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Original Article

Phase 1 Evaluation of a Novel Otoscope Tip Aimed at Improving Pediatric Otoscopy Visualization and Cerumen Management: The Otoshow

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ABSTRACT

Aim: Cerumen is a common barrier to accurate otoscopic examinations in children, yet pediatricians lack effective removal tools. The Otoshow is a novel otoscope speculum with a retractable curette attachment designed to address this gap. This study aimed to characterize cerumen impaction as a barrier to tympanic membrane (TM) visualization and to evaluate the safety, effectiveness, and clinician satisfaction of the Otoshow.

Materials and Methods: A prospective, non-randomized, survey-based, phase 1 study was conducted in two pediatric otolaryngology clinics from March to May 2025. Five Advanced Practice Providers (APPs) used the Otoshow tip during clinic encounters, replacing or supplementing standard specula and cerumen removal tools at their discretion. The data consisted of clinician surveys including pre-study, per-encounter, and post-study surveys.

Results: A total of 101 encounters were surveyed. The children ranged in age from 6 months to 17 years, with 80% aged 1-10 years. The pre-survey showed all clinicians encountered cerumen at least occasionally, and none were very satisfied with current removal methods. Per-encounter surveys showed cerumen obstructed the TM in 29% of the children and 33% with ear-related complaints. The Otoshow curette was used in 72% of obstruction cases, improving TM visualization in 43%. The APPs were satisfied with its use in 34% of encounters. In the post-study survey, the Otoshow was rated as equally safe or safer, more time-efficient, and more comfortable than the standard methods. No device-related adverse events occurred.

Conclusion: Cerumen is a significant barrier to TM visualization in children. The Otoshow otoscope tip demonstrated safety, feasibility, and the potential to improve visualization and child comfort without prolonging procedure times. While satisfaction with the device was modest, iterative design enhancements may increase clinical adoption. Future studies are warranted to assess the device's impact in primary care and emergency settings where cerumen impaction poses an equal or greater diagnostic challenge.

Keywords: Pediatrics, otoscopy, cerumen managment, otitis media

Introduction

Cerumen is a frequent and often overlooked impediment to an efficient otoscopic exam in children, particularly for acute otitis media (AOM). In the emergency department, AOM is the second most common pediatric diagnosis after upper respiratory infection, with 80% of children experiencing an episode of AOM by the age of three years (1,2). Additionally, there are approximately 30 million

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visits related to AOM in the United States each year (1,2). According to the American Academy of Pediatrics, pediatricians must clearly visualize the tympanic membrane (TM) to evaluate for bulging, otorrhea, or erythema in order to make a diagnosis of AOM (3). In routine clinical practice, pediatricians and urgent care practitioners encounter obstacles performing an adequate examination of the TM due to complete or partial obstruction by cerumen impaction, leading to diagnostic ambiguity and potentially unnecessary antibiotic prescription (3,4-10).

Studies have shown that physicians are uncertain of AOM diagnosis in up to 40% of cases, yet still prescribe antibiotics in 75% of instances when the perceived probability of an ear infection is 50% or lower (2). This practice of overdiagnosis can lead to increased adverse drug reactions, rising antibiotic resistance, and unnecessary surgical interventions such as tympanostomy tube placement (4). The non-specific symptoms of AOM in children, such as fever and irritability, occur in approximately 72% of children without AOM, which further complicates the diagnostic process and increases reliance on accurate physical exam findings (2). When cerumen obstructs visualization, clinical decision-making becomes compromised, increasing the likelihood of overtreatment (4,5,11).

Additionally, several studies have documented the high incidence of cerumen in children and its effect on the accuracy of diagnosis. In one study of 819 children aged 1 month to 12 years, cerumen was found in 70% of the ears examined, and in over 40%, the cerumen obstructed at least half of the canal (5). In another study, children with unilateral AOM required mechanical removal of cerumen in about 30% of cases in order to adequately visualize the TM, which rose to over 50% in infants (7). Both studies indicated that cerumen is more than a minor nuisance and a significant barrier to pediatric ear examinations. Adequate visualization of the TM is the only way to differentiate between AOM and otitis media with effusion (OME), which directly influences treatment decisions (3,8).

