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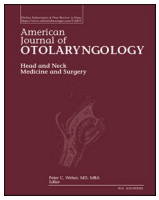

A novel autoinflation device for persistent pediatric otitis media with effusion: A prospective single-arm cohort study

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ABSTRACT

Background: Autoinflation is a non-surgical option for pediatric otitis media with effusion (OME), but existing devices are limited to children ≥4 years and lack objective adherence confirmation. EarFlo® is a novel prototype autoinflation device designed for younger children with built-in objective treatment detection.
Design: Prospective single-arm cohort study.
Setting: Single pediatric otolaryngology practice, Western Australia.
Participants: Children aged 1–12 years with persistent OME after ≥3 months of watchful waiting, assessed for tympanostomy tube placement.
Intervention: Four weeks of twice-daily home use of EarFlo® (10 successful treatments per session), followed by 8 weeks of observation without device use.
Primary outcomes: Within-patient serial tympanometric and audiometric changes over 12 weeks.
Results: 18 participants completed the study (median age 6 years, range 2–11; 22% < 4 years). Objectively measured adherence was 99% (median). Mean pure tone average (PTA) in ears with baseline hearing loss improved by 12.9 dB HL (95% CI: 7.8 to 17.9) at 2 weeks and 9.7 dB HL (95% CI: 3.7 to 15.7) at 4 weeks in adjusted analyses. Tympanometric improvement was observed in 91% of ears during active device use; 35% (95% CI: [19.7% to 53.5%]) exhibited sustained improvement at final follow-up. 89% of participants (16/18) were not recommended for tympanostomy tube surgery during the observed follow-up period. No adverse events were recorded.
Conclusions: In children with persistent OME meeting criteria for surgical intervention, EarFlo® demonstrated high objective adherence, no adverse events, and clinically meaningful within-patient tympanometric and audiometric improvements. These findings support further evaluation in randomized controlled trials.
This trial is registered with the Australian New Zealand Clinical Trials Registry (ANZCTR12621000949886; registered 15 April 2024, prior to first enrollment in May 2024).

1. Introduction

Otitis media with effusion (OME) is defined as unresolved fluid accumulation in the middle ear following an acute otitis media, without symptomatology of acute infection. It is the most common cause of hearing loss in children with approximately 2.2 million cases diagnosed annually in the United States [1,2]. OME persists for 3 months or longer in up to 25% of cases following acute otitis media, and in up to 44% of spontaneous cases with unknown onset [1,3]. As such, the current American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS) guidelines recommend a period of "Watchful Waiting" of 3 months for pediatric OME patients who are not at increased risk for speech, language, or learning problems, after which tympanostomy tube placement is typically recommended [1,4]. Of note, the AAO-HNS guidelines strongly recommend against using intranasal or systemic steroids, systemic antibiotics, antihistamines, and decongestants for

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treatment of OME [1]. Untreated, chronic OME may lead to chronic conductive hearing loss and reduced vestibular function, which may negatively impact speech and language development, behavior, and quality of life [1,4–6].

OME is the leading indication for tympanostomy tube placement [1]. Though commonly performed and minimally invasive, tympanostomy tube placement is not without risks, including tympanostomy tube otorrhea, persistent tympanic membrane perforation, iatrogenic cholesteatoma, and the need for general anesthesia [1,4]. Patients in limited resource environments or with lower socioeconomic status may also experience prolonged surgical wait times [7]. There are few nonsurgical interventions available for the management of pediatric OME, which rely on either the Valsalva maneuver or the Politzer method. Devices such as EarPopper® and Otovent® have demonstrated good efficacy in improving hearing outcomes and reducing the need for tympanostomy tube surgery in older pediatric patients [8–14]. However, a significant limitation of these devices is decreased treatment adherence in the younger pediatric population due to difficulty with treatment administration [8,9]. This limits their usability to children aged 4 years or above [8,9], though OME and tympanostomy tube surgery are most prevalent in the younger pediatric population below 4 years of age [4,15]. These devices also do not provide confirmation that therapy is delivered to the patient. Furthermore, existing prospective autoinflation studies have predominantly enrolled children aged 4 years and older, leaving a gap in clinical outcome and adherence data for the age group with the highest OME burden and tympanostomy tube utilization rates.

