



Complication rates of Reuter Bobbin titanium versus Sheehy Collar Button fluoroplastic tympanostomy tubes in children with otitis media: a retrospective cohort study

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ABSTRACT

Background: Tympanostomy tube (TT) insertion is one of the most common pediatric otologic procedures. This study compares postoperative complications between two commonly used tympanostomy tubes: Reuter Bobbin titanium tubes and Sheehy Collar Button fluoroplastic tubes. **Design:** Retrospective cohort study. **Methods:** The medical records of children aged 6 months to 7 years who underwent TT insertion at a tertiary care center between July 2022 and June 2023 were reviewed. Patients were divided according to the inserted tube model: Reuter Bobbin titanium or Sheehy Collar Button fluoroplastic. The main outcomes were postoperative ear drainage and complications, including tube clogging, granulation tissue formation, premature extrusion, and tympanic membrane perforation, assessed across the first, second, and third follow-up visits. **Results:** A total of 138 patients who underwent TT insertion in 268 ears were included; 181 ears received Sheehy Collar Button fluoroplastic tubes and 87 ears received Reuter Bobbin titanium tubes. At the third follow-up visit (7.46 ± 2.93 months), the overall complication rate was higher in ears with Reuter Bobbin titanium tubes than in those with Sheehy Collar Button fluoroplastic tubes (44.4% vs. 5.6%, $p < 0.001$). Ear drainage was more frequent in the fluoroplastic tube group across follow-up visits (7.2%, 18.4%, and 27.8% vs. 1.1%, 7.4%, and 0%, respectively; $p = 0.054$, $p = 0.12$, and $p < 0.001$). **Conclusion:** In this retrospective cohort, Reuter Bobbin titanium tubes were associated with higher later complication rates, whereas Sheehy Collar Button fluoroplastic tubes were associated with higher postoperative drainage.

KEYWORDS

tympanostomy, pediatric otolaryngology, ventilating tubes, middle ear effusion.

1 Introduction

Acute otitis media is a frequently encountered condition in children, marked by inflammation of the middle ear and often progressing to recurrent infections or persistent middle ear effusion. These complications can negatively affect auditory function and speech development. Tympanostomy tube (TT) placement remains the standard surgical approach for managing recurrent or chronic otitis media with effusion. As one of the most commonly performed pediatric outpatient procedures, TT insertion effectively reduces fluid accumulation in the middle ear, enhances hearing ability, and improves overall quality of life by relieving symptoms and enabling more precise antibiotic delivery when needed (American Academy of Family Physicians et al., 2004; Kong and Coates, 2009).

Despite its advantages, TT insertion carries both short- and long-term risks. Common complications include otorrhea, occurring in 16% of children within the first four weeks, with 7% experiencing recurrent episodes (Kay et al., 2001; Rovers et al., 2005; Browning et al., 2010; Hellström et al., 2011; Rosenfeld et al., 2011, 2022). Additional complications include tube occlusion (7%),

granulation tissue formation (4%), premature extrusion (4%), and, in rare cases, tube displacement into the middle ear (0.5%) (Kay et al., 2001). Long-term tympanic membrane sequelae, such as myringosclerosis, atrophy, and retraction pockets, are frequent but typically resolve without intervention (Kay et al., 2001; Rosenfeld et al., 2011). However, persistent tympanic membrane perforation occurs in 1–6% of cases, often necessitating surgical repair (Browning et al., 2010).

Tympanostomy tubes are manufactured from various materials, with fluoroplastic and stainless steel being the most commonly used due to their biocompatibility and minimal foreign body reactions (Nagar and Deshmukh, 2022). These tubes are broadly categorized into short-term and long-term designs, depending on their intended duration of placement. The most commonly used short-term tympanostomy tubes globally include the Armstrong II, Paparella I, Donaldson, Shepard, Sheehy, and Reuter bobbins. These tubes typically feature a grommet-style design, consisting of two flanges of different sizes connected by a short shaft. While variations in design and material may influence factors such as the likelihood of occlusion, infection risk, duration of tube patency, and the incidence of persistent perforation after the tube falls out,

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no single model has demonstrated clear superiority over the others (Isaacson, 2020).

This study aims to compare complication rates associated with two commonly used tympanostomy tube models: the Reuter Bobbin titanium tube and the Sheehy Collar Button fluoroplastic tube.

2 Materials and Methods

2.1 Study Design

This was a retrospective cohort study conducted to compare complication rates between Reuter Bobbin titanium and Sheehy Collar Button fluoroplastic tympanostomy tubes in children undergoing TT insertion.

