

WHITE PAPER

IS THERE A NEED TO ASPIRATE MIDDLE EAR EFFUSION DURING TYMPANOSTOMY TUBE PLACEMENT?

Summary of Peer-Reviewed Literature and Hummingbird® TTS Clinical Study Data

Introduction

Otolaryngologists are taught as residents to aspirate (i.e., suction) middle ear effusions (MEE) during tympanostomy procedures. However, what are the arguments for doing this and is it necessary? When performing a tympanostomy procedure, otolaryngologists make an incision in the tympanic membrane (TM) and aspirate the middle ear space to remove MEE prior to placing a tympanostomy tube (TT). Aspiration of MEE is easy to perform, especially if the patient is under general anesthesia (GA). But does aspiration of effusion help the patient? Is there additional risk of tube-related complications if aspiration does not occur?

Anatomical Background

The presence of MEE indicates the presence of fluid in the mastoid air cells. Aspiration of the middle ear does not remove all fluid from the temporal bone and fluid will likely remain in the mastoid air cells.

With the passage of time, improved aeration is provided by the TT, which allows fluid to be cleared from the mastoid cavity and the middle ear space. The primary clinical argument for aspirating fluid from the middle ear space at the time of TT placement, besides visualization, is that it could reduce post-procedural TT plugging or early TT extrusion.

Data Analysis

Preceptis Medical reviewed plugging and early extrusion rates with and without aspiration after TT placement with standard surgical instruments under GA (Table 1). Also studied was published Hummingbird (HB) clinical data regarding plugging and extrusion rates using one-pass delivery devices under local anesthesia (Table 2).

Table 1: Literature Data – TT Placement under GA with Standard Instruments

Study	Summary
Youngs, et al., 1988 ¹	53 children (106 ears) with bilateral MEE underwent bilateral TT placement and served as their own control, having one ear randomized to aspiration and the other no aspiration. At 3 months, the plugging rate in the aspirated ears was 13% and the plugging rate in the non-aspirated ears was 7.5%.
McRae, et al., 1989 ²	55 children with bilateral MEE underwent bilateral TT placement and were randomized to aspiration of only their left or right ear. Of these 55, 38 children were available for long-term follow-up. At intervals of 3, 6, 12, 18 and 24 months, there were no statistically significant differences in extrusion between aspirated and non-aspirated ears (p-value range: 0.71 - 1.00).
Dawes, et al., 1991 ³	50 children (100 ears) with bilateral MEE underwent bilateral TT placement and were randomized to aspiration or no aspiration. At follow-up (mean of 19 days with a range of 12 - 74 days), the aspirated group had a plugging rate of 2.3% and the non-aspirated group had a plugging rate of 2.2%.
Egeli, et al., 1998 ⁴	A prospective randomized study investigated if aspiration was necessary. 50 TT placements were performed on 27 patients (24 children). A "suction instrument" was utilized in 24 left ears and was not used in 27 right ears. At 3 months follow-up, the plugging rate in the aspirated group was 4.3% and the plugging rate in the non-aspirated group was 3.7%
Laina, et al., 2006 ⁵	Laina is a meta-analysis from 2006 of data listed on this topic. Of the 7 studies published prior to 2005 on this topic, only 3 studies met the criteria to be included in their analysis. However, the findings concluded there is no evidence that aspiration of the middle ear at time of TT placement results in any clinical improvement for TT blockage.

Table 2: Literature Data and Hummingbird Clinical Study Data – One-Pass Device, In-Office

Study	Summary
Waldman, et al., 2023 ⁶ Lustig, et al., 2020 ⁷	TT placement occurred with the TULA device in-office in 445 ears using iontophoresis with limited suctioning (7.6 - 12.3% of ears). At 3 weeks follow-up, the plugging rate was 5.4% and the early extrusion rate was 0.4%. Waldman did not break out plugging or early extrusion rates between aspirated and non-aspirated ears.
Hummingbird In-Office ⁸	TT placement occurred with the Hummingbird device in-office utilizing local anesthetic in 415 ears. Plugging and early extrusion rates with aspiration of effusion (112 ears) were 3.8% and 4.5%, respectively. For ears not aspirated (303 ears), plugging and early extrusion rates were 8.1% and 1.0%, respectively. Rates observed were at first follow-up at 3 - 10 weeks. Aspiration associated with the Hummingbird device was around or through the tube (excepting mucoid effusion, which was not pulled through the tube).

Discussion

Plugging and early extrusion are known sequelae of TTs. The expected plugging rate is 7% and the expected early extrusion rate is 4%, as reported in the meta-analysis by Isaacson⁹ in *Up to Date*.

The published studies in Table 1 show that aspiration of MEE following myringotomy for TT placement under GA in a predominantly pediatric population did not reduce complications such as plugging or early extrusion. To our knowledge, there are no peer-reviewed publications or unpublished data which demonstrate that aspiration of MEE at the time of TT placement under GA prevents or reduces the rate of plugging or early extrusion.

The studies in Table 2 were conducted in-office in pediatric patients using one-pass surgical devices, which precluded standard aspiration of MEE as the tube was placed in one-pass without a preceding myringotomy incision. In-office one-pass devices also show similar results to Table 1. With limited suction in 7.6 - 12.3% of ears, the plugging and early extrusion rates for the TULA device were not unusual. The Hummingbird device results showed that not aspirating or aspirating MEE around/through the tube ear space yielded tube functionality rates that are comparable to expected rates as reported by Isaacson⁹ in *Up to Date* (7% plugging and 4% early extrusion).

Conclusion

Peer-reviewed literature and Hummingbird device clinical data demonstrate that aspiration of MEE did not significantly affect TT plugging or early extrusion rates for both traditional and one-pass tympanostomy procedures. These analyses affirm the hypothesis that aspiration of MEE is not necessary during TT placement.

References

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