A novel prototype autoinflation device called EarFlo® provides a non-invasive option specifically designed to address usability and adherence limitations in younger children with persistent OME. Our pilot feasibility study demonstrated encouraging short-term tympanometric and audiometric signals, successful use in children as young as 2 years, and objective confirmation of treatment delivery [16]. Autoinflation is an established non-surgical strategy for pediatric OME, yet the existing evidence base is largely restricted to children aged 4 years and older, despite the highest OME incidence and tympanostomy tube utilization occurring in children aged 2 to 4 years. Additionally, prior devices have been limited by adherence challenges and the inability to objectively confirm treatment delivery. The present prospective single-arm cohort study provides longitudinal tympanometric and audiometric outcome data, objectively measured adherence, and usability information in a clinically relevant population: children with persistent OME after at least 3 months of watchful waiting who were already being assessed for surgical intervention.

This trial is registered with the Australian New Zealand Clinical Trials Registry (ANZCTR12621000949886; registered 15 April 2024, prior to first enrollment in May 2024).

2. Methods

2.1. Study design

This prospective single-arm cohort study was conducted from May 2024 to January 2025. The study was approved by the Curtin University Human Research Ethics Committee (HREC; protocol number HRE2020-0526). Written informed consent was obtained from the parents or legal guardians of all participants prior to enrollment. HREC approved that parental consent was obtained for all children in lieu of child assent. No identifiable patient information is reported in this manuscript.

Participants were recruited from a single Pediatric Otolaryngology practice (Paediatric ENT Services clinic, Western Australia), where they were assessed by a Pediatric Otolaryngologist for potential tympanostomy tube placement after referral from a Family Medicine provider due to unresolved OME following at least 3 months of “Watchful Waiting.” This study was designed to describe serial within-patient clinical outcome changes and objectively measured adherence in this persistent OME cohort and was not designed to estimate comparative efficacy against spontaneous resolution or standard care. No compensation or reimbursement was provided to participants or their families for participation. Inclusion criteria were children aged 1 to 12 years, with a confirmed diagnosis of OME by otoscopic examination by a Pediatric Otolaryngologist, and either a type B (flat) or C (negative pressure) tympanogram in at least one ear. Exclusion criteria included children with craniofacial abnormalities, current upper respiratory or middle ear infections, existing tympanostomy tubes, velopharyngeal insufficiency or known swallowing dysfunction. Children were excluded if they were unable to demonstrate correct device usage following a short period of training with the research assistant.

No preoperative medical treatment was administered as part of the study protocol, consistent with AAO-HNS guidelines that strongly recommend against intranasal steroids, systemic antibiotics, antihistamines, and decongestants for OME [1]. Nasal suctioning was not performed.

2.2. Autoinflation device

A novel prototype autoinflation device (Earflo®; Model EF001, Device firmware v0.8.9, Clinical trial app v0.13.6) was used, as described in our pilot study (Fig. 1) [16]. EarFlo® is a registered trademark of Earflo Inc. The device was used under investigational conditions, approved for research use by the Curtin University HREC (HRE2020-0526) and under the Therapeutic Goods Administration (TGA) Clinical Trial Notification (CTN) Scheme (CT-2020-CTN-04380-1). The device design resembles a drinking cup featuring a nasal mask, which tightly seals the patient's nose when drinking through the spout. A pressure sensor within the device detects when the patient's soft palate retracts during the oropharyngeal swallow phase. Soft palate retraction during swallowing transiently opens the Eustachian tube, creating a window for pressurized air to enter the middle ear space. In coordination with this, the device delivers a controlled puff of air into the nasal cavity via a micro-controlled air pump with a set-point of 1 psi (approximately 69 daPa). The 1 psi set-point was selected based on bench testing and the physiologic safety data reported in our pilot study [16]. LED lights at the device base turn green when a successful treatment ($>$0.5 psi for $>$100 ms) is delivered.

The companion application (EarFlo Clinical Trial v0.13.6) stores de-identified treatment data locally on the user's device and on a secure cloud platform (Firebase). Transmitted data is limited to device Bluetooth MAC address, pressure measurements, and timestamps, with no patient-identifiable information collected or linked to device logs, consistent with the Australian Privacy Principles (Privacy Act 1988). The application also includes a rocket ship game interface that rewards correct device use to improve compliance.

