my personal experience so far.

# Moving patients out of the operating room: a paradigm shift

A key advantage of the Solo+ device is that it enables the procedure to be performed outside of the traditional operating room setting. This shift is significant because it allows for greater flexibility in patient scheduling, reduces costs, and may help to reduce the pressure on operating room resources. By moving the procedure to an outpatient or office-based environment, children and their families may experience less disruption to their daily lives and the hospital staff may optimise operating room time for more complex procedures.



# No general anaesthesia implications for patient preparation

The elimination of general anaesthesia with this procedure has profound implications, especially for paediatric patients. One of the main concerns with general anaesthesia is the requirement for fasting beforehand, which can be particularly challenging and distressing for young children. By removing the need for general anaesthesia, this procedure may help to alleviate the potential stress associated with preoperative fasting and help to reduce the overall preparation time. Without the risks and recovery time associated with general anaesthesia, children can undergo the procedure with minimal preparation and may return to their daily activities almost immediately. If a child is not a suitable candidate for topical / local anaesthesia and anaesthesiology support is needed, since the procedure is so quick only sedation is required, avoiding general anaesthesia with intubation.

#### No suction of the effusion: clinical outcomes

Another distinctive aspect of the procedure is that it does not need the suction of middle ear effusion before grommet placement. This is such a paradigm shift for ENT surgeons, many will have to see it to believe it. As ENT surgeons, we learned during training that we



must suction the middle effusion before inserting the grommet. Studies have shown that patients treated with Solo+ exhibit similar improvement in hearing and reduction in OME-related symptoms compared to those who undergo traditional grommet insertion with suction. When I started using the device, I was monitoring my patients (with otoscopy) in the first two hours after the procedure and I was surprised to see that, in this short space of time, the 'glue-ear' was already a 'clear-ear' with a patent grommet and the child's hearing was normal again. This approach not only shortens the procedure but also may help to reduce potential trauma to the tympanic membrane and middle ear structures.

Regulatory compliance: meeting the European MDR

The Solo+ device is currently the only all-in-one product for grommet insertion that has achieved certification under the European Medical Device Regulation (MDR). This certification is a testament to its safety, efficacy, and compliance with stringent regulatory standards. The MDR places rigorous requirements on medical devices, particularly those intended for use in paediatric populations, ensuring that the highest levels of safety and performance are maintained. It has also achieved Food and Drug Administration (FDA) 510(k) clearance for US patients aged 6–24 months old.

In conclusion, the Solo+ device represents a significant advancement in the management of OME and has brought more than one paradigm shift. Its ability to streamline the grommet insertion procedure, eliminate the need for general anaesthesia and suction, and provide a solution for patients of varying ages – all while meeting stringent regulatory standards – positions it as a highly effective device in otolaryngology.

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