However, cerumen was removed in only 30% of children with a final diagnosis of AOM by general pediatricians compared to over 95% of the time by otolaryngologists which could be due to the specialized cerumen removal tools available in specialized clinics (5). Standard manual removal methods, such as using a curette, carry a notable risk of aural trauma. One study reported bleeding of the ear canal in up to 10% of children undergoing these procedures (7). Although irrigation is generally considered safer than curettage, it is often slower, more cumbersome, and uncomfortable (6). Furthermore, irrigation is contraindicated with a perforated TM, which is present in approximately 30% of children with AOM (9).

This suggests that improving diagnostic accuracy for AOM and ensuring high-quality routine ear examinations in pediatric care requires a renewed emphasis on effective cerumen management tools which can be utilized in general care settings (5,10). The Otoshow is a novel otoscope speculum designed to fill this gap. It consists of a retractable curette within the wall of the otoscope speculum, allowing for simultaneous cerumen removal and visualization. Its design also incorporates a guide rail and an elastic joint ensuring safety and the maneuverability of the curette while in use. Furthermore, the Otoshow incorporates an ergonomic handle which can be operated by one finger and a standardized base which can fit most standard otoscopes, enabling easy use and adoption by a large number of clinicians (Figure 1).

Although the Otoshow is primarily designed for general pediatric settings, the choice of a specialized pediatric ear, nose, and throat clinic for this phase 1 evaluation was intentional and strategic. It ensured that any safety concerns would be immediately addressed by experienced clinicians, while also facilitating high-quality feedback for iterative improvement. With safety data and user feedback from this phase 1 study, the Otoshow has the potential to become an effective tool in broader clinical settings, significantly improving otoscopic exams and thereby reducing the misdiagnosis of AOM and inappropriate antibiotic use.

Materials and Methods

Study Design

A prospective, non-randomized, survey-based, exploratory pilot study was carried out in two pediatric otolaryngology clinics between March and May 2025.

Participants

Five Advanced Practice Providers (APPs) in a pediatric otolaryngology clinic were recruited by convenience sampling without a separate comparator arm. Verbal consent was obtained from the clinicians, and they received no financial incentives for participation. Children were enrolled through convenience sampling as they presented during periods of APP availability. The inclusion criteria were: (i) children aged 0-18 years, (ii) scheduled clinic visit in which a routine otoscopic ear examination was to be performed, and (iii) willingness to use the Otoshow device during the visit. The exclusion criteria were children with any

major craniofacial abnormalities and non-English speaking parents. Written consent was obtained from the caregivers prior to the clinic visit. IRB approval was obtained.

Intervention

Each APP used either a small or large Otoshow otoscope tip according to their choice with the Welch Allyn MacroView otoscope during otoscopic examinations. The device replaced or augmented standard methods (curettes, suction, irrigation) at the APP's discretion. The APPs were trained on how to use the device via a 1-minute video which explained how to place the Otoshow on the otoscope, how to best hold the otoscope for Otoshow use, and how to maneuver the curette attachment. Any further questions regarding device functionality were answered in the clinic by the study team.

Instruments and Data Collection

Data was obtained electronically via three non-validated Redcap surveys made by the research team based on prior studies evaluating the use of novel otoscope examination tools (12,13). The pre-survey measured perceived cerumen prevalence in practice, prior cerumen-removal experience, and any limitations of the existing tools using a 5-point Likert scale and free text questions (Supplementary Figure 1). A per-encounter survey was completed immediately after each device use, documenting information pertaining to, but not limited to, the child's age, cerumen prevalence, percentage of TM visualization impairment by cerumen, complications, clinician satisfaction, perceived child comfort, and the efficiency and effectiveness of the Otoshow using a 5-point Likert scale and free text prompts. The post-survey included questions assessing overall satisfaction, intent to continue use, comparative effectiveness, and final recommendations about the Otoshow using a 5-point Likert scale and free-text questions. Descriptive statistics were used to summarize the findings. Given the pilot nature and small sample size (n=5 clinicians), inferential statistics were not performed. A full list of the questions and response options for the surveys can be found in Supplementary Figure 1. Semi-structured verbal interviews were conducted exploring ergonomics, workflow integration, and feature refinements.