2.2 Study Setting and Population

The study reviewed medical records of pediatric patients aged 6 months to 7 years who underwent TT insertion at a tertiary care center between July 2022 and June 2023. Patients were categorized into two groups according to the TT model used: Reuter Bobbin titanium or Sheehy Collar Button fluoroplastic. The comparison of the two tube models is shown in Table 1. Tube insertion was performed for chronic otitis media with effusion lasting more than 3 months or recurrent otitis media, according to the documented surgical indication. None of the operated patients had active middle ear infection at the time of surgery.

2.3 Inclusion and Exclusion Criteria

Children were included in the study if they met the following criteria:

Aged between 6 months and 7 years.

Diagnosed with chronic otitis media (lasting >3 months) or recurrent otitis media.

Presented with reduced quality of life due to otitis media, such as symptoms of ear discomfort, poor school performance, behavioral problems, hearing loss, speech delay, vestibular issues, or other related complications.

Patients were excluded if they had any of the following:

A history of prior tympanic membrane or external ear canal surgery.

Tympanic membrane perforation, myringosclerosis/tympanosclerosis, or external auditory canal stenosis.

2.4 Data Collection and Variables

Medical records were reviewed to extract demographic and

clinical information, including age, sex, diagnosis, and type of TT inserted. Middle ear bacteriology was not included because cultures were not routinely obtained and none of the patients had active infection at the time of the surgery. Outcomes were assessed at three postoperative follow-up visits, reflecting routine surveillance for early, intermediate, and later complications. The primary outcomes included:

Postoperative Ear Drainage: Presence or absence of ear discharge during follow-up visits.

Complications: Incidence of tube clogging, granulation tissue formation, premature extrusion, and tympanic membrane perforation. Other complications were not consistently documented and were therefore not included in comparative analyses.

2.5 Ethical Considerations

This study received ethical approval from the Institutional Review Board of the American University of Beirut Medical Center (IRB ID: BIO-2023-0210). Given the retrospective design of the research, the requirement for informed consent was waived. All patient data were de-identified before analysis to ensure confidentiality and protect patient privacy throughout the study process.

2.6 Statistical Analysis

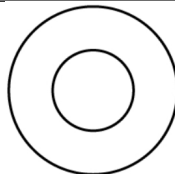
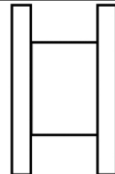
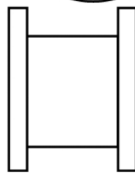
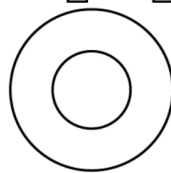
Data analysis was conducted using IBM SPSS Statistics, version 29.0. Descriptive statistics were used to summarize demographic characteristics and clinical outcomes. Group comparisons between ears receiving Sheehy Collar Button fluoroplastic versus Reuter Bobbin titanium tympanostomy tubes were carried out using the chi-square test or Fisher's exact test for categorical variables, and independent t-tests or Mann-Whitney U tests for continuous variables, based on data distribution. Repeated-measures analyses, including generalized estimating equations, and time-to-event analyses, including Cox proportional hazards models, were considered. However, these were not performed because follow-up intervals were not standardized, exact complication onset dates were not consistently available, and some outcome categories had sparse event counts. Therefore, chi-square or Fisher's exact tests were used for visit-specific categorical comparisons. Statistical significance was set at a p-value less than 0.05.

3 Results

3.1 Demographic Data

A total of 138 pediatric patients were included in the study,

Table 1 Comparison of tympanostomy tube model characteristics

Tympanostomy tube type	Material	Inner diameter	Image	
Reuter Bobbin	Titanium	1.14 mm		
Sheehy Collar Button	Fluoroplastic	1.27 mm		

with a total of 268 ears undergoing TT insertion. Of these, 181 ears received Sheehy Collar Button fluoroplastic tubes, and 87 ears received Reuter Bobbin titanium tubes. The mean age of the patients was 3.78 ± 1.5 and 4.11 ± 1.8 years in the fluoroplastic and titanium tube groups, respectively. The cohort comprised more males than females at a ratio of 1.76 and 1.58, respectively. More than 90% of cases were bilateral in both groups. The primary indications included chronic middle ear effusion (55.3% and 61.3%), followed by recurrent otitis media (44.7% and 38.7%). [Table 2](#).