2.3. Data collection

During enrollment, baseline audiometry and tympanometry assessments were performed. All audiometric testing was conducted using age-appropriate behavioral audiometry techniques: visual reinforcement audiometry for the youngest children, conditioned play audiometry for children aged approximately 2.5 to 5 years, and conventional pure tone audiometry for older children, all performed and interpreted by a credentialed audiologist. Ear-specific thresholds were obtained for all 18 analyzed participants. Following baseline assessments, patient families were instructed on how to use the device and companion phone application, and participants completed an in-clinic treatment training session, defined by five successful administrations of the controlled puff of air. Tympanometry was repeated immediately after the training session to assess for any acute tympanometric shift following supervised device use. Of 32 ears with available post-training tympanograms (2 ears excluded due to missing post-training measurements), 15 ears (46.9%; 95% CI: 29.1% to 65.3%) demonstrated a tympanogram shift, defined as conversion from type B to A, type B to C, type C to A, or

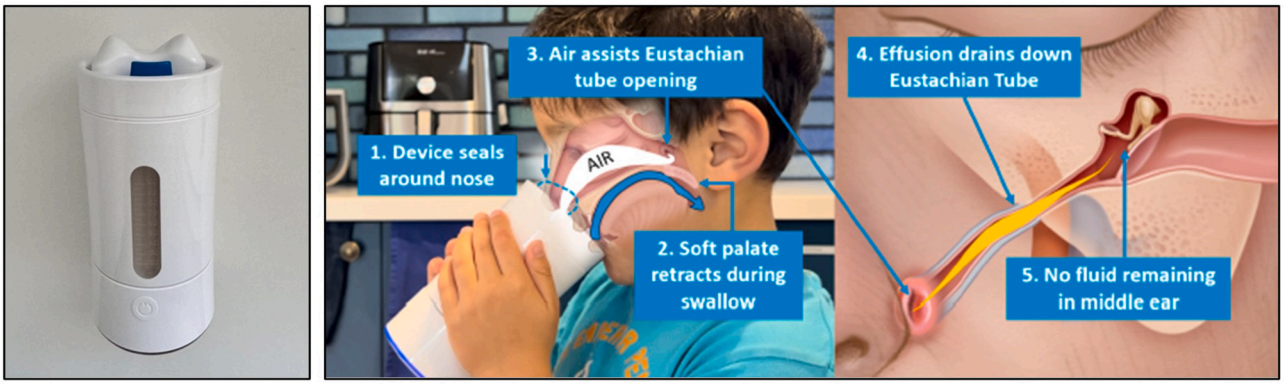

Fig. 1. Prototype device used in the study. (a) The prototype device. (b) Mechanism of action of prototype device (illustration by Chris Gralapp) [16,21].

improvement of ≥50 daPa in mean ear pressure within type C tympanograms. Of the 15 ears demonstrating a shift, 8 converted from type C to type A, 4 converted from type B to type C, and 3 type C ears showed ≥50 daPa MEP improvement without changing type. No ears converted directly from type B to type A in the single training session. This finding demonstrates that the device can acutely inflate the middle ear with supervised in-clinic use.

Families were then instructed to use the device at home for 4 weeks, completing 2 sessions per day (10 successful treatments daily). Device use was discontinued at the 4-week timepoint, with no treatments performed between 4 and 12 weeks. Follow-up visits occurred at 2, 4, 8, and 12 weeks, with tympanometry performed at all visits. Tympanograms were classified using the modified Jerger classification, with a type A tympanogram defined by a peak within ±100 daPa, a type C tympanogram by a peak below −100 daPa, and a type B tympanogram by the absence of a peak [17]. Middle ear pressure (MEP) was also recorded.

Audiometric testing was repeated at the 2-week and 4-week follow-up visits. Audiometric assessment was not performed beyond the 4-week timepoint; the durability of hearing improvements beyond the active treatment period therefore could not be assessed and is acknowledged as a limitation of this study. Pure tone averages (PTA) were calculated by averaging the thresholds in decibels hearing loss (dB HL) for the 500, 1000, 2000, and 4000 Hz frequencies. Normal hearing was defined as PTA ≤ 20 dB HL, according to the AAO-HNS classification [1]. Upper respiratory infection (URI) symptoms were recorded by self-report from parents or legal guardians at each follow-up visit using a standardized yes/no question regarding the presence of cold, nasal congestion, or respiratory symptoms since the last visit. URI status was treated as a time-varying covariate in adjusted analyses.

To mitigate potential bias arising from author financial interests in the device, all audiometric and tympanometric assessments were performed and interpreted by an independent credentialed audiologist with no financial interest in EarFlo®. Decisions regarding tympanostomy tube referral were made by the treating Pediatric Otolaryngologist, independent of the device inventors. Data collection and analysis were performed by study research personnel without financial stake in the outcomes.