Outcome Measures

The primary outcome measures were the safety of the Otoshow device, measured by complication rates and clinician perceived safety, the effectiveness and efficiency of the device, clinician satisfaction with Otoshow, and feedback regarding design changes. Secondary outcomes included the prevalence of cerumen partially or fully obstructing visualization of the TM, the frequency of Otoshow curette attachment use, and the prevalence of cerumen obstruction with suspicion of AOM.

Ethical Considerations

The University of Texas Southwestern Institutional Review Board Office of Clinical Research (approval no.: STU-2024-0470, date: 19.08.2024) evaluated and approved this study along with measures to mitigate any conflicts of interest of the researchers who invented the Otoshow. No patient-identifying data was stored. Verbal consent was obtained from the participating APPs, and written consent was obtained from the caregivers.

Results

On the pre-survey, four out of the five APPs reported that they frequently encounter cerumen obstructing their view of the TM with one answering very frequently (Figure 2a). All reported preferring the use of a curette to clear the obstruction compared to irrigation or cerumenolytics with three of five (60%) stating that they frequently used curettes to remove cerumen, one selecting very frequently, and one selecting occasional use of cerumen removal tools (Figure 2b). Four of the five (80%) were satisfied with the current cerumen removal tools, indicating that the tools were mostly effective but could be improved, and one APP was neutral. None were very satisfied with their current cerumen removal tools.

A total of 101 surveys were collected over the study period. Ages ranged from 0 to 17 years with the largest number of children being in the 1-5 year range (42%),

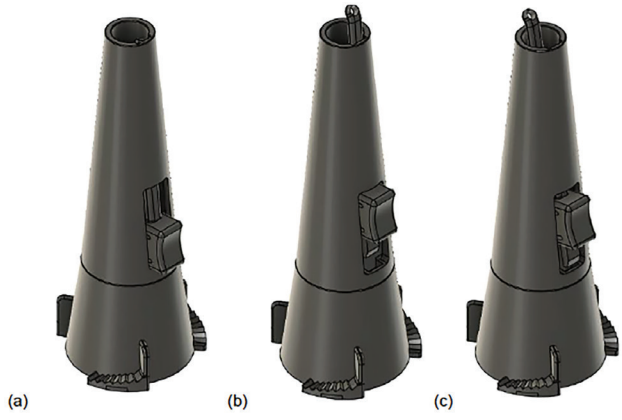

Figure 1. Otoshow otoscope speculum design in three different configurations. **(a)** Standard configuration with curette not engaged. **(b)** Curette engaged in the forward position. **(c)** Curette engaged forward and advanced along the depth axis, utilizing an elastic hinge mechanism for enhanced maneuverability

followed by 5-10 years (40%), over 10 years (13%), and 0 months to 1 year (6%). Further demographic information can be seen in Supplementary Figure 2. The small Otoshow tip was used in 55% and the large Otoshow tip was used in 45% of encounters. APPs reported that they suspected AOM in 34% of children, and of those, 28% had partial to complete obstruction of the TM by cerumen. A total of 29% of the children had cerumen which obstructed the view of the TM (Figure 3a). In those children with cerumen obstruction, APPs used the Otoshow curette attachment in 72% of encounters. Of the children with cerumen obstruction, visualization was improved by using the Otoshow tip's curette attachment in 43% of encounters (Figure 3b). Overall, APPs reported satisfaction with using the Otoshow tip in 34% and dissatisfaction in 7% of encounters. Of the encounters in which the Otoshow curette attachment was