3.2 Outcomes Data

Complications such as clogging and granulation tissue formation were more prominent with Reuter Bobbin titanium tubes. At the third follow-up visit (mean duration: 7.46 ± 2.93 months), the complication rate was significantly higher in ears with Reuter Bobbin titanium tubes (44.4%) compared to ears with Sheehy Collar Button fluoroplastic tubes (5.6%) ($p < 0.001$). The rate of postoperative ear drainage showed an upward trend in ears with Sheehy Collar Button fluoroplastic tubes across all three follow-up visits: 7.2% vs. 1.1% ($p = 0.054$) at the first follow-up visit, 18.4% vs. 7.4% ($p = 0.12$) at the second follow-up visit, and 27.8% vs. 0% ($p < 0.001$) at the third follow-up visit. The overall upward trend in ear drainage rates for fluoroplastic tubes was noted but did not reach statistical significance until the third visit. [Table 3](#). When comparing the rate of complications by etiology, there was no statistically significant difference in the rate of complications if the etiology was chronic middle ear effusion or recurrent otitis media between the Sheehy Collar Button fluoroplastic ($p = 0.481$) and Reuter Bobbin titanium tubes ($p = 0.296$).

4 Discussions

In this retrospective cohort study, the authors compared complication rates between Reuter Bobbin titanium and Sheehy Collar Button fluoroplastic tympanostomy tubes in children aged six

months to seven years. At the third follow-up visit, complications were significantly more frequent in Reuter Bobbin titanium tubes (44.4%) than in Sheehy Collar Button fluoroplastic tubes (5.6%) ($p < 0.001$), including tube clogging, granulation tissue formation, and tympanic membrane perforation among others. However, Sheehy Collar Button fluoroplastic tubes exhibited a progressive increase in ear drainage rates across follow-up visits (7.2%, 18.4%, 27.8%) compared with Reuter Bobbin titanium tubes (1.1%, 7.4%, 0%).

Several studies in the literature have compared different types of ventilating tubes for various reasons, including their complication rates, longevity, biocompatibility, and overall clinical effectiveness. In a 2018 study, Knutsson *et al* investigated how tympanostomy tube characteristics—specifically material (silicone vs. fluoroplastic) and design (short vs. long)—affected clinical outcomes in a cohort of 378 pediatric patients. The findings indicated that short tubes were associated with earlier extrusion compared to long tubes, with Long Armstrong tubes demonstrating the greatest stability. Silicone tubes were linked to a delayed onset of the first infection, and Donaldson tubes exhibited the lowest rate of infections. Notably, infection occurrence did not significantly impact extrusion timing. Additionally, no meaningful differences were found between groups regarding tube occlusion, the need for tube removal, or the incidence of persistent tympanic membrane perforation ([Knutsson et al., 2018](#)).

In a 2019 study, [Kim et al](#) explored how different tympanostomy tube materials influence clinical outcomes such as extrusion duration, tube patency, and the incidence of otorrhea in a cohort of 75 children with bilateral chronic otitis media with effusion. Each participant received a thermoplastic elastomer tube (1.02 mm) in one ear and a silicone tube (1.14 mm) in the other, with follow-up assessments conducted every two months. The results demonstrated that thermoplastic elastomer tubes remained in place significantly longer (mean extrusion time: 10.28 months) than silicone tubes (7.36 months), even though sili-

Table 2 Demographic Data of Study Participants

Demographics	Sheehy Collar Button fluoroplastic tubes (n = 181)	Reuter Bobbin titanium tubes (n = 87)
Number of ears	181	87
Mean age $\pm$ SD (years)	3.78 ± 1.5	4.11 ± 1.8
Male-to-female ratio	1.76	1.58
Bilateral cases (%)	92.6%	97.8%
<i>Primary Indications for TT Insertion</i>		
Chronic middle ear effusion (%)	55.3	61.3
Recurrent otitis media (%)	44.7	38.7

SD: Standard Deviation; TT: Tympanostomy Tube

Table 3 Outcomes Data of Sheehy Collar Button Fluoroplastic vs Reuter Bobbin Titanium Tympanostomy Tubes

Outcome	Sheehy Collar Button fluoroplastic tubes	Reuter Bobbin titanium tubes	p-value
Complication rate at 3rd follow-up	5.6%	44.4%	$< 0.001^*$
<i>Postoperative Ear Drainage Rates</i>			
1st follow-up visit	7.2%	1.1%	0.054
2nd follow-up visit	18.4%	7.4%	0.12
3rd follow-up visit	27.8%	0%	$< 0.001^*$

*: Statistically Significant ($p \leq 0.05$)

cone tubes had a larger inner diameter—a feature typically linked to longer retention. However, the elastomer tubes were associated with a higher frequency of occlusion. These outcomes underscore the role of tube material properties in determining clinical performance and may inform tailored tube selection based on individual patient characteristics (Kim *et al.*, 2019).

In 2022, Alshammari *et al* compared the postoperative outcomes and complication rates between titanium and fluoroplastic ventilation tubes in 34 children with otitis media with effusion. Results showed that early extrusion was the most frequent postoperative complication following TT insertion, particularly in the titanium group. Other early complications, such as transient otorrhea, tube blockage, and recurrent AOM, occurred at lower rates and were similar between groups. The authors concluded that complication rates did not significantly differ between the two types of tympanostomy tubes (Alshammari *et al.*, 2022).