2.4. Outcomes

The primary outcome measures were within-patient serial tympanometric and audiometric changes over the study period. Secondary outcomes included objectively measured device adherence and the proportion of participants not recommended for tympanostomy tube surgery during the follow-up period. For tympanometry, participant ears were categorized into 5 subgroups with the following definitions:

1. **Sustained improvement:** ears with a change from an initial type B or C tympanogram to a type A, OR from a type B to a type C, OR improvement of 50 daPa or greater in MEP in a type C tympanogram at week 4, maintained at final follow-up.
2. **Transient improvement during treatment:** ears that met criteria for the Sustained Improvement subgroup after initial device use or at week 2, but no longer met Sustained Improvement criteria at week 4 (end of treatment time point).
3. **Improvement with post-treatment relapse:** ears meeting criteria for sustained improvement at week 4, but not at final follow-up after device cessation.
4. **No improvement:** ears with no change in tympanometry outcomes from baseline through the study period of up to 12 weeks.
5. **Worsened:** ears with a shift from type A or C tympanogram to type B, OR a shift from type A to type C, OR worsening of greater than or equal to 50 daPa in MEP in a type C tympanogram from baseline compared to the final follow up.

Ears with baseline type A tympanograms were excluded.

For audiometry, improvement was defined as a change in PTA of 10 dB HL or greater [18], OR a shift into the normal hearing range (PTA 20 dB HL or better), consistent with AAO-HNS criteria [1,4]. Participant ears with baseline hearing loss were categorized into 5 subgroups with the following definitions:

1. **Early improvement:** ears with an improvement by week 2 which maintained improved at week 4 compared to baseline.
2. **Late improvement:** ears with no improvement by week 2 but an improvement by week 4 compared to baseline.
3. **Transient improvement during treatment:** ears with improvement in PTA by week 2 that no longer met the improvement criteria by week 4.
4. **No improvement:** ears without any improvement by the above criteria.
5. **Worsened:** ears with worsening in the PTA by 10 dB HL by week 4.

Ears with normal baseline hearing were excluded.

Treatment compliance was defined by the number of successful treatments over the recommended total number of treatments during the 4-week study period. Compliance was recorded as an overall measurement of adherence to the treatment throughout the 4-week study period.

2.5. Statistical analysis

All analyses were conducted using STATA 18. All statistical tests were two-sided with a significance threshold of p less than 0.05. Descriptive statistics were performed for baseline data. Because many

participants contributed data from both ears, ear-level analyses account for within-subject correlation: mixed-effects or generalized estimating equation (GEE) approaches were used where appropriate to handle bilateral non-independence. For tympanometry outcomes, bivariate analysis was performed using Chi-square, Kruskal-Wallis, and ANOVA tests as appropriate; multinomial logistic regression was used to evaluate the impact of covariates on tympanometry subgroup classification. For audiometry outcomes, bivariate analysis used *t*-tests and linear regression; a mixed-effects regression model was used to evaluate longitudinal change in PTA, adjusting for sex (parent reported), presence of illness, device compliance, and tympanogram type. Effect estimates are reported with 95% confidence intervals (CIs) for key outcomes. Missing data from withdrawals (3 of 21 participants) were handled by complete-case analysis, as all withdrawn participants exited prior to any post-baseline assessment. Participants who reported URI symptoms were retained in all analyses, with illness included as a time-varying covariate.

3. Results

3.1. Demographics

The timeline of study enrollment, participation, and data collection is summarized in Fig. 2. Twenty-one participants were enrolled. Three participants (aged 2 years, $n = 1$; aged 4 years, $n = 2$) withdrew because they were unable to use the device correctly following the training session, despite completing the session. A total of 18 participants were included in the analysis (5 females, 28%; median age 6 years, range 2 to 11 years) (Table 1). Of 34 analyzed ears, 47% had type B tympanograms ($n = 16$) and 53% had type C tympanograms ($n = 18$) at baseline. URI symptoms were reported by parents at one or more follow-up visits in up to 44% of participants. Objectively measured device compliance was 99% (median; mean 94%). All 18 participants enrolled in the treatment period were monitored for adverse events at every follow-up visit across the 4-week treatment period and through the 12-week follow up, with monitoring continuing for as long as each participant remained in the study. No adverse events (including ear pain, otorrhea, epistaxis, dizziness, or barotrauma) were reported in any participant across 57 total person-weeks of device use.

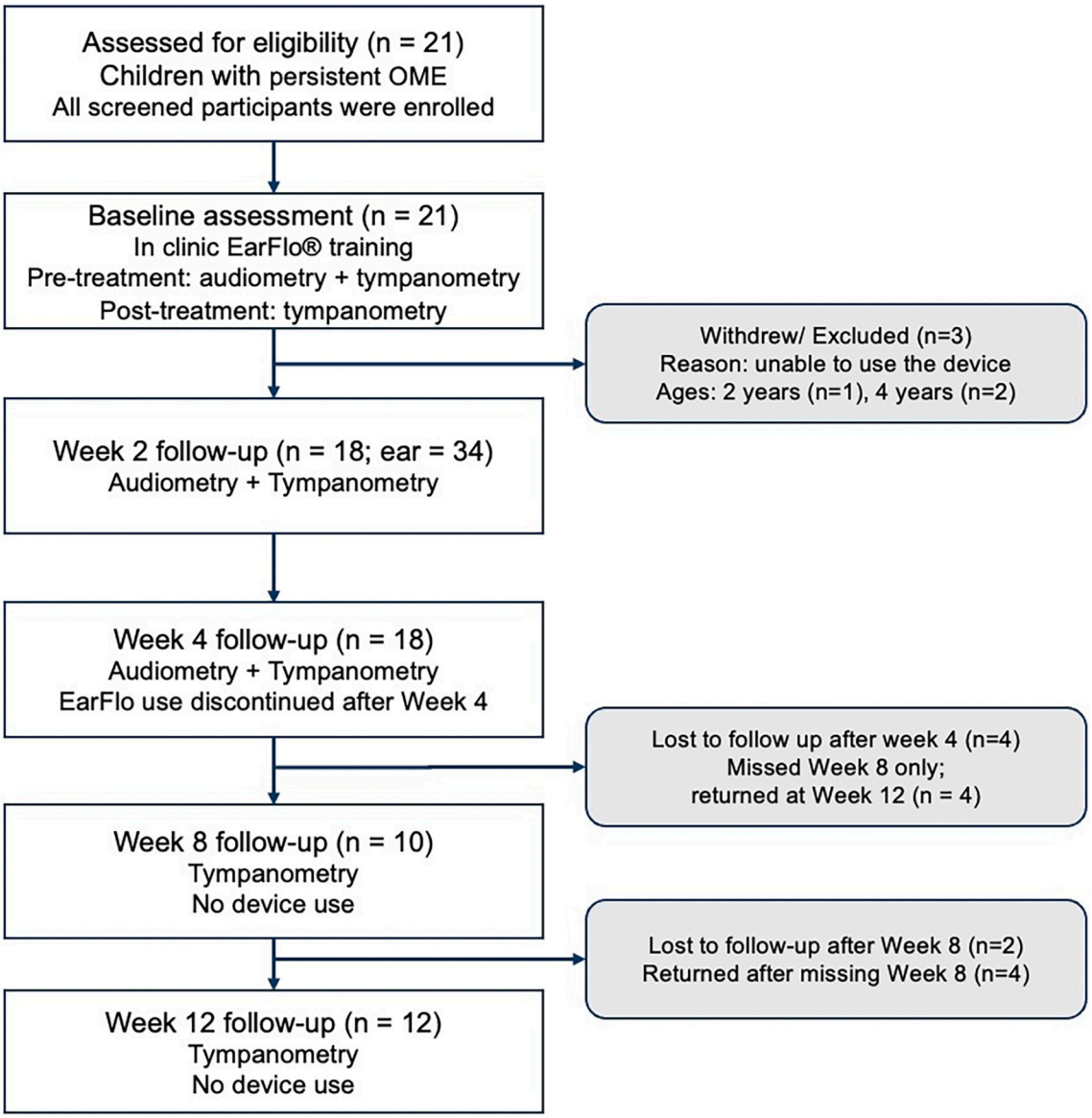

Fig. 2. Enrollment and data collection flow diagram.

Table 1
Descriptive statistics ($n = 18$).

Variables	n (%)
Age (years)	
2–4	4 (22.2)
5–8	12 (66.7)
9–11	2 (11.1)
Sex	
Male	13 (72.2)
Female	5 (27.8)
Compliance	
Overall (Median (IQR))	98.6 (35)

IQR: Interquartile Range.

3.2. Tympanometry results

Tympanometry results by ear are summarized in Table 2. Overall, 91% of ears demonstrated at least initial tympanometric improvement during the 4 weeks of active device use. 35% of ears (12/34; 95% CI: [19.7% to 53.5%]) demonstrated sustained tympanometric improvement at final follow-up. 9% of ears (3/34; 95% CI: [1.9% to 23.7%]) showed no change or worsening in tympanometry outcomes across the study period. These patterns were observed in children who had already undergone at least 3 months of watchful waiting without resolution, providing context for interpreting the within-patient changes.

Tympanometry results by participant are summarized in Table 2. Participants were classified as achieving sustained improvement if either ear converted from type B to type A or C, or from type C to type A. Participants were classified as achieving partial improvement if either ear demonstrated transient improvement during treatment, improvement with post-treatment relapse, or a 50 daPa or greater MEP improvement in a type C tympanogram. All 18 participants demonstrated either sustained or partial improvement (Table 2).

Multinomial logistic regression analysis was used to assess the impact of covariates on tympanometry outcome subgroup classification. Age, sex, device compliance, presence of illness, and ear laterality did not significantly affect the risk of being in the tympanometric type B vs. type A or type C vs. type A subgroups (Supplementary Table 1).

3.3. Audiometric results

The distribution in PTA over time in 17 participant ears with baseline hearing loss is shown in Fig. 3. The baseline PTA of all ears with hearing loss was 29.6 dB HL (median 27.5 dB HL). After 2 weeks of device use, mean PTA improved to 15.4 dB HL (median 15.0 dB HL); after 4 weeks of device use, mean PTA was 19.0 dB HL (median 16.3 dB HL). In adjusted analyses (Supplementary Table 2), the mean PTA improvement was 12.9 dB HL (95% CI: 7.8 to 17.9; $p < 0.001$) at 2 weeks and 9.7 dB HL (95% CI: 3.7 to 15.7; $p = 0.002$) at 4 weeks.

Table 2
Tympanometry outcomes.

Outcome	n (%)
Outcomes by Ear ($n = 34$ ears)	
Improvement Observed	
Sustained improvement	12 (35.3)
Transient improvement during treatment	10 (29.4)
Improvement with post-treatment relapse	9 (26.5)
No Improvement Observed	
No improvement	2 (5.9)
Worsened	1 (2.9)
Outcomes by Participant (n = 18)	
Complete Improvement	10 (55.6)
Partial improvement	8 (44.4)

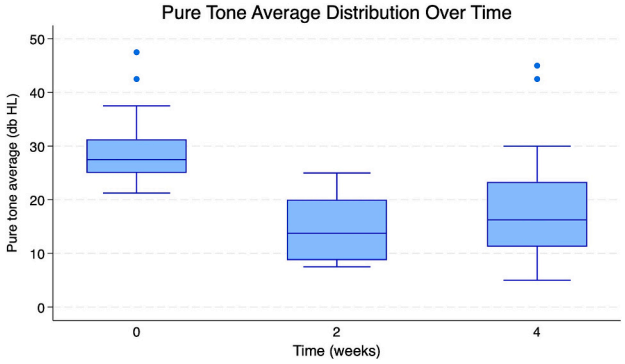

Fig. 3. Boxplot showing distribution of pure tone average over time.

Audiometry results by subgroup classification are summarized in Table 3. Overall, 94% of ears with baseline hearing loss (16/17; 95% CI: [71.3% to 99.8%]) demonstrated PTA improvement at either the 2-week or 4-week timepoint during active device use. Of these, 58.8% of ears had improvement in PTA that persisted throughout the period of device use. The remaining 6% of ears (1/17) showed no improvement or worsening in PTA.

Mixed-effects regression analysis was used to assess the impact of covariates on change in PTA. Age, sex, device compliance, presence of illness, tympanogram type at baseline, and tympanometry outcome subgroup classification did not significantly affect audiometric outcome subgroup classification (Supplementary Table 2).

Of the 18 participants who completed 4 weeks of device use, 16 (89%) were not recommended tympanostomy tube surgery at any point during the observed follow-up period; 2 (11%) were referred for surgery based on insufficient clinical improvement.

4. Discussion

In this cohort, tympanometric improvement was observed in most participants during active device use. A subset demonstrated sustained improvement through final follow-up, while others showed transient improvement with relapse either during the treatment period or after cessation of device use. Thirty-five percent of ears demonstrated sustained improvement at final follow-up. For context, this exceeds the reported 19% spontaneous resolution rate of chronic OME at 3 months in a broadly comparable population [3], though direct comparison is limited by differences in study design, population, and outcome definitions. This pattern is clinically informative: it suggests that some children may achieve durable benefit from a defined treatment course, whereas others may require extended treatment duration, a repeat course, or ultimately surgical intervention. The serial within-patient measurements, initiated immediately after supervised first use and continuing through active treatment and short-term follow-up, provide clinically useful data on response temporality and patterns in a population already being assessed for surgery.

Audiometric results were encouraging. In within-patient adjusted

Table 3
Audiometric outcomes by ear ($n = 17$).

Outcome	n (%)
Improvement Observed	
Early improvement	10 (58.8)
Late improvement	1 (5.9)
Transient improvement during treatment	5 (29.4)
No Improvement Observed	
No improvement	0 (0.0)
Worsened	1 (5.9)

analyses, mean PTA in ears with baseline hearing loss improved by 12.9 dB HL (95% CI: 7.8 to 17.9) at 2 weeks and by 9.7 dB HL (95% CI: 3.7 to 15.7) at 4 weeks of device use. The magnitude of within-patient hearing improvement observed here is contextually similar to the hearing gains associated with tympanostomy tubes, as reported in a Cochrane meta-analysis (5.2 dB HL) and AAO-HNS guidelines (5 to 12 dB HL) [4,19] though direct comparative efficacy cannot be inferred from a single-arm study. These within-patient hearing improvements are contextually notable given that tympanostomy tubes carry risks including the need for general anesthesia, otorrhea, and access delays [4,7]. These results are similar to audiometric outcomes from the EarPopper®, which showed hearing improvement of 10.9 dB HL after 7 weeks in a randomized trial of children aged 4 years and older [8], though differences in design, follow-up, and population preclude direct comparison. The early hearing improvement observed at 2 weeks, prior to completion of the full treatment course, is notable and warrants further investigation regarding optimal treatment duration. Audiometric relapse occurred in 29% of ears during the treatment period, suggesting that extended treatment duration may be required in select patients.

The tympanometry and audiometry outcomes are particularly notable given the high incidence of URI symptoms during the study. As shown in Figs. 4 and 5, illness status was not significantly associated with audiometry outcomes, but it was significantly associated with tympanometry outcomes. Specifically, participants with concurrent illness showed less improvement in MEP by weeks 2 and 4 compared to those without illness, supporting a role for extended or repeated treatment in children who experience a URI while using the device. In contrast, audiometric improvements from device use occurred even in the context of illness. Both tympanometry and audiometry outcome improvements were also independent of patient demographics (age and sex).

A particular strength of this cohort is the inclusion of children younger than 4 years, with 22% of participants in this age group and the youngest successfully treated participant aged 2 years. No statistically significant age-based differences were observed in tympanometry or audiometry subgroup outcomes. Despite the young age of our cohort, compliance was excellent, with a median of 99%, as measured objectively via the device's pressure sensor. This exceeds reported compliance for the EarPopper® (94%) and Otovent® (80–89%), which were based on self-reported data and included only children aged ≥4 years [8,9]. Moreover, a recent study using the EarPopper® reported that up to 19% of participants were unable to use the device secondary to crying, pain, “ear swelling,” and “recurrent ear inflammation” [20]. EarFlo® adds prospective clinical outcome and objective adherence data in children under 4 years, a group largely excluded from prior autoinflation studies, and no adverse events were reported in this cohort. Audiometric testing in the youngest participants (aged 2 to 4 years) was performed using age-appropriate behavioral techniques (visual reinforcement or conditioned play audiometry), as is standard practice; all included participants yielded ear-specific audiometric data. The reliability of behavioral audiometry in this age group is well established when administered by a credentialed audiologist, as was the case in this study.

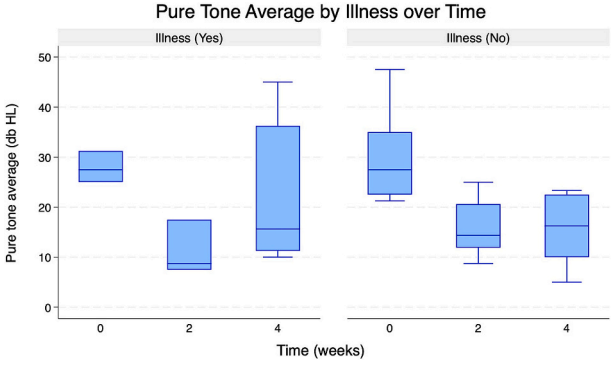

Fig. 4. Boxplot showing distribution of pure tone average by illness over time.

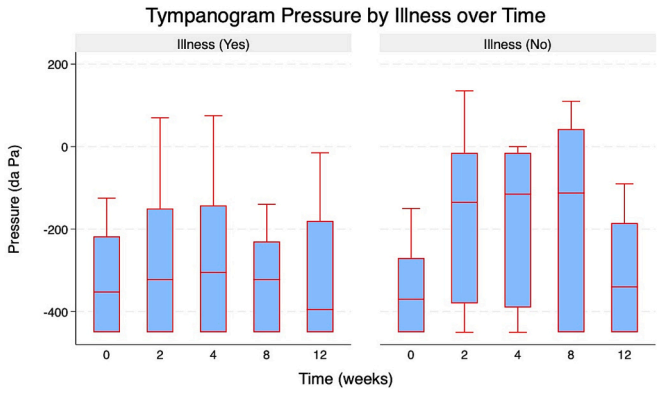

Fig. 5. Boxplot showing distribution of tympanogram pressure by illness over time.

It is important to acknowledge that the 3 participants who withdrew (14% of those enrolled) did so because they were unable to use the device correctly despite training. This introduces a selection effect toward participants with sufficient developmental readiness and cooperation to use the device, which may limit generalizability to the full population of children presenting with persistent OME in this age range. Training requirements and participant selection should be explicitly addressed in the design of future trials. Additionally, this study did not systematically assess for adenoid hypertrophy or inferior turbinate hypertrophy, which may reduce nasal airway patency and limit the ability of pressurized air to reach the Eustachian tube orifice. Future studies should consider these anatomical factors as potential effect modifiers.

At final follow-up, 16 of 18 participants (89%) who completed the 4-week device use period were not recommended tympanostomy tube surgery during the observed follow-up period. This is an encouraging management outcome in a cohort that had already met AAO-HNS criteria for surgical intervention at enrollment. For context, this compares favorably with the 53% surgery avoidance rate reported after 7 weeks of EarPopper® use [8], though surgical referral decisions were made by the treating clinician and influenced by multiple factors including parental preference and cannot be attributed to device efficacy alone. While the absence of a control group means this finding cannot be attributed to device use alone, the observed rate compares favorably against historical surgical progression rates in comparable persistent OME populations. This supports the feasibility of EarFlo® as a management option during the watchful-waiting period and provides a strong rationale for future randomized trials.

This study has several limitations. First, its single-arm design precludes direct causal attribution of improvement to device use in a condition with a well-described natural history, though the observed improvement rates substantially exceed published historical spontaneous resolution rates. Second, the sample size was relatively small and derived from a single specialty practice, which may limit generalizability. Third, follow-up was limited to 12 weeks, and audiometric assessment was not performed beyond the 4-week timepoint, limiting conclusions about the durability of hearing improvements. Future studies should include audiometric follow-up beyond the treatment period. Fourth, the study did not assess effusion resolution directly (e.g., through otomicroscopy or imaging); tympanometric normalization and surgery avoidance were used as proxies, and these outcomes may be influenced by factors other than device efficacy, including spontaneous resolution and parental preference around surgical referral. Fifth, the absence of a comparator group limits causal inference, and future randomized controlled trials comparing EarFlo® with continued observation or other non-surgical management strategies are warranted to establish efficacy definitively.

5. Conclusion

In a prospective single-arm cohort of children with persistent OME after at least 3 months of watchful waiting, including children as young as 2 years, EarFlo® was associated with high objectively measured adherence, no adverse events, and clinically meaningful within-patient tympanometric and audiometric improvements. For context, improvement rates substantially exceeded published historical spontaneous resolution rates, though causal attribution is not possible in the absence of a control group. Response patterns varied across participants, suggesting that individualized treatment duration may be important. These findings support further randomized evaluation of EarFlo® as a non-surgical management option during the watchful-waiting period.

CRediT authorship contribution statement

Nanki Hura: Writing – original draft, Formal analysis. **Maria-Jose Soto:** Methodology, Investigation, Data curation. **Zarna Lalwani:** Writing – original draft, Formal analysis, Data curation. **Intan Oldakowska:** Supervision, Formal analysis, Conceptualization. **Matthew Oldakowski:** Writing – original draft, Methodology, Formal analysis, Data curation, Conceptualization. **Paul Bumbak:** Writing – review & editing, Supervision, Methodology, Investigation. **Peter L. Santa Maria:** Writing – review & editing, Validation, Supervision, Project administration, Methodology, Investigation, Formal analysis, Conceptualization.

Ethics statement

This study was approved by the Curtin University Human Research Ethics Committee (protocol number HRE2020-0526). Written informed consent was obtained from the parents or legal guardians of all participants. HREC approved that parental consent was obtained for all children in lieu of child assent. No identifiable patient information is reported in this manuscript.

Trial registration

This trial is registered with the Australian New Zealand Clinical Trials Registry (ANZCTR12621000949886; registered 15 April 2024, prior to first enrollment in May 2024).

Declaration of Generative AI and AI-assisted technologies in the writing process

During the preparation of this work, the authors used ChatGPT and Claude to help refine phrasing and improve manuscript readability. After using this tool/service, the authors reviewed and edited the content as needed and take full responsibility for the content of the published article.

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Declaration of competing interest

P.L. Santa Maria, I. Oldakowska, and M. Oldakowski are co-inventors of EarFlo® and hold equity interest in the device. M.-J. Soto is an employee of the EarFlo® company. All other authors declare no competing interests.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.amjoto.2026.104862.

Data availability

De-identified aggregated data and analysis code are available from the corresponding author on reasonable request. Individual-level device log data cannot be shared due to privacy and proprietary constraints.

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