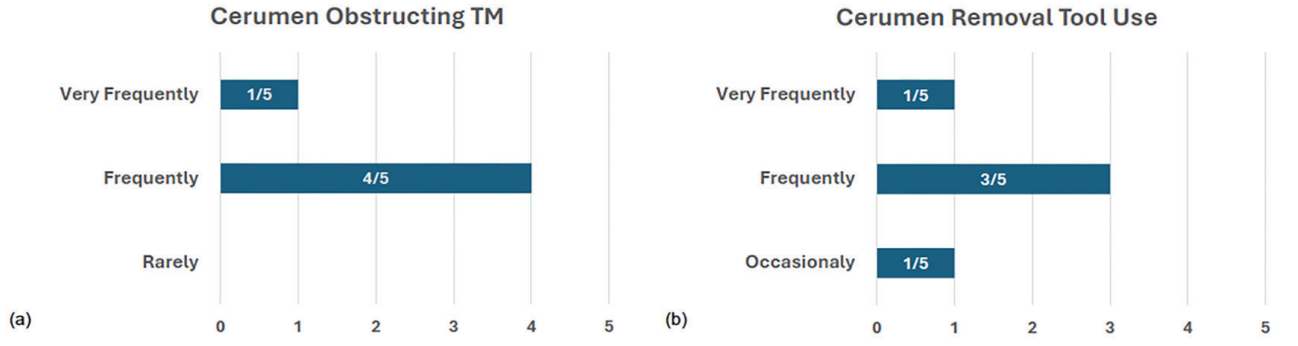

Figure 2. Pre-survey responses completed by 5 APPs. **(a)** Frequency of reported cerumen obstructing the view of the TM. **(b)** Frequency of use of cerumen removal tools
APPs: Advanced Practice Providers, TM: Tympanic membrane

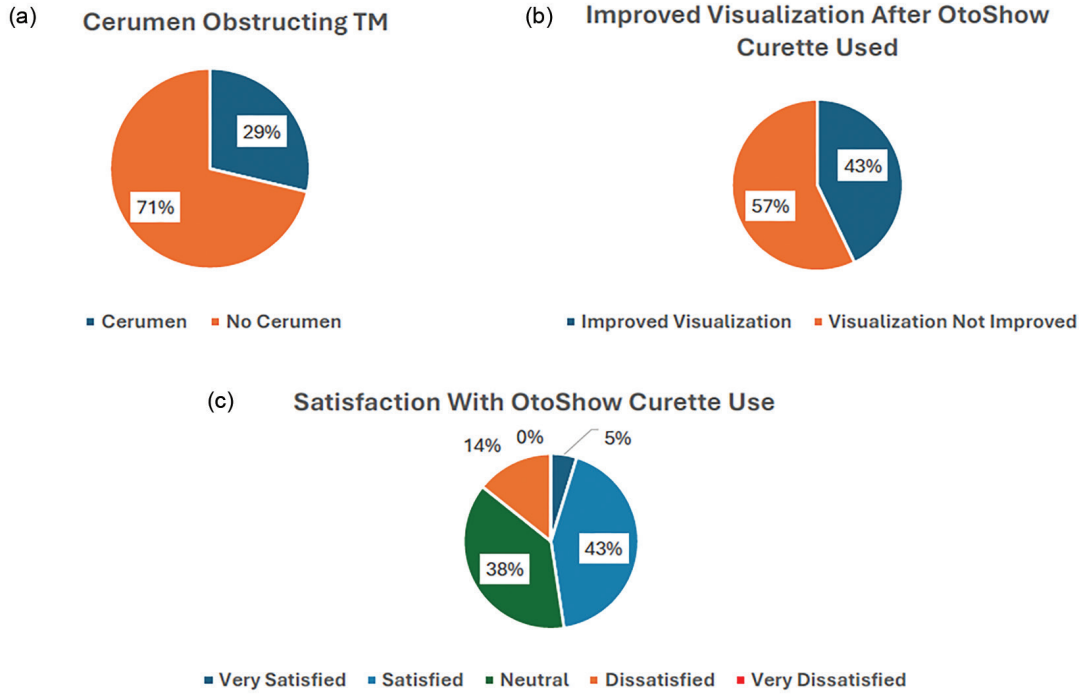

Figure 3. Per-encounter survey findings illustrated in pie chart format. **(a)** Frequency of patients with any amount of TM obstruction by cerumen in at least one ear. **(b)** Frequency of improved TM visualization after the Otoshow curette attachment was used. **(c)** APP satisfaction with Otoshow use on a 5-point Likert scale
APP: Advanced Practice Provider, TM: Tympanic membrane

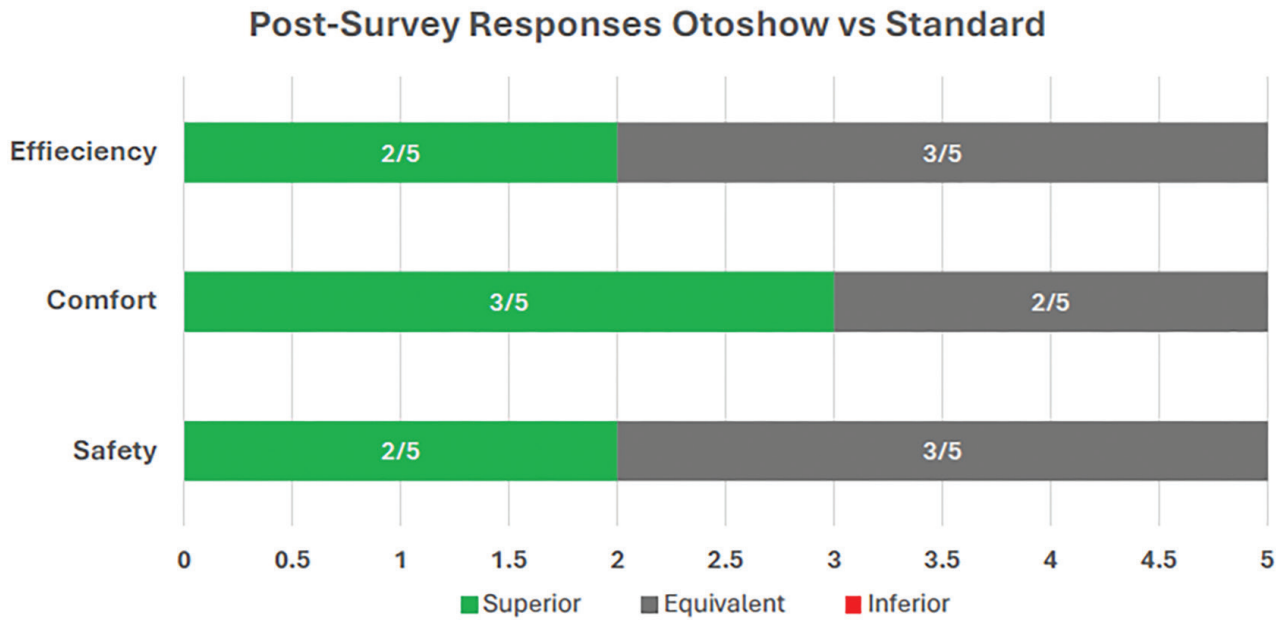

Figure 4. Post-survey responses completed by 5 APPs. Perceived efficiency, comfort, and safety of the Otoshow compared to standard otoscopy tools used in the ENT office
APPs: Advanced Practice Providers, ENT: Ear, Nose, and Throat

used, satisfaction increased to 48% (Figure 3c). Of the 101 patients, only 6 required the use of additional cerumen removal tools to be able to see the TM. None of the APPs reported any Otoshow related complications or adverse events during the study period.

Post-surveys showed that three of five (60%) APPs encountered cerumen obstructing the TM at least 50% of the time during the study period. All APPs found the Otoshow tip to be safe for children, with two of the five (40%) reporting that it was safer than their standard tools (Figure 4). Additionally, all perceived that the children felt comfortable with the Otoshow tip, and three out of five (60%) felt it was more comfortable for children than their traditional cerumen removal methods (Figure 4). Furthermore, they indicated that visualization with the Otoshow otoscope speculum took the same amount of time or was faster than using a standard otoscope speculum (Figure 4). Yet, four of the five (80%) were either unlikely or very unlikely to continue to use the current Otoshow in their practice. Although when asked if changes were made to improve the Otoshow, how likely it was that they would replace the standard otoscope tip with the Otoshow, only two selected unlikely with the others indicating either neutral or likely. The most common feedback on the design was that the curette attachment was too short and obstructed too much of the view.

Discussion

This study characterized the clinical barrier posed by cerumen impaction and evaluated the safety, feasibility, and clinician impressions of the Otoshow otoscope tip.

Safety and Feasibility Outcomes

Safety was a key outcome in this phase 1 study. No device-related complications or adverse events were reported, and all clinicians rated the Otoshow as either equally safe or safer than standard cerumen removal tools. This is notable given that manual curettage is known to cause trauma, with prior studies reporting canal bleeding in up to 10% of children (6). In contrast, no trauma or bleeding was reported in this study. Furthermore, three of the five (60%) APPs reported that children appeared more comfortable with the Otoshow than with traditional techniques, and the remaining two reported equal comfort.

Clinician satisfaction was modest: 34% of all encounters were satisfactory, and 7% were unsatisfactory. The satisfaction rate increased to 48% in encounters where the curette attachment was used, indicating that during encounters in which cerumen was present and needed to be removed, clinicians were more satisfied with the Otoshow. Notably, the clinicians were able to use the device after a single 1-minute instructional video, demonstrating that the

training burden is minimal and the device can be rapidly adopted.

This pilot study showed that the Otoshow was effective in improving perceived TM visualization for 43% of children. Multiple providers stated that this could be significantly improved by simply increasing the curette attachment length in order to be able to reach cerumen deeper in the ear canal. In terms of efficiency, all five APPs rated the time to TM visualization with the Otoshow as equivalent to or faster than standard techniques. This is clinically meaningful, particularly in settings where time constraints limit the thoroughness of otoscopic exams, such as emergency departments or urgent care clinics. The sub-analysis of the encounters in which the curette attachment was used showed that for the provider with the most frequent curette attachment use (n=7), visualization success rates improved from 33% to 75% from the first half to the second half of the study period. However, other providers with fewer encounters did not demonstrate a consistent trend, suggesting that while individual learning curves may exist, the small sample size limits the ability to characterize a broader learning effect.

With less than 6% of patients requiring the use of any additional tools other than the Otoshow for cerumen removal, the Otoshow alone was seen to be effective for standard otoscope exams in the majority of patients. Previous research has shown that cerumen impaction can lead to diagnostic ambiguity, unnecessary antibiotic prescriptions, and delayed treatment (5,7). A tool such as the Otoshow which allows for simultaneous removal and visualization has the potential to streamline effective care.

Clinical Implications

The study population was predominantly between the ages of 1 and 10, an age group which accounts for the majority of AOM diagnoses and where cerumen is frequently encountered (2,4). These demographics support the clinical relevance of targeting cerumen management in this group.

The prevalence of cerumen partially or fully obstructing the TM was common, with obstruction present in 29% of children and in 28% with suspected AOM. This supports prior studies demonstrating a high prevalence of cerumen in children. For example, one study found cerumen in 72% of ears examined and at least partial canal obstruction in 44% of children (5). Even in this specialized otolaryngology setting, where children are likely to receive more frequent ear exams and better cerumen hygiene, obstruction remained a consistent impediment to TM visualization.

In cases where cerumen was present, clinicians used the Otoshow curette attachment in 72% of encounters, and of those, 43% reported improved TM visualization. These preliminary observations suggest this device was selectively and meaningfully deployed. Importantly, clinicians suspected AOM in over one-third of those children, and when cerumen obstructed the TM, visualization was critical for diagnosis. Given that TM assessment is essential to differentiate AOM from OME (2,3), these findings reinforce the need for effective cerumen management tools in children. However, this study did not directly measure changes in diagnostic accuracy or antibiotic prescribing behavior.

While only one clinician indicated that they would replace their current tool with the Otoshow, most expressed an openness to continued use depending on further improvements. This indicates that this device is still in its early developmental stages and requires design improvements. The clinicians noted that small design changes including increasing the length of the curette attachment and moving it more out of view could enhance the device's usability and increase adoption.

Study Limitations

The study design demonstrated the Otoshow as a safe and feasible adjunct in pediatric otolaryngology settings, but further studies are needed in order to evaluate the use of the Otoshow as a standalone device in option-limited sections such as primary care or emergency departments. The sample size of the study only included a small number of participating clinicians. In addition, the clinician reported outcomes relied on subjective survey responses. The surveys used were developed for this initial pilot study and were not validated instruments. They were created in order to efficiently capture early safety, satisfaction, and usability data in this phase 1 evaluation.

Furthermore, this study has several potential biases which may have occurred due to the study design. Selection bias was a known risk as device use was at the clinician's discretion. The absence of blinding and a control group introduced potential observer and expectation bias. Improvement of visualization was a subjective measurement which could have increased reporter bias. The absence of validation possibly limited reproducibility and limits the interpretation of outcomes such as perceived diagnostic accuracy and satisfaction. The clinician assessments of child comfort were observational rather than self or caregiver reported which limits the interpretation of these findings.

Additionally, the exclusion of non-English-speaking parents, which was necessary for this initial pilot due to

resource constraints, may further limit the generalizability of this study's results. The device's impact on AOM diagnosis and management are also needed in order to assess its clinical impact. These factors underscore the need for broader trials with objective performance metrics such as validated usability, comfort, and satisfaction scales along with objective assessment of TM visualization using video otoscopy and a blinded image assessment.

Future Directions

Having demonstrated its safety and feasibility, the next step is to evaluate the Otoshow in general pediatric and urgent care settings, where cerumen impaction may be more frequent and challenging. Future studies should incorporate direct patient feedback, validated outcome measures, and video-based assessments of TM visualization. Given the impact of cerumen on diagnostic accuracy, efficiency, and antibiotic stewardship, broader adoption of improved tools such as the Otoshow could contribute to more accurate AOM diagnoses and reduced overtreatment in pediatric care (3,5,7,14).

Ethics

Ethics Committee Approval: The study was approved by the University of Texas Southwestern Institutional Review Board Office of Clinical Research on August 19th, 2024 with study number STU-2024-0470.

Informed Consent: Verbal consent was obtained from the participating APPs, and written consent was obtained from the caregivers.

Footnotes

Authorship Contributions

Concept: L.N., A.M., R.M., Design: L.N., A.M., R.M., Data Collection or Processing: L.N., A.M., N.B., R.M., Analysis or Interpretation: L.N., A.M., N.B., R.M., Literature Search: L.N., A.M., N.B., R.M., Writing: L.N., A.M., N.B., R.M.

Conflict of Interest: Lith Nasif and Ron Mitchell are the co-inventors of the Otoshow device described in this manuscript. Ron Mitchell's involvement in this study was limited to the study design and manuscript review. Lith Nasif was involved in the study design, patient consent, and manuscript review. The data analysis and writing of the manuscript were primarily completed by the other authors with feedback from Ron Mitchell and Lith Nasif when needed. While there are no current financial deals or gains, there is the potential for future financial gain. The institutional review board evaluated and approved this study along with measures to mitigate the conflict of interest of the researchers who invented the Otoshow.

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Supplementary Figure 1: https://d2v96fxpocvxx.cloudfront.net/1dda20c2-8b22-466b-a98e-85ecfb39ceaf/content-images/3af15e34-9a01-41dd-9f87-b1c358ecda29.pdf

Supplementary Figure 2: https://d2v96fxpocvxx.cloudfront.net/1dda20c2-8b22-466b-a98e-85ecfb39ceaf/content-images/d9c9f70d-7c36-4a15-aaf7-ee869ff6c6f3.pdf

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