A recent 2024 study by Morissette *et al* examined the clinical performance of four commonly used short-term ventilation tubes in pediatric patients, focusing on rates of otorrhea, tympanic membrane perforation, and extrusion duration. Through a retrospective review of 387 patient charts over a two-year period, the study found that Armstrong beveled tubes were associated with the highest incidence of otorrhea and the longest retention time, averaging 19 months. In contrast, Paparella type-I tubes demonstrated the shortest extrusion time (9 months) and the lowest monthly rate of otorrhea. No statistically significant differences were noted among the tube types with respect to tympanic membrane perforation. The authors concluded that each tube presented distinct advantages and drawbacks, highlighting the importance of selecting ventilation tubes based on patient needs and clinical circumstances (Morissette *et al.*, 2024).

The higher complication rates associated with Reuter Bobbin titanium tubes may be related to material properties, surface characteristics, tube diameter, or tube design. Titanium and fluoroplastic materials may differ in surface texture, debris adhesion, inflammatory response, and biofilm behavior; however, the present study cannot separate the independent effect of material from the effects of lumen diameter and morphology. Surface topography, particularly roughness, has been associated with increased protein adsorption, cell adhesion, and differentiation, all of which may contribute to chronic inflammation (Albrektsson *et al.*, 2018). A study by Huang *et al* examined how macrophage-induced M1 and M2 immune microenvironments influence fibroblast behavior on titanium alloy surfaces, revealing that M1 macrophages promote inflammation, while M2 macrophages enhance fibroblast adhesion, regeneration, and contraction (Huang *et al.*, 2023). Additionally, metals may undergo oxidative surface reactions that can contribute to local inflammatory responses (Klopfleisch and Jung, 2017).

Foreign body response and biofilm formation may also contribute to tube-related complications. Biofilm formation on titanium surfaces is influenced by bacterial adhesion, surface charge, roughness, and composition, with implications for implanted medical devices (Barkarmo *et al.*, 2019; Krsmanovic *et al.*, 2021). A study by Sheikh *et al* demonstrated that foreign body reactions involve monocyte and macrophage adhesion to biomaterial surfaces, leading to multinucleated giant cell formation and potentially compromising device biocompatibility (Sheikh *et al.*, 2015). These mechanisms remain biologically plausible but should be interpreted cautiously in the present study because microbiology and biofilm data were not available.

Tube diameter and design are central potential confounders. In the present study, the Sheehy Collar Button fluoroplastic tube had a larger inner diameter than the Reuter Bobbin titanium tube (1.27 mm vs. 1.14 mm). Larger lumen may facilitate middle ear drainage and reduce occlusion, but it may also increase postoperative otorrhea. Conversely, a smaller lumen may limit drainage and ventilation, thereby increasing susceptibility to clogging. Therefore, the higher drainage rate in the fluoroplastic group and higher clogging/granulation rate in the titanium group may reflect a combined effect of tube material, diameter, and design.

This study has several limitations. Its retrospective design may introduce selection bias and incomplete data collection. Being a single-center study, the findings may not be generalizable to other institutions with differing patient populations or protocols. Follow-up intervals were based on routine clinical practice rather than a standardized study protocol. Middle ear bacteriology was not routinely available, limiting assessment of infection-related contributors to postoperative drainage. Most importantly, the two compared tubes differed simultaneously in material, inner diameter, and design; therefore, the study cannot isolate the effect of material alone. Surgeon preference, baseline disease severity, and other unmeasured confounders may have influenced tube selection and outcomes. Future prospective studies comparing tubes with similar designs and diameters are needed to better isolate the contribution of material to postoperative outcomes. Because outcomes were analyzed at each follow-up visit separately, within-ear temporal correlation was not fully accounted for. Future prospective studies with standardized follow-up and precise event timing should consider GEE or Cox proportional hazards models.

5 Conclusion

Reuter Bobbin titanium tubes were associated with higher later complication rates, particularly clogging and granulation tissue formation, whereas Sheehy Collar Button fluoroplastic tubes were associated with higher postoperative drainage. Because the two models differ in material, inner diameter, and design, these findings should be interpreted as model-specific associations rather than evidence of an isolated material effect. Prospective studies with standardized follow-up and matched tube dimensions are needed to confirm these findings.

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Data Availability Statement

The data that support the findings of this study are available upon request from the corresponding author.

Ethical Approval

This study received ethical approval from the Institutional Review Board of the American University of Beirut Medical Center (IRB ID: BIO-2023-0210).

Informed Consent Statement

Patient consent was waived due to the retrospective nature of this chart review study.

Conflicts of Interest

The authors have no competing interests to declare that are relevant to the content of this